**Registration Statement No. 333-**

United States SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

### **FORM F-10**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## THERATECHNOLOGIES INC.

(Exact name of Registrant as specified in its charter)

**Québec, Canada** (Province or other jurisdiction of company or organization) 2834 (Primary Standard Industrial Classification Code Number) NOT APPLICABLE (I.R.S. Employer Identification Number)

2310 Alfred-Nobel Boulevard Montréal, Québec, Canada H4S 2B4 (514) 336-7800 (Address and telephone number of Registrant's principal executive offices)

> CT Corporation System 111 8<sup>th</sup> Avenue New York, NY 10011 (212) 894-8800

(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

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Approximate date of commencement of proposed sale of the securities to the public: As soon as practicable after the effective date of this Registration Statement.

> Province of Québec, Canada (Principal jurisdiction regulating this offering)

It is proposed that this filing shall become effective (check appropriate box):

A.o upon filing with the Commission, pursuant to Rule 467(a) (if in connection with an offering being made contemporaneously in the United States and Canada).

#### Copies to:

#### B. at some future date (check the appropriate box below):

- 1. o pursuant to Rule 467(b) on (date) at (time) (designate a time not sooner than 7 calendar days after filing).
- 2. o pursuant to Rule 467(b) on (*date*) at (*time*) (designate a time 7 calendar days or sooner after filing) because the securities regulatory authority in the review jurisdiction has issued a receipt or notification of clearance on (*date*).
- 3. o pursuant to Rule 467(b) as soon as practicable after notification of the Commission by the Registrant or the Canadian securities regulatory authority of the review jurisdiction that a receipt or notification of clearance has been issued with respect hereto.
- 4. 🗵 after the filing of the next amendment to this Form (if preliminary material is being filed).

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to the home jurisdiction's shelf prospectus offering procedures, check the following box. o

#### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered(1)	Proposed maximum offering price per share(2)	Proposed maximum aggregate offering price(1)(2)	Amount of registration fee
Common Shares	12,650,000	US\$5.23	US\$66,159,500	US\$7,681.12

(1) Includes 1,650,000 common shares that the underwriters have the option to purchase to cover over-allotments, if any, as well as associated common share purchase rights.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457 of the Securities Act of 1933, based on the average of the high and low prices of the Registrant's common shares on the Toronto Stock Exchange on February 18, 2011 converted into U.S. dollars at the U.S.-Canadian dollar exchange rate of U.S.\$1.00 = C\$1.0142 on February 18, 2011.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registration statement shall become effective as provided in Rule 467 under the Securities Act of 1933 or on such date as the Commission, acting pursuant to Section 8(a) of the Act, may determine.

#### PART I

#### INFORMATION REQUIRED TO BE DELIVERED TO OFFEREES OR PURCHASERS

Information contained herein is subject to completion or amendment. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any State in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such State.

#### PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION, DATED FEBRUARY 22, 2011

### 11,000,000 Shares



## THERATECHNOLOGIES INC.

### **Common Shares**

We are offering 11,000,000 common shares. This is the initial public offering of our common shares in the United States. Our common shares are listed on the Toronto Stock Exchange under the symbol "TH". We have applied to have our common shares listed on the Nasdaq Global Market under the symbol "THER". On February 18, 2011, the closing price of our common shares on the Toronto Stock Exchange was Cdn\$5.01 per share or U.S. \$5.08, based on the U.S.-Canadian dollar closing exchange rate on February 18, 2011, as guoted by the Bank of Canada.

Investing in our common shares involves a high degree of risk. Please read "Risk Factors" beginning on page 7 of this prospectus.

This offering is made by a foreign issuer that is permitted, under a multijurisdictional disclosure system adopted by the United States, to prepare this prospectus in accordance with the disclosure requirements of Canada. Prospective investors should be aware that such requirements are different from those of the United States. Financial statements included or incorporated herein been prepared in accordance with International Financial Reporting Standards, and are subject to foreign auditing and auditor independence standards, and thus may not be comparable to financial statements of United States companies. Prospective investors should be aware that the acquisition of the securities described herein may have tax consequences both in the United States and in Canada. Such consequences for investors who are resident in, or citizens of, the United States may not be described fully herein.

The enforcement by investors of civil liabilities under the federal securities laws may be affected adversely by the fact that we are incorporated under the laws of the Province of Québec, that most of our officers and directors are residents of Canada, that some of the underwriters and experts named in the registration statement are residents of a foreign country, and that all or a substantial portion of our assets and those of said persons are located outside the United States.

THESE SECURITIES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE SECURITIES AND EXCHANGE COMMISSION NOR HAS THE COMMISSION PASSED UPON THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

	PER SHARE	TOTAL
Public Offering Price	U.S.\$	U.S.\$
Underwriting Discounts and Commissions	U.S.\$	U.S.\$
Proceeds to Company before expenses	U.S.\$	U.S.\$

Delivery of the common shares is expected to be made on or about , 2011. We have granted the underwriters an option to purchase for a period of 30 days following the date of the prospectus, on the same terms and conditions set forth above, up to an additional common shares. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ , and the total proceeds to us, before expenses, will be \$ .

Joint Book-Running Managers

Jefferies	Stifel Nicolaus Weisel	<b>RBC Capital Markets</b>	<b>BMO Capital Markets</b>

Co-Managers

**Desjardins Securities International Inc** 

**NBF Securities (USA) Corp** 

Prospectus dated , 2011

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#### **ABOUT THIS PROSPECTUS**

You should rely only on the information contained in or incorporated by reference into this prospectus or in any free writing prospectus that we may provide to you. Neither we nor the underwriters have authorized anyone to provide you with information different from that contained in this prospectus or in any free writing prospectus that we may provide to you. We are offering to sell, and seeking offers to buy, our common shares only in jurisdictions where, and to persons to whom, offers and sales are lawfully permitted. The information contained in or incorporated by reference into this prospectus is accurate only as of the date of this prospectus or the date of the document incorporated by reference, as applicable, regardless of the time of delivery of this prospectus or of any sale of our common shares.

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Certain statistical data and other information regarding the size of our potential markets are based on industry publications and/or derived from our own internal analysis of such industry publications. While we believe our internal company research and internal analysis are reliable and the market definitions, methodology and hypotheses we use are appropriate, such research, analysis, methodology or definitions have not been verified by an independent source. We cannot and do not provide any assurance as to the accuracy or completeness of such information. Market forecasts, in particular, are likely to be inaccurate, especially over long periods of time.

In this prospectus, references to *EGRIFTA*<sub>TM</sub> refer to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy regardless of the trade name used for such product in any particular territory. *EGRIFTA*<sub>TM</sub> is the trade name used in the United States for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*<sub>TM</sub> is our trademark.

All monetary amounts set forth in this prospectus are expressed in Canadian dollars, except where otherwise indicated. References to "\$" and "C\$" are to Canadian dollars and references to "US\$" are to U.S. dollars.

In this prospectus, references to "Theratechnologies", the "Company", "we", "our" and "us" refer to Theratechnologies Inc. and its subsidiaries, unless the context otherwise states.



#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, and the documents incorporated by reference in this prospectus and any prospectus supplement, contains forward-looking statements and forward-looking information within the meaning of applicable securities laws that are based on our management's belief and assumptions and on information currently available to our management, collectively, "forward-looking statements". In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "expect", "plan", "anticipate", "believe", "estimate", "project", "predict", "intend", "potential", "continue" and similar expressions intended to identify forward-looking statements. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- our expectations related to the use of proceeds from this offering;
- our ability, and the ability of our commercial partners, to commercialize *EGRIFTA*™ in the United States and other territories;
- whether we will receive regulatory approvals for tesamorelin from regulatory agencies in territories other than the United States in which we wish to expand the commercialization of tesamorelin, and the timing and costs of obtaining such regulatory approvals;
- our recognition of milestones, royalties and other revenues from our commercial partners related to future sales of EGRIFTA<sub>TM</sub>;
- our plans to conduct a new clinical program for tesamorelin in muscle wasting in chronic obstructive pulmonary disease, or COPD, including the timing and results of these clinical programs;
- the continuation of our collaborations and other significant agreements with our existing commercial partners and our ability to establish and maintain additional development collaborations;
- our estimates of the size of the potential markets for EGRIFTATM, tesamorelin and our other product candidates;
- the rate and degree of market acceptance of *EGRIFTA*™ and our other product candidates;
- our success in obtaining, and the timing and amount of, reimbursement for EGRIFTA™ and our other product candidates;
- the benefits of tesamorelin and our other product candidates as compared to others';
- the success and pricing of other competing drugs or therapies that are or may become available;
- our ability to maintain and establish intellectual property rights in tesamorelin and our other product candidates;
- the manufacturing capacity of third-party manufacturers, including the manufacturer of tesamorelin in commercial quantities;
  our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital
- expenditures and income taxes; and
- our need for additional financing and our estimates regarding our capital requirements and future revenues and profitability.

Such statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed in or implied by the forward-looking statements. Certain assumptions made in preparing the forward-looking statements include that:

- tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will receive approval in territories other than the United States covered in our commercialization agreements;
- no additional clinical studies will be required to obtain said regulatory approval of tesamorelin;
- EGRIFTA™ will be accepted by the marketplace in the United States and will be on the list of reimbursed drugs by thirdparty payors;
- our relations with third-party suppliers of *EGRIFTA*<sub>TM</sub> will be conflict-free and that such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA*<sub>TM</sub> to meet market demand and on a timely basis;

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- we will obtain positive results from our clinical program for the development of tesamorelin for muscle wasting in COPD patients; and
- our business plan will not be substantially modified.

Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these risks and uncertainties, the forward-looking events and circumstances discussed in this prospectus may not occur, and you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" as well as in the documents incorporated by reference herein and therein. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this prospectus. We undertake no obligation and do not intend to update or revise these forward-looking statements, unless required by law. We qualify all of the information presented in this prospectus, and particularly our forward-looking statements, with these cautionary statements.

This prospectus also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry and target indications. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

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#### **PROSPECTUS SUMMARY**

The following summary highlights selected information contained elsewhere in this prospectus or in the documents incorporated by reference into this prospectus. This summary does not contain all of the information that you should consider before making a decision to invest in our common shares. You should carefully read the entire prospectus, including the section entitled "Risk Factors" and the documents and consolidated financial statements included or incorporated by reference into this prospectus.

#### **Our Business**

We are a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on growth-hormone releasing factor, or GRF, peptides. Our strategy is to leverage our expertise in the field of metabolism and GRF peptides to address serious health disorders while remaining actively involved in the commercialization of our future products. Our first product, *EGRIFTA*<sub>TM</sub> (tesamorelin for injection), was approved by the United States Food and Drug Administration, or FDA, in November 2010 and launched in January 2011. *EGRIFTA*<sub>TM</sub> is currently the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

#### The Condition

Excess abdominal fat in HIV-infected patients with lipodystrophy is a serious medical condition. We estimate that it affects approximately 29% of HIV-infected patients treated with antiretroviral therapies and approximately 12% of untreated patients. In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. Lipodystrophy is characterized by abnormalities in the production and storage of fat, which lead to excess abdominal fat, or lipohypertrophy, and the loss of fat tissue, or lipoatrophy, generally occurring in the limbs and facial area.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood, and hyperglycemia, an increase in the amount of sugar in the blood, both of which lead to increased risks for cardiovascular disease and diabetes. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy.

Using data compiled by the United States Center for Disease Control, or CDC, and the World Health Organization and UNAIDS, or WHO/UNAIDS, we estimate that in 2012 there will be approximately 540,000 HIV-infected patients treated with antiretroviral therapies suffering from lipohypertrophy in our primary target markets: 190,000 in the United States, 170,000 in Europe, and 180,000 in Latin America. We also estimate that in 2012 an additional 117,000 HIV-infected untreated patients in those territories will develop lipohypertrophy.

#### **EGRIFTATM - Our Lead Product**

EGRIFTATM was approved by the FDA in November 2010 following a unanimous vote by the Endocrinology and Metabolic Drugs Advisory Committee of the FDA.

*EGRIFTA*<sup>TM</sup> is the trade name used for our first marketed product using our most advanced compound, tesamorelin. Tesamorelin is a GRF analogue that stimulates the synthesis and pulsatile release of endogenous growth hormone. Tesamorelin was synthesized using our internally-developed peptide stabilization method. This method increases a protein's resistance to enzymatic degradation, which prolongs its duration of action and enhances its effectiveness in clinical use. We believe this compound and future GRF analogues that we are developing can be used in a number of additional high-value indications. Clinical data have shown tesamorelin to have both lipolytic (fat-burning) and anabolic (muscle-building) properties. Our initial development of *EGRIFTA*<sup>TM</sup> focused on the lipolytic properties of the compound.

#### Commercialization of EGRIFTATM

*EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy is currently marketed exclusively in the United States by EMD Serono Inc., or EMD Serono, pursuant to a collaboration and licensing agreement. In January 2011, EMD Serono launched *EGRIFTA*<sup>TM</sup> in the United States. EMD Serono is executing a launch program that consists of (i) increasing disease awareness through medical education to doctors, patient advocacy and advertising, (ii) marketing and promotion through its experienced sales force and (iii) supporting market access through patient support, co-pay programs, reimbursement education and support for payors. We believe *EGRIFTA*<sup>TM</sup> will achieve a high degree of physician and payor acceptance, driven by our product's safety and efficacy, the lack of approved alternative therapies for these patients and the prominent medical and social need to treat HIV/AIDS patients.

EMD Serono is responsible for establishing the sale price of *EGRIFTA*<sub>TM</sub> in the United States. The wholesale acquisition cost has been set at US\$23,900 per patient per year. We expect to receive our first royalty payments in the second quarter of 2011.

We have also recently entered into distribution and licensing agreements for *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy with Sanofi Winthrop Industries S.A., or Sanofi, granting Sanofi the exclusive commercialization rights in Latin America, Africa and the Middle East and with Ferrer Internacional S.A., or Ferrer, granting Ferrer the exclusive commercialization rights in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

#### Muscle Wasting in COPD - Our Next Indication

Tesamorelin's anabolic properties have led us to pursue its development in muscle wasting in patients with chronic obstructive pulmonary disease, or COPD, as our second indication. COPD is characterized by progressive airflow obstruction due to chronic bronchitis or emphysema leading in certain cases to muscle wasting, a decrease of muscle mass and deterioration in functionality. We have completed a Phase 2 trial which demonstrated a statistically significant increase in lean body mass. We intend to commence a second Phase 2 clinical study in the second half of 2011 to test different dosages of tesamorelin with a new formulation.

Based on available market and industry data, we estimate that in 2009 there were approximately 3.1 million diagnosed COPD patients with muscle wasting in the United States, France, Germany, Italy, United Kingdom, Spain and Japan.

#### **Future Product Candidates**

To solidify our leadership position in the field of GRF therapeutics, we have embarked on a program to discover new generations of GRF analogues. We believe that GRF compounds have the potential to improve patient outcomes in many high-value indications. We also believe that we can improve the route of administration of GRF peptides to make them quicker and easier to use for patients.

#### **Our Strategy**

Our goal is to leverage our expertise in the field of metabolism and GRF peptides to become a leading specialty pharmaceutical company with the necessary infrastructure to take innovative therapeutic products from research and development to full commercialization in worldwide markets. Key elements of this strategy include:

- Maximize the global commercial potential of EGRIFTATM. We will continue to support our commercial partners in their
  respective territories, including regulatory support, manufacture and supply of EGRIFTATM and potential co-promotion.
- **Develop tesamorelin for muscle wasting in COPD.** We will be conducting a new clinical program in muscle wasting in COPD. We have demonstrated in a first Phase 2 clinical trial that tesamorelin has increased muscle mass in COPD patients. We believe tesamorelin could improve patients' functionality in daily activities and address a significant unmet need in a large and potentially lucrative market.
- Solidify our position as a leader in the field of novel GRF products. We will leverage our expertise in peptide discovery, drug development and regulatory affairs to continue our development of new peptides, primarily

- GRF peptides, in order to expand our portfolio of product candidates and solidify our position as a leader in this field.
  Be actively involved in the commercialization of our products. We intend to retain commercial rights to our future products for indications and territories where we believe we can effectively market them. We may also co-promote EGRIFTA™ in certain territories and tesamorelin in other indications.
- **Pursue external growth opportunities.** In addition to developing products internally, we will opportunistically pursue inlicensing arrangements or acquisitions of complementary businesses, compounds or products.

#### **Recent Developments**

On September 1, 2010, we announced the appointment of Mr. John-Michel T. Huss as our President and Chief Executive Officer. Mr. Huss joins us from Sanofi-aventis S.A., a leading global pharmaceutical company, having most recently acted as Chief of Staff to the company's Chief Executive Officer. He brings to us more than 20 years of global experience and leadership in the pharmaceutical industry.

On November 30, 2010, we received a US\$25 million milestone payment from EMD Serono associated with the FDA approval of *EGRIFTA*<sub>TM</sub> in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

On December 6, 2010, we entered into a distribution and licensing agreement granting Sanofi the exclusive commercialization rights to *EGRIFTA*<sub>TM</sub> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East.

On February 3, 2011, we entered into a distribution and licensing agreement granting Ferrer the exclusive commercialization rights to *EGRIFTA*<sub>TM</sub> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

On February 22, 2011, we announced a second indication for tesamorelin: muscle wasting in COPD. We intend to commence a second Phase 2 clinical study in the second half of 2011 to test different dosages of tesamorelin with a new formulation.

#### **Corporate Information**

We are incorporated under the laws of the Province of Québec, Canada. Our office is located at 2310 Alfred-Nobel Boulevard, Montréal, Québec, H4S 2B4, and our telephone number is (514) 336-7800. Our website address is www.theratech.com. Information contained on our website, or which can be accessed through our website, is not a part of, and is not incorporated by reference in, this prospectus.



	THE OFFERING
Common shares offered by us	11,000,000 common shares
Common shares to be outstanding after the offering	71,515,764 common shares
Over-allotment option	We have granted the underwriters an option to purchase up to an additional 1,650,000 common shares from us at the public offering price, less underwriting discounts and commissions, to cover over-allotments. This option is exercisable in whole or in part for a period of 30 days from the date of the underwriting agreement.
Use of proceeds	We expect to use the net proceeds from this offering to advance our clinical program relating to muscle wasting in COPD, to complete our new formulation of $EGRIFTA_{TM}$ and tesamorelin, to continue the research and development of novel GRF peptides, for potential acquisitions, and for working capital and other general corporate purposes. See "Use of Proceeds".
Toronto Stock Exchange symbol	ТН
Proposed Nasdaq Global Market symbol	THER
Risk factors	An investment in our common shares involves certain risks that you should carefully consider. See "Risk Factors".
Dividend Policy	We have never paid dividends and do not anticipate paying dividends in the foreseeable future. See "Dividend Policy".
The number of common charge to be outstan	ding immediately after the completion of this offering is based on the number of

The number of common shares to be outstanding immediately after the completion of this offering is based on the number of common shares outstanding as of February 18, 2011 and excludes:

- 3,038,971 common shares issuable upon the exercise of stock options then outstanding at a weighted average exercise price of \$5.12 (approximately US\$5.19) per share;
- 788,172 common shares reserved for future issuance under our stock option plan;
- 207,306 common shares reserved for future issuance under our common share purchase plan; and
- up to 1,650,000 common shares, if any, issuable pursuant to the underwriters' over-allotment option as described under "Underwriting".

Except as otherwise indicated, information in this prospectus assumes no exercise of the underwriters' over-allotment option.

#### SUMMARY CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the accompanying notes included elsewhere in this prospectus. The consolidated statement of comprehensive Income data for the years ended November 30, 2010 and 2009, and the consolidated statement of financial position data as at November 30, 2010 and 2009, set forth below, have been derived from our consolidated financial statements that have been audited by KPMG LLP, and which are included elsewhere in, or incorporated by reference into, this prospectus. Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Our financial statements were previously prepared in accordance with Canadian Generally Accepted Accounting Principles, or GAAP. For more information regarding the conversion to IFRS, please refer to the heading "Conversion to IFRS" in our Management's Discussion and Analysis of Financial Statements prepared in accordance with IFRS. Our historical results from any prior period are not necessarily indicative of results to be expected for any future period.

IFRS differ in some significant respects from accounting principles generally accepted in the United States, or U.S. GAAP, and thus may not be comparable to the financial statements of United States companies. These differences between IFRS and U.S. GAAP might be material to the financial information presented in this prospectus. In addition, differences may arise in subsequent periods related to changes in IFRS or U.S. GAAP or due to new transactions we enter into. We are not required to prepare a reconciliation of our consolidated financial statements and related footnote disclosures between IFRS and U.S. GAAP and have not quantified such differences. In making an investment decision, potential investors must rely upon their own examination of the company, the terms of this offering and the financial information included herein. Potential investors should consult their own professional advisors for an understanding of the differences between IFRS and U.S. GAAP and how those differences might affect the financial information herein.

#### **Consolidated Statement of Comprehensive Income Data:**

	YEAR ENDED	YEAR ENDED NOVEMBER 30	
	2010	2009	
		(in thousands, except per share amounts)	
Milestone payments	\$25,000	\$10,884	
Other revenue	6,868	6,584	
Total revenue	31,868	17,468	
Research and development expenses, net of tax credits	14,064	20,810	
Total operating expenses	25,205	34,215	
Total net financial income	2,381	1,591	
Net profit (loss) before income taxes	9,044	(15,156)	
ncome tax expense	114	_	
Net profit (loss)	8,930	(15,156)	
Total comprehensive income (loss) for the year	8,214	(14,246)	
Basic and diluted earnings (loss) per share	0.15	(0.25)	

The following table describes our cash and bonds, total assets, total liabilities and total equity:

- as at November 30, 2010 and 2009, on an actual basis; and
- as at November 30, 2010, on an as adjusted basis to give effect to our sale of 11,000,000 common shares in this offering at
  an assumed public offering price of US\$5.08 per share (which represents the U.S. dollar equivalent of the \$5.01 closing
  price of our common shares as reported on the TSX on February 18, 2011) and our receipt of estimated net proceeds of
  US\$50,231,000 (\$49,528,000), after deducting estimated underwriting discounts and commissions and estimated offering
  expenses payable by us.

#### **Consolidated Statement of Financial Position Data:**

		AS AT NOVEMBER 30,		
		2010		
	ACTUAL	AS ADJUSTED (in thousands)	2009 ACTUAL	
Cash and bonds	\$64,550	\$114,078	\$63,362	
Total assets	71,651	121,179	69,154	
Total liabilities	18,995	18,995	26,106	
Total equity	52,656	102,184	43,048	



#### **RISK FACTORS**

Before you invest in our common shares, you should understand the high degree of risk involved. You should consider carefully the following risks and uncertainties described below and other information included in or incorporated by reference into this prospectus, including our consolidated financial statements and related notes included elsewhere in this prospectus, before you decide to purchase our common shares. The following risks may adversely impact our business, financial condition, operating results and prospects. Additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also adversely affect our business, financial condition, operating results or prospects. As a result, the trading price of our common shares could decline and you could lose all or part of your investment.

#### Risks Related to the Commercialization of our Product and Product Candidates

### Our commercial success depends largely on the commercialization of EGRIFTA™; the failure of EGRIFTA™ to obtain commercial acceptance would have a material adverse effect on us.

Our ability to generate revenues in the future is primarily based on the commercialization of *EGRIFTA*TM for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. In the short term, these revenues should be primarily derived from the U.S. market alone. Although we have entered into a collaboration and licensing agreement with EMD Serono for the commercialization of *EGRIFTA*TM in the United States, there can be no assurance that *EGRIFTA*TM will be successfully commercialized in the United States, or in any other country. Although we are developing other peptides, all of them are at earlier stages of development and none of them may reach the clinical trial phase, obtain regulatory approval or, even if approved, be successfully commercialized.

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

- receipt of regulatory approvals for *EGRIFTA*™ from regulatory agencies in the territories other than the United States in which we wish to expand the commercialization of tesamorelin;
- market acceptance of *EGRIFTA*<sub>TM</sub> by the medical community, patients and third-party payors (such as governmental health administration authorities and private health coverage insurers);
- the amount of resources devoted by our commercial partners to commercialize EGRIFTA™ in their respective territories;
- maintaining manufacturing and supply agreements to ensure the availability of commercial quantities of *EGRIFTA*™ through validated processes;
- the number of competitors in our market; and
- protecting and enforcing our intellectual property and avoiding patent infringement claims.

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

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

Although our collaboration and licensing agreements with EMD Serono, Sanofi and Ferrer contain provisions governing their respective responsibilities as partners for the commercialization of *EGRIFTA*<sub>TM</sub> in their respective territories, our dependence on these partners to commercialize *EGRIFTA*<sub>TM</sub> is subject to a number of risks, including:

 our limited control of the amount and timing of resources that our commercial partners will be devoting to the commercialization, marketing and distribution of tesamorelin, including obtaining patient reimbursement for EGRIFTATM, which could adversely affect our ability to obtain or maximize our royalty payments;

- disputes or litigation that may arise between us and our commercial partners, which could adversely affect the commercialization of tesamorelin, all of which would divert our management's attention and our resources;
- our commercial partners not properly defending our intellectual property rights or using them in such a way as to expose us
  to potential litigation, which could, in both cases, adversely affect the value of our intellectual property rights; and
- corporate reorganizations or changes in business strategies of our commercial partners, which could adversely affect a
  commercial partner's willingness or ability to fulfill its obligations under its respective agreement.

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

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

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

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

Our reliance on third-party manufacturers exposes us to a number of risks. We may be subject to delays in or suspension of the manufacturing of *EGRIFTA*<sub>TM</sub> and tesamorelin if a third-party manufacturer:

- becomes unavailable to us for any reason, including as a result of the failure to comply with good manufacturing practices, or GMP, regulations;
- experiences manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with GMP or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis.

Any delay in or suspension of the supply of *EGRIFTA*<sub>TM</sub> could delay or prevent the sale of *EGRIFTA*<sub>TM</sub> and, accordingly, adversely affect our revenues and results of operations. In addition, any manufacturing delay or delay in delivering *EGRIFTA*<sub>TM</sub> may result in our being in default under our collaboration agreements. If the damage to a

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

Any delay in or suspension of the supply of tesamorelin could delay or interrupt the conduct of clinical trials of our new clinical programs relating to muscle wasting in COPD.

## Even though we have received regulatory approval for EGRIFTATM in the United States, we still may not be able to successfully commercialize it if we do not gain market acceptance and the revenue that we generate from its sales, if any, may be limited.

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

- acceptance of the product by physicians and patients as safe and effective treatments and addressing a significant unmet medical need;
- product price;
- the effectiveness of our sales and marketing efforts (or those of our commercial partners);
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects;
- · competitive products;
- the ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness and ability of patients to pay out-of-pocket in the absence of third-party coverage.

If *EGRIFTA*<sup>TM</sup> does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from this product, and we may not be able to achieve profitability. Our efforts, and the efforts of our commercial partners, to educate the medical community and third-party payors on the benefits of tesamorelin may require significant resources and may never be successful.

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

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

In the event of any such termination, in order to continue commercialization, we would be required to build our own sales force or enter into agreements with third parties to provide such capabilities. We currently have limited

marketing capabilities and we have limited experience in developing, training or managing a sales force. The development of a sales force would be costly and would be time-consuming given the limited experience we have in this area. To the extent we develop a sales force, we could be competing against companies that have more experience in managing a sales force than we have and that have access to more funds than we with which to manage a sales force. Consequently, there can be no assurance that a sales force which we develop would be efficient and would maximize the revenues derived from the sale of *EGRIFTA*TM or any future products.

#### We are substantially dependent on revenues from EGRIFTATM.

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

#### Our levels of revenues are highly dependent on obtaining patient reimbursement for EGRIFTATM.

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

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

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

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

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

- differing regulatory requirements for drug approvals in foreign countries;
- · potentially reduced protection for intellectual property rights;
- · potential third-party patent rights in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in foreign economies and markets;
- compliance with tax, employment, immigration and labour laws for employees traveling abroad;
- foreign taxes;

- foreign exchange contracts and foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labour unrest is more common than in the United States and Canada;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

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

In several countries, including countries which are in Europe, Latin America, Africa, and the Middle East, the pricing of prescription drugs may be subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the marketing of a product. To obtain reimbursement or pricing approval in some countries, a clinical trial that compares the cost-effectiveness of a product candidate to other available therapies may be required. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our commercial partners may not be willing to devote resources to market and commercialize *EGRIFTA*TM or may decide to cease marketing such product. In such case, our business, prospects and results of operations could be materially adversely affected.

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

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

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

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

We import and export products and raw materials from and to several jurisdictions around the world. This process requires us and our commercial partners to operate in a number of jurisdictions with different customs and import/export regulations. The regulations of these countries are subject to change from time to time and we cannot predict the nature, scope or impact of these changes upon our operations. We and our commercial partners are subject to periodic reviews and audits by U.S. and foreign authorities responsible for administering these regulations. To the extent that we or our commercial partners are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties and increased duties, which may, individually or in the aggregate, negatively impact our business, operating results and financial condition.

#### **Risks Related to the Regulatory Review Process**

# Even after regulatory approval has been obtained regulatory agencies may impose limitations on the indicated uses for which our products may be marketed, subsequently withdraw approval or take other actions against us that would be adverse to our business.

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

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

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

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

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

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

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

All of our product candidates are subject to preclinical and clinical studies. If the results of such studies are not positive, we may not be in a position to make any filing to obtain the regulatory approval for the product candidate



or, even where a product candidate has been filed for approval, we may have to conduct additional clinical trials or testing on such product candidate in an effort to obtain results that further support the safety and efficacy of such product candidate. Such studies are often costly and may also delay a filing or, where additional studies or testing are required after a filing has been made, the approval of a product candidate.

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

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

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

Obtaining FDA approval for the commercialization of drug products requires a demonstration through preclinical studies and clinical trials that the drug is safe and effective. All of our product candidates are at the discovery stage, except our peptide for the treatment of acute kidney injury, or AKI, which is in preclinical development. In addition, in order to market tesamorelin for other indications, we will need to demonstrate its effectiveness and safety through additional studies and clinical trials. Favorable results in our trials of tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy may not be predictive of the efficacy and safety results in our Phase 2 clinical trials of tesamorelin for the treatment of muscle wasting in COPD.

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

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

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the



U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and sales price that we receive for *EGRIFTA*TM or any other approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

#### **Risks Related to Our Intellectual Property**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have not been served with any notice alleging that we infringe a third-party patent, but there may be issued patents that we are unaware of that our products may infringe, or patents that we believe we do not infringe but ultimately could be found to infringe. We are aware of third-party patents for the reduction of accumulation of fat tissue in HIV patients and, if a patent infringement suit was brought against us, we believe that we should not be found to infringe any valid claims of these patents. If we were to challenge the validity of a competitor's issued United States patent in a United States court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. We cannot guarantee that a court would find in our favour on questions of infringement and validity. Any finding that we infringe or violate a third-party patent or other intellectual property right could materially adversely affect our business, financial condition and operating results.

#### Other Risks Related to Our Business

#### We have a history of net losses and we may never achieve high profitability.

We have been reporting losses since our inception (except for the financial years ended November 30, 2010, 2001 and 2000) and, as at November 30, 2010, we had an accumulated deficit of \$235,116,000. We do not expect to generate significant recurrent revenues sufficient to cover our overall activities in the immediate future. As a result of the foregoing, we will need to generate significant revenues to achieve profitability.

Our profitability will depend on, among other things, our commercial partners' ability and willingness to successfully commercialize *EGRIFTA*TM and to obtain regulatory approval for the use of tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Latin America, Africa and the Middle East. However, there is no guarantee that our commercial partners will succeed in commercializing *EGRIFTA*TM or that our product candidates will ever receive approval for commercialization in any jurisdiction and, accordingly, we may never sustain profitability.

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

We have limited human resources to conduct preclinical studies and clinical trials and must rely on third-party service providers to conduct our studies and trials and carry out certain data gathering and analyses. If our third-party service providers become unavailable for any reason, including as a result of the failure to comply with the rules and regulations governing the conduct of preclinical studies and clinical trials, operational failures such as equipment failures or unplanned facility shutdowns, or damage from any event such as fire, flood, earthquake, business restructuring or insolvency or, if they fail to perform their contractual obligations pursuant to the terms of our agreements with them, such as failing to perform the testing, compute the data or complete the reports further to the testing, we may incur delays which may be significant in connection with the planned timing of our trials and studies which could adversely affect the timing of the development program of a product candidate or the filing of an application for marketing approval in a jurisdiction where we rely on third-party service providers to make such



filing. In addition, where we rely on such third-party service provider to help in answering any question raised by a regulatory agency during its review of one of our files, the unavailability of such third-party service provider may adversely affect the timing of the review of an application and, could ultimately delay the approval. If the damages to any of our third-party service providers are material, or, for any reason, such providers do not operate in compliance with Good Laboratory Practices, or GLP, or are unable or refuse to perform their contractual obligations, we would need to find alternative third-party service providers.

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

Any selection of new third-party service providers to carry out work related to preclinical studies and clinical trials would be timeconsuming and would result in additional delays in receiving data, analysis and reports from such third-party service providers which, in turn, would delay the filing of any new drug application with regulatory agencies for the purposes of obtaining regulatory approval to commercialize our product candidates. Furthermore, such delays could increase our expenditures to develop a product candidate and materially adversely affect our financial condition and operating results.

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

The conduct of clinical trials requires the enrolment of patients. We may have difficulties enrolling patients for the conduct of our future clinical trials as a result of design protocol, the size of the patient population, the eligibility criteria to participate in the clinical trials, the availability of competing therapies, the patient referral practices of physicians and the availability of clinical trial sites. Difficulty in enrolling patients for our clinical trials could result in the cancellation of clinical trials or delays in completing them. Once patients are enrolled in a clinical trial, the occurrence of any adverse drug effects or side effects observed during the trial could result in the clinical trial adverse consequences on the timely development of our product candidates, the filing of an NDA, or its equivalent, with regulatory agencies and the commercialization of such product candidates.

# We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements, including to continue and complete the research and development of our product candidates and their commercialization.

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

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

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

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

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

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

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

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

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

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

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

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

#### We may not achieve our publicly announced milestones on time.

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

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

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

#### **Risks Related to this Offering and our Common Shares**

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

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

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

#### Our common shares have no prior trading history in the United States, and an active market may not develop.

Our common shares are currently listed on the Toronto Stock Exchange, or TSX, but are not listed on any U.S. stock exchange or quoted on any U.S. quotation system. Accordingly, prior to this offering, there has been no public market in the United States for our common shares. The initial U.S. public offering price for our common shares may bear no relationship to the price at which our common shares will trade upon the completion of this offering. The price of our common shares may be lower than the price of the shares sold in this offering. In addition, because the liquidity and trading patterns of the common shares listed on the TSX may be substantially different from those of securities quoted on the Nasdaq Global Market, or Nasdaq, historical trading prices may not be indicative of the prices at which our shares will trade in the future. Although we have applied to have our common shares approved for quotation on the Nasdaq, an active trading market for our shares may never develop or be sustained in the United States following this offering. If an active market for our common shares does not develop, it may be difficult for U.S. residents to sell the shares they purchase in this offering without depressing the market price for the shares or at all.



#### We will incur increased costs as a result of becoming a reporting company in the United States.

As a U.S. reporting company, we will incur significant legal, accounting, insurance and other expenses that we have not incurred as a public company in Canada, including costs associated with reporting requirements. We also have incurred and will incur additional costs associated with compliance with the Sarbanes-Oxley Act of 2002, or SOX, and related rules implemented by the Securities and Exchange Commission, or SEC, and Nasdaq. The expenses incurred by U.S. reporting companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty.

#### Our quarterly operating results may fluctuate significantly.

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

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

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

#### We may allocate the net proceeds from this offering in ways that you and other shareholders may not approve.

We currently intend to use the proceeds from this offering to develop tesamorelin to advance our clinical program relating to muscle wasting in COPD, to complete our new formulation of *EGRIFTA*TM and tesamorelin, to finance our portion of the costs related to post-approval commitments required by the FDA, to continue the research and development of novel GRF peptides, for potential acquisitions, and for working capital and other general corporate purposes. Because of the number and variability of factors that will determine our use of the proceeds from this offering, their ultimate use may vary substantially from their currently intended use. As such, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common shares. For a further description of our intended use of the proceeds of the offering, see "Use of Proceeds."

## You will experience immediate and substantial dilution in the shares that you purchase in this offering because the per share price in this offering is substantially higher than the net tangible book value of existing common shares.

If you purchase shares in this offering, you will pay more for your shares than the net tangible book value of existing common shares. As a result, you will experience an immediate and substantial dilution in the pro forma net tangible book value of your shares. We have previously granted options to certain officers, directors, consultants and other employees to acquire our common shares at prices significantly below the public offering price. To the extent these outstanding options are exercised in the future, you will incur further dilution. See "Dilution."



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

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

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

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

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

#### Future sales of our common shares may cause our stock price to decline.

The market price of our common shares could decline as a result of issuances by us or sales by our existing shareholders of common shares in the market after this offering, or the perception that these sales could occur. Sales by shareholders might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. Upon the closing of this offering, there will be 71,515,764 common shares outstanding, 70,791,792 of which will be freely tradable immediately after this offering on either the TSX or the Nasdaq. An additional 723,972 common shares held by our directors and officers may be sold 90 days after the date of this offering.

#### We may be adversely affected by currency fluctuations.

A substantial portion of our revenue is earned in U.S. dollars, but a substantial portion of our operating expenses are incurred in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and other currencies, such as the Canadian dollar, may have a material adverse effect on our business, financial condition and operating results. We do not currently engage in transactional hedging schemes but we do attempt to hedge or mitigate the risk of currency fluctuations by actively monitoring and managing our foreign currency holdings relative to our foreign currency expenses.

#### Because we are a Canadian company, certain civil liabilities and judgments may not be enforceable against us.

We are incorporated under the laws of the Province of Québec, Canada. Most of our directors and officers and certain of the experts named elsewhere in this prospectus are residents of Canada. All or a substantial portion of our assets and the assets of these persons are located outside of the United States. As a result, it may be difficult for a shareholder to initiate a lawsuit within the United States against these non-U.S. residents, or to enforce in the



United States judgments that are obtained in a U.S. court against us or these persons. It may also be difficult for shareholders to enforce a U.S. judgment in Canada, or to succeed in a lawsuit in Canada, based solely on violations of U.S. securities laws. See "Enforceability of Civil Liabilities".

#### 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. See "Description of Share Capital – Shareholder Rights Plan".

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.

### Our independent registered public accounting firm may not be able to conclude that our internal control over financial reporting are effective as required by Section 404 of Sarbanes Oxley Act of 2002.

Pursuant to Section 404 of SOX, beginning with our Annual Report on Form 40-F for the fiscal year ended November 30, 2012, our independent registered public accounting firm will be required to furnish a report on our internal controls over financial reporting. We can provide no assurance as to our independent registered public accounting firm's conclusions with respect to the effectiveness of our internal controls over financial reporting under Section 404 of SOX. In connection with the attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favourable attestation. If our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and our stock price could decline.

### We believe that we are not currently a PFIC for U.S. federal income tax purposes, but PFIC classification is fundamentally factual in nature, determined annually and subject to change.

We do not believe that we are currently a passive foreign investment company, or PFIC, and do not expect to become a PFIC for U.S. federal income tax purposes in the foreseeable future. However, if we are a PFIC or if we were to become a PFIC in future taxable years while a U.S. Holder (as defined below under the heading "Certain U.S. Federal Income Tax Considerations") holds common shares, such U.S. Holder would generally be subject to adverse U.S. federal income tax consequences, including the treatment of gain realized on the sale of common shares as ordinary (rather than capital gain) income, potential interest charges on those gains and certain other distributions made by us and ineligibility for the preferential tax rates on dividends paid by qualified foreign corporations generally available to certain non-corporate U.S. Holders. For a more detailed discussion of the consequences of our company being classified as a PFIC, including discussion of certain elections that (if available) could mitigate some of the adverse consequences described above, see below under the heading "Certain Material Income Tax Considerations – Certain U.S. Federal Income Tax Considerations – *Passive Foreign Investment Company*".

U.S. purchasers are urged to consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the acquisition, ownership, and disposition of the Offered Shares as may be applicable to their particular circumstances.

### As a foreign private issuer, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our shareholders.

As a foreign private issuer we are not required to comply with all the periodic disclosure requirements of the Securities Exchange Act of 1934, as amended, and therefore there may be less publicly available information about us than if we were a U.S. domestic issuer. In addition, our officers, directors, and principal shareholders are exempt from the reporting and "short swing" profit recovery provisions of Section 16 of the Securities Exchange Act of



1934, as amended, and the rules promulgated thereunder. Therefore, our U.S. shareholders may not know on a timely basis when our officers, directors and principal shareholders purchase or sell our common shares.

### We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses to us.

In order to maintain our current status as a foreign private issuer, a majority of our common shares must be either directly or indirectly owned by non-residents of the United States unless we also satisfy one of the three additional requirements in accordance with the definition of "foreign private issuer" under the Securities Exchange Act of 1934. In addition to the possibility of a majority of our common shares being owned by residents of the United States, if (i) the majority of our executive officers or directors are United States citizens or residents, (ii) more than fifty percent of our assets are located in the United States and (iii) our business is administered principally in the United States, then we would lose our foreign private issuer status. At this time, we satisfy all requirements to preserve our status as a foreign private issuer, but we cannot be certain that we will meet any or all of these requirements in the future. The regulatory and compliance costs to us under U.S. federal securities laws as a U.S. domestic issuer may be significantly more than the costs we incur as a Canadian foreign private issuer eligible to use the multijurisdictional disclosure system, or MJDS. If we are not a foreign private issuer, we would not be eligible to use the MJDS or other foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. We may also be required to prepare our financial statements in accordance with U.S. GAAP. In addition, we may lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.

#### **EXCHANGE RATE INFORMATION**

The following table sets forth for each period indicated: (i) the closing exchange rates in effect at the end of the period; (ii) the high and low closing exchange rates during such period; and (iii) the average closing exchange rates for such period, for one Canadian dollar, expressed in U.S. dollars, as quoted by the Bank of Canada.

	PERIOD FROM DECEMBER 1, 2010 TO FEBRUARY 18, 2011	YEAR ENDED NOVEMBER 30, 2010	YEAR ENDED NOVEMBER 30, 2009
Period End	US\$1.0142	US\$0.9741	US\$0.9473
High	US\$1.0153	US\$1.0012	US\$0.9748
Low	US\$0.9828	US\$0.9307	US\$0.7698
Average	US\$1.0060	US\$0.9613	US\$0.8692

The average closing exchange rate is calculated based on the last business day of each month for the applicable period. On February 18, 2011, the closing exchange rate for one Canadian dollar, expressed in U.S. dollars, as quoted by the Bank of Canada was US\$1.0142.

#### **USE OF PROCEEDS**

Based on an assumed public offering price of US\$5.08 per share (which represents the U.S. dollar equivalent of the \$5.01 closing price of our common shares as reported on the TSX on February 18, 2011), the net proceeds to us from the sale of our common shares in this offering will be approximately US\$50.2 million, or approximately US\$58.1 million if the over-allotment option is exercised in full, in each case, after deducting estimated underwriting discounts and commissions and estimated expenses of this offering.

We expect to use the net proceeds from this offering (i) to advance our clinical program relating to muscle wasting in COPD, (ii) to complete our new formulation of *EGRIFTA*<sub>TM</sub> and tesamorelin, (iii) to continue the research and development of novel GRF peptides, (iv) for potential acquisitions, and (v) for working capital and other general corporate purposes.

Pending such uses, we plan to invest the net proceeds of this offering in short-term, interest-bearing investment-grade securities and government securities. We will retain broad discretion in allocating the net proceeds of this offering based on budgets approved by our board of directors and consistent with established internal control guidelines. There may, however, be circumstances where, for sound business reasons, a reallocation of the net proceeds may be necessary and our actual use of such net proceeds may vary depending on our operating and capital needs from time to time.

#### TRADING PRICE AND VOLUME

Our common shares are traded on the TSX under the symbol "TH". We have applied to list our common shares on the Nasdaq under the symbol "THER". The following table sets forth the high and low closing sale prices for our common shares for the periods indicated, as reported on the TSX. However, you should not view this presentation as an indication that the market price of our common shares will continue at such levels.

MONTH	HIGH	LOW	VOLUME
Feb. 1 to Feb. 18, 2011	\$5.88	\$5.01	4,371,300
January 2011	\$5.90	\$5.43	3,319,500
December 2010	\$5.69	\$5.27	4,038,000
November 2010	\$5.80	\$4.91	8,127,400
October 2010	\$5.15	\$4.44	2,944,000
September 2010	\$4.98	\$4.78	1,230,300
August 2010	\$5.08	\$4.75	1,934,900
July 2010	\$5.48	\$4.82	3,795,500
June 2010	\$5.59	\$4.61	6,188,600
May 2010	\$5.02	\$2.09	11,593,700
April 2010	\$5.20	\$4.82	1,960,000
March 2010	\$5.50	\$4.80	2,612,100
February 2010	\$5.03	\$4.67	2,205,500

On February 18, 2011, the closing price of our common shares as reported on the TSX was \$5.01.

#### **DIVIDEND POLICY**

We have never declared or paid cash dividends on our common shares and do not anticipate paying any cash dividends on our common shares in the foreseeable future. We presently intend to retain future earnings, if any, to finance the expansion and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors the board of directors deems relevant. In addition, the terms of any future debt or credit facility may preclude us from paying dividends.

#### CAPITALIZATION

The following table describes our cash, short-term and long-term investments and our capitalization as at November 30, 2010: • on an actual basis; and

on an as-adjusted basis to give effect to our sale of 11,000,000 common shares in this offering at an assumed public offering price of US\$5.08 per share (which represents the U.S. dollar equivalent of the \$5.01 closing price of our common shares as reported on the TSX on February 18, 2011) and our receipt of estimated net proceeds of US\$50,231,000 (\$49,528,000), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information below with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this prospectus.

	AS AT NOVEMBER 30, 2010	
	ACTUAL	AS ADJUSTED
	\$	\$
	(in th	ousands)
		(unaudited
Cash and short-term investments	\$ 28,509	\$ 78,037
Long-term investments	36,041	36,041
Total	64,550	114,078
Shareholders' equity:		
Common shares, without par value; unlimited number of shares authorized; 60,512,764 shares issued and outstanding, actual and 71,512,764 common shares issued and outstanding, as		
adjusted	279,398	334,508
Contributed surplus	7,808	7,808
Deficit	(235,116)	(240,698)
Accumulated other comprehensive income	566	566
Total shareholders' equity	52,656	102,184
Total capitalization	\$ 52,656	\$ 102,184

# DILUTION

Our net tangible book value as at November 30, 2010 was approximately \$52.7 million, or \$0.87 per common share. Net tangible book value per share represents the total amount of our tangible assets (which consists of all of our assets) less total liabilities, divided by the number of common shares outstanding. Dilution in net tangible book value per share represents the difference between the amount per share that you pay in this offering and the net tangible book value per share after this offering.

Without taking into account any changes in such net tangible book value after November 30, 2010 other than to give effect to the issuance and sale by us of 11,000,000 common shares in the offering at an assumed public offering price of US\$5.08 per share (which represents the U.S. dollar equivalent of the \$5.01 closing price of our common shares as reported on the TSX on February 18, 2011) and after deducting estimated underwriting discounts and commissions and estimated offering expenses of approximately \$5.6 million payable by us, our pro forma net tangible book value as at November 30, 2010 is \$102.2 million, or \$1.43 per share. This represents an immediate increase in the net tangible book value of \$0.56 per share to existing shareholders and an immediate dilution of \$3.58 per share to new investors. The following table illustrates the per share dilution.

	\$
Canadian dollar equivalent of assumed U.S. public offering price per share	5.01
Net tangible book value per share as at November 30, 2010	0.87
Increase per share to existing investors	0.56
Pro forma net tangible book value per share after this offering	1.43
Dilution per share to new investors	3.58

The foregoing discussion and table assumes no exercise of any outstanding stock options and no issuance of common shares reserved for future issuance under our stock option plan or our common share purchase plan. As at November 30, 2010, there were options outstanding to purchase 2,849,138 common shares at a weighted average exercise price of \$5.12 per share. In addition, we may grant more options in the future.

Assuming the exercise in full of the underwriters' over-allotment option, our pro forma net tangible book value as at November 30, 2010 would have been \$109.9 million, or \$1.50 per share. This represents an immediate increase in the net tangible book value of \$0.63 per share to existing shareholders and an immediate dilution of \$3.51 per share to new investors.

#### SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and the accompanying notes included elsewhere in this prospectus. The consolidated statement of comprehensive income data for the years ended November 30, 2010 and 2009, and the consolidated statement of financial position data as at November 30, 2010 and 2009, set forth below, have been derived from our consolidated financial statements that have been audited by KPMG LLP, and which are included elsewhere in, or incorporated by reference into, this prospectus. Our consolidated financial statements have been prepared in accordance with IFRS as issued by the IASB. Our financial statements were previously prepared in accordance with GAAP. For more information regarding the conversion to IFRS, please refer to the heading "Conversion to IFRS" in our Management's Discussion and Analysis of Financial Condition and Results of Operations and to note 27 of the consolidated financial statements, which are our first consolidated financial statements prepared in accordance with IFRS. Our historical results from any prior period are not necessarily indicative of results to be expected for any future period.

IFRS differ in some significant respects from U.S. GAAP, and thus may not be comparable to the financial statements of United States companies. These differences between IFRS and U.S. GAAP might be material to the financial information presented in this prospectus. In addition, differences may arise in subsequent periods related to changes in IFRS or U.S. GAAP or due to new transactions we enter into. We are not required to prepare a reconciliation of our consolidated financial statements and related footnote disclosures between IFRS and U.S. GAAP and have not quantified such differences. In making an investment decision, potential investors must rely upon their own examination of the Company, the terms of this offering and the financial information included herein. Potential investors should consult their own professional advisors for an understanding of the differences between IFRS and U.S. GAAP and have the financial information herein.

### **Consolidated Statement of Comprehensive Income Data:**

	YEAR ENDED	YEAR ENDED NOVEMBER 30,		
	2010	2009		
		ls, except per mounts)		
Milestone payments	\$25,000	\$10,884		
Other revenue	6,868	6,584		
Total revenue	31,868	17,468		
Research and development expenses, net of tax credits	14,064	20,810		
Total operating expenses	25,205	34,215		
Total net financial income	2,381	1,591		
Net profit (loss) before income taxes	9,044	(15,156)		
Income tax expense	114	_		
Net profit (loss)	8,930	(15,156)		
Total comprehensive income (loss) for the year	8,214	(14,246)		
Basic and diluted earnings (loss) per share	0.15	(0.25)		

The following table describes our cash and bonds, total assets, total liabilities and total equity:

- as at November 30, 2010 and 2009, on an actual basis; and
- as at November 30, 2010, on an as adjusted basis to give effect to our sale of 11,000,000 common shares in this offering at an assumed public offering price of US\$5.08 per share (which represents the U.S. dollar equivalent of the \$5.01 closing price of our common shares as reported on the TSX on February 18, 2011) and our receipt of estimated net proceeds of US\$50,231,000 (\$49,528,000), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

#### **Consolidated Statement of Financial Position Data:**

		As at November 30,		
		2010		
	Actual	Actual As Adjusted (in thousands)		
Cash and bonds	\$64,550	\$114,078	\$63,362	
Total assets	71,651	121,179	69,154	
Total liabilities	18,995	18,995	26,106	
Total equity	52,656	102,184	43,048	

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following information should be read in conjunction with the section entitled "Selected Consolidated Financial Data" and our audited consolidated financial statements and related notes thereto included elsewhere in this prospectus. Our audited consolidated financial statements have been prepared in accordance with IFRS. The interim financial statements from which the numbers under the heading "Quarterly Financial Information" below have been derived have not been reviewed by our auditors. To the extent any statements made in this prospectus contain information that is not historical, these statements are forward-looking and are subject to risks and uncertainties, as activity, performance, or achievements could differ materially from those projected in this prospectus and depend on a number of factors, including the successful and timely completion of clinical studies, the uncertainties related to the regulatory process, and the commercialization of product candidates thereafter. See "Special Note Regarding Forward-Looking Statements".

# **Operating Results**

### Revenue

Our consolidated revenue for the year ended November 30, 2010 was \$31,868,000, compared to \$17,468,000 in 2009. The increased revenue in fiscal 2010 was related to the milestone payment of US\$25,000,000 (C\$25,000,000) received by us from EMD Serono on November 30, 2010 associated with the satisfaction of the condition of approval of *EGRIFTA*TM by the FDA. In fiscal 2009, a payment of US\$10,000,000 (C\$10,884,000) was received by us from EMD Serono following the acceptance by the FDA of the Company's NDA for *EGRIFTA*TM in conformity with the collaboration and licensing agreement with EMD Serono.

The initial payment of US\$22,000,000 (C\$27,097,000) received on December 15, 2008, upon the closing of the transaction with EMD Serono, has been deferred and is being amortized over its estimated service period of four years on a straight-line basis. For the year ended November 30, 2010, an amount of \$6,846,000 related to this transaction was recognized as revenue. At November 30, 2010, the deferred revenue related to this transaction recorded on the consolidated statement of financial position amounted to \$13,692,000.

We expect to generate revenue from sales of *EGRIFTA*<sub>TM</sub> to EMD Serono throughout fiscal 2011. We also expect to receive royalties on sales of *EGRIFTA*<sub>TM</sub> in the United States by EMD Serono beginning in the second quarter of fiscal 2011 upon receipt and confirmation of the sales report relating to the previous quarter. The royalty rate we receive from EMD Serono is based on the level of annual net sales achieved, with the rate increasing as higher levels of net sales are attained.

### **R&D** Activities

For the year ended November 30, 2010, consolidated research and development ("R&D") expenses, net of tax credits, amounted to \$14,064,000, compared to \$20,810,000 in 2009, a decrease of 32.4%. The majority of R&D expenses incurred in fiscal 2010 are related to follow-up on work derived from the regulatory filing with the FDA, notably responding to the FDA's questions, and preparation for the FDA Advisory Committee meeting. In parallel with the United States FDA review, we continued to advance our regulatory filing in Europe and to work on a new presentation of the existing formulation of *EGRIFTA*TM. Furthermore, we are in the process of evaluating the initiation of a new clinical program to develop tesamorelin for a new indication. In our discovery and preclinical groups, we continued to develop new peptides and to advance our preclinical program for acute kidney injury ("AKI"). In fiscal 2009, the expenses incurred were principally associated with completing the Phase 3 clinical trials evaluating tesamorelin in HIV-associated lipodystrophy and the preparation of the NDA, which was submitted to the FDA in May 2009. The significant decline in R&D expenses was in accordance with our projected R&D expenses for fiscal 2010. We expect the amount of our R&D expenses for fiscal 2011 to be similar to those of 2010.

## Cost of Sales

In fiscal 2010, we began producing through our third-party suppliers inventories in anticipation of the launch of *EGRIFTA*<sub>TM</sub> in the United States. Cost of sales in fiscal 2010 related to this activity amounted to \$469,000 which includes a charge of \$192,000, in order to value the inventories at their net realizable value. This write-down was due to raw materials that were not originally bought under the conditions of our current long-term procurement



agreements. Cost of sales also included unallocated costs related to the production fees associated with the start-up of the manufacturing process. We expect the cost of sales to increase significantly over the next fiscal year as sales of *EGRIFTA*<sup>TM</sup> grow and as we secure additional suppliers for raw materials and finished products.

# General and Administrative Expenses

For the year ended November 30, 2010, general and administrative expenses were \$8,002,000, compared to \$6,543,000 for the same period in fiscal 2009.

The higher expenses for the year ended November 30, 2010 are primarily due to the cost and expenses associated with professional fees for the recruitment of the new President and Chief Executive Officer, increased corporate communication associated with the FDA Advisory Committee meeting and FDA approval, and conversion of our financial statements to IFRS, as well as costs and expenses related to variations in share-based compensation expenses. The expenses for the year ended November 30, 2009 include the costs associated with the revision of our three-year business plan which were not repeated in fiscal 2010.

# Selling and Market Development Expenses

For the year ended November 30, 2010, selling and market development expenses were \$2,670,000, compared to \$6,862,000 in fiscal 2009.

The selling and market development expenses in fiscal 2010 are principally composed of business development expenses and market research outside the United States and the costs of managing the agreement with EMD Serono. In fiscal 2009, we incurred expenses totaling \$4,269,000 in connection with professional fees related to the transaction with EMD Serono.

## Net Financial Income

For the year ended November 30, 2010, interest income was \$1,562,000 compared to \$2,123,000 in fiscal 2009. The year-over-year decline is due to lower average cash positions and a decrease in yield on our bond portfolio. Receipt of the \$25,000,000 milestone payment from EMD Serono in November 2010 strengthened the Company's cash position to a level comparable to that of year-end 2009. Finance costs in fiscal 2010 were a gain of \$493,000 compared to an expense of \$661,000 in fiscal 2009. Finance costs in fiscal 2010 benefited from a net foreign currency gain of \$511,000 compared to a net foreign currency loss of \$635,000 in 2009.

## Net Results

Reflecting the changes in revenue and expenses described above, we realized a net profit of \$8,930,000 (\$0.15 per share) for the year ended November 30, 2010, compared to a net loss of \$15,156,000 (\$0.25 loss per share) for the same period in fiscal 2009. The net profit included revenue of \$31,846,000 related to the collaboration and licensing agreement with EMD Serono.

# **Quarterly Financial Information**

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

		201	.0			20	09	
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
		(in t	thousands of	Canadian dolla	ars, except pe	r share amour	nts)	
Revenue	\$26,717	\$1,717	\$1,717	\$1,717	\$1,718	\$12,601	\$1,717	\$1,432
Net profit (net loss)	\$21,299	\$(3,357)	\$(4,771)	\$(4,241)	\$(4,654)	\$5,779	\$(5,454)	\$(10,827)
Basic and diluted earnings (loss) per								
share	\$0.35	\$(0.06)	\$(0.08)	\$(0.07)	\$(0.08)	\$0.10	\$(0.09)	\$(0.18)

As described above, the higher revenue in the third quarter of 2009 is related to the milestone payment of \$10,884,000 received from EMD Serono following the FDA's acceptance to file the Company's NDA for *EGRIFTA*<sub>TM</sub>. The higher revenue in the fourth quarter of 2010 is related to the receipt from EMD Serono of a milestone payment of \$25,000,000 following marketing approval of *EGRIFTA*<sub>TM</sub> by the FDA.



# Fourth Quarter Comparison

Consolidated revenue for the three-month period ended November 30, 2010, amounted to \$26,717,000, compared to \$1,718,000 for the same period in fiscal 2009. The higher revenue in the three-month period ended November 30, 2010 is related to the milestone payment of \$25,000,000 received at the end of the fourth quarter, following marketing approval of *EGRIFTA*<sub>TM</sub> by the FDA in the United States.

Consolidated R&D expenses, net of tax credits, totaled \$3,172,000 for the fourth quarter of 2010, compared to \$4,212,000 for the same period in 2009, a decrease of 24.7%. The R&D expenses incurred in 2009 principally included expenses related to preparing for the FDA Advisory Committee meeting, which was held on May 27, 2010. The R&D expenses incurred in the fourth quarter of fiscal 2010 were mainly related to managing responses to the FDA's questions and the FDA approval process, in addition to the advancement of our regulatory filing in Europe and on a new presentation of the existing formulation of *EGRIFTA*TM. Furthermore, we are in the process of evaluating the initiation of a new clinical program to develop tesamorelin for a new indication. In our discovery and preclinical groups, we continued to develop new peptides and to advance our preclinical program in AKI.

General and administrative expenses were \$2,036,000 in the fourth quarter of 2010, compared to \$1,563,000 for the same period in 2009. The higher expenses for 2010 are principally related to the conversion of our financial statements to IFRS and FDA approval of *EGRIFTA*<sub>TM</sub> in the United States.

Selling and market development expenses amounted to \$761,000 for the fourth quarter of 2010, compared to \$1,069,000 for the same period in 2009. The sales and market development expenses in fiscal 2010 are principally composed of business development expenses outside the United States and the costs of performing our obligations under the agreement with EMD Serono. The increased costs in 2009 were principally due to market development costs in Europe to increase the awareness of lipodystrophy as a disease.

Consequently, we recorded a net profit for the three-month period ended November 30, 2010, of \$21,299,000 (\$0.35 per share), compared to a net loss of \$4,654,000 (\$0.08 per share) for the same period in 2009.

In the three-month period ended November 30, 2010, cash flows from operating activities, excluding changes in operating assets and liabilities, was \$22,037,000, compared to a use of cash of \$4,333,000 for the same period in 2009.

### Liquidity and Capital Resources

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

To fund our activities, we have relied primarily on public offerings of common shares in Canada and private placements of our common shares as well as on up-front payments and milestone payments primarily associated with the agreement with EMD Serono. When possible, we try to optimize our liquidity position using non-dilutive sources, including investment tax credits, grants and interest income.

For the year ended November 30, 2010, cash flow from operating activities, excluding changes in operating assets and liabilities, was \$11,160,000 compared to a use of cash of \$13,547,000 in fiscal 2009. The cash flow generated in fiscal 2010 is principally related to payments received under the agreement with EMD Serono as well as decreases in R&D expenses and in selling and market development expenses.

At November 30, 2010, cash and bonds amounted to \$64,550,000 and tax credits and grants receivable amounted to \$332,000, for a total of \$64,882,000.

At this time, apart from our unused \$1,800,000 revolving credit facility, we do not have any additional arrangements for external debt financings, and are not certain whether any proposed debt financing in the future, would be available on acceptable terms, or available at all. We may seek additional capital through the incurrence of debt, the issuance of equity or other financing alternatives.

We invest our available cash in highly liquid fixed income instruments from governmental, municipal and paragovernmental bodies (\$37,542,000 at November 30, 2010) as well as corporate bonds with high credit ratings (\$359,000 at November 30, 2010).



In the year ended November 30, 2010, the Company received share subscriptions amounting to \$15,000 (\$96,000 in fiscal 2009) for the issuance of 2,880 common shares (34,466 in 2009) in connection with the share purchase plan. Under the terms of the agreement with EMD Serono, we issued 2,179,837 common shares for a cash consideration of US\$8,000,000 (C\$9,854,000) during the first quarter of 2009.

In fiscal 2010, our third-party suppliers began to manufacture inventory of *EGRIFTA*<sub>TM</sub> for commercialization in the United States. We expect to continue to build our inventory until we reach an adequate level of finished goods to meet the needs of our partners and this will significantly increase our working capital needs in fiscal 2011.

## **Contractual Obligations**

#### Commitments

We rent our headquarters and main office pursuant to a lease expiring in April 2021. At November 30, 2010 and 2009, and at December 1, 2008, the minimum payments required under the terms of the non-cancellable lease were as follows:

	NOVEMBER 30, 2010	NOVEMBER 30, 2009	DECEMBER 1, 2008	
	(in thou	(in thousands of Canadian dollars		
Less than one year	55	340	816	
Between one and five years	2,239	2,020	340	
More than five years	3,943	4,216		
	6,237	6,576	1,156	

#### Long-Term Procurement Agreements

During and after the years ended November 30, 2010 and 2009, we entered into long-term procurement agreements with thirdparty suppliers in anticipation of the commercialization of *EGRIFTA*<sub>TM</sub>.

### **Credit Facility**

We have a \$1,800,000 revolving credit facility, bearing interest at prime plus 0.5%. Under the term of the revolving credit facility, the market value of investments held must always be equivalent to 150% of amounts drawn under the facility. If the market value falls below \$7,000,000, we will provide the bank with a first rank movable hypothec (security interest) of \$1,850,000 on securities judged satisfactory by the bank. As at November 30, 2010, we did not have any borrowings outstanding under this credit facility.

### **Post-Approval Commitments**

See "Our Business — EGRIFTA™ – Our Lead Product".

### **Contingent Liability**

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

The Motion has not yet been heard by the Superior Court of Quebec and a date has not been set for the hearing.

The Company has subscribed to insurance covering its potential liability and the potential liability of its directors and officers in the performance of all their duties for the Company subject to a \$200,000 deductible. At November 30, 2010, an amount of \$96,000 in legal fees had been accrued and included in general and administrative expenses, of which \$61,000 was paid during the year and \$35,000 remained in accounts payable and accrued liabilities.

# **Off-Balance Sheet Arrangements**

We were not involved in any off-balance sheet arrangements for the year ended November 30, 2010, with the exception of the lease of our headquarters as described above.

# **Subsequent Events**

# **Distribution and Licensing Agreements**

On December 6, 2010, we announced the signing of a distribution and licensing agreement with Sanofi covering the commercial rights for *EGRIFTA*™ in Latin America, Africa, and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

Under the terms of the Agreement, we will sell *EGRIFTA*<sub>TM</sub> to Sanofi at a transfer price equal to the higher of a percentage of Sanofi's net selling price and a predetermined floor price. We have retained all future development rights to *EGRIFTA*<sub>TM</sub> and will be responsible for conducting research and development for any additional potential indications. Sanofi will be responsible for conducting all regulatory activities for *EGRIFTA*<sub>TM</sub> in the aforementioned territories, including applications for approval in the different countries for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. We also granted Sanofi an option to commercialize tesamorelin for other indications in the territories mentioned above. If such option is not exercised, or is declined, by Sanofi, we may commercialize tesamorelin for such indications on our own or with a third-party.

On February 3, 2011, we entered into a distribution and licensing agreement with Ferrer covering the commercial rights for *EGRIFTA*<sub>TM</sub> for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the Agreement, we will sell *EGRIFTA*TM to Ferrer at a transfer price equal to the higher of a significant percentage of Ferrer's net selling price and a predetermined floor price. We have retained all development rights to *EGRIFTA*TM for other indications and will be responsible for conducting research and development for any additional programs. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with *EGRIFTA*TM for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTA*TM to Ferrer. We have the option to co-promote *EGRIFTA*TM for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Ferrer has the option to enter into a co-development and commercialization agreement using tesamorelin relating to any such new indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development.

## Deferred Share Unit Plan

In December 2010, we adopted a deferred share unit plan ("Plan") to provide long-term incentive compensation for our directors and executive officers. Under the Plan, directors must receive their annual remuneration as a board member in fully vested deferred share units ("DSUs") until they reach a percentage of their annual remuneration and, once such percentage is attained, they have the option to elect to receive part or all of their annual remuneration in DSUs. Under the plan, executive officers have the option of receiving all or a portion of their annual bonus in the form of fully-vested DSUs. The units are only redeemable for cash when a participant ceases to be an employee or member of the Board of Directors. We manage the risk associated with the issuance of the DSU by entering into a yearly forward contract with a third-party. As at February 7, 2011, all of the 99,912 DSUs outstanding were covered by a prepaid forward contract.

## Stock Option Plan

Between December 1, 2010 and February 7, 2011, the Company granted 250,000 options at an exercise price of \$5.65 per share. Also, 27,832 options were forfeited and expired at a weighted exercise average price of \$12.06 per share and 3,000 options were exercised at a weighted exercise average price of \$1.80 per share for a cash consideration of \$5,000.



# **Financial Risk Management**

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

## Credit Risk

The Company's exposure to credit risk currently relates to accounts receivable with only one customer (see note 4 of the Audited Consolidated Financial Statements). Credit risk is the risk of an unexpected loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. We regularly monitor credit risk exposure and take steps to mitigate the likelihood of this exposure resulting in losses.

Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. We invest our available cash in highly liquid fixed income instruments from governmental, paragovernmental and municipal bodies (\$37,542,000 as at November 30, 2010) as well as from companies with high credit ratings (\$359,000 as at November 30, 2010). As at November 30, 2010, we were not exposed to any credit risk over the carrying amount of the bonds.

# Liquidity Risk

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

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

The required payments on the contractual maturities of financial liabilities, as well as the payments required under the terms of the operating lease, as at November 30, 2010, are presented in notes 20 and 23 of the Audited Consolidated Financial Statements.

## **Currency Risk**

We are exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of our business transactions denominated in currencies other than the Canadian dollar, primarily revenues from milestone payments and expenses for research and development incurred in U.S. dollars, euros and pounds sterling ("GBP"). We do not use derivative financial instruments to reduce our foreign exchange exposure.

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

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



# The following table provides significant items exposed to currency risk as at November 30, 2010:

	NOVEN	NOVEMBER 30, 2010		
	\$US	EURO	GBP	
	(in thous	ands of do	ollars)	
Cash	26,424	_	1	
Trade and other receivables	—	_	—	
Accounts payable and accrued liabilities	(465)	(26)	(81)	
Items exposed to currency risk	25,959	(26)	(80)	

The following exchange rates applied during the year ended November 30, 2010:

	AVERAGE RATE	REPORTING DATE RATE
US\$ – C\$	1.0345	1.0266
EURO – C\$	1.3848	1.3326
GBP – C\$	1.6051	1.5969

In fiscal 2010, based on our foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the Canadian dollar would have increased the net profit as follows, assuming that all other variables remained constant:

	\$US	EURO	GBP
	(in thousa	nds of dol	lars)
Increase in net profit	1,298	(1)	(4)

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

#### Interest Rate Risk

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

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

Based on the value of our short and long-term bonds at November 30, 2010, 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 \$336,000; an assumed increase in interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

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

Based on the average value of variable interest-bearing cash during year ended November 30, 2010 (\$3,219,000), an assumed 0.5% increase in interest rates during such period would have increased the future cash flow and the net profit by approximately \$16,000; an assumed decrease of 0.5% would have had an equal but opposite effect.

# **Financial Instruments**

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

Bonds are stated at estimated fair value, determined by inputs that are primarily based on broker quotes at the reporting date (level 2 inputs – see note 22 – Determination of fair values).

#### **Critical Accounting Estimates**

#### Use of Estimates and the Exercise of Judgment

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

Information about critical judgments in applying accounting policies and assumption and estimation uncertainties that have the most significant effect on the amounts recognized in the consolidated financial statements is included in the following notes to the Audited Consolidated Financial Statements:

Note 4 – Revenue and deferred revenue Note 15 (iv) – Stock option plan Note 16 – Income taxes Note 18 – Contingent liability

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

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

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

# **Conversion to IFRS**

In February 2008, the Accounting Standards Board of Canada ("AcSB") announced that accounting standards in Canada, as used by public companies, would converge with IFRS, for financial periods beginning on and after January 1, 2011 with the option to early adopt IFRS upon receipt of approval from the Canadian Securities regulatory authorities. In the fourth quarter, we filed a request to adopt IFRS two years in advance of the date required under the AcSB, using December 1, 2008 as the date of transition and December 1, 2009 as the changeover date. Our request was granted and as a result, the consolidated financial statements for the year ended November 30, 2010 are our first annual financial statements prepared in conformity with IFRS.

Because we had previously filed financial statements and MD&As for the first, second and third quarters of 2010 with comparisons to 2009 in accordance with Canadian GAAP, these statements were restated and re-filed on February 8, 2011 to reflect our adoption of IFRS. Periods prior to December 1, 2008 have not been restated.

In preparing these first IFRS financial statements, we used the IFRS accounting policies in effect as at November 30, 2010, including IFRS 1 – *First-time Adoption of International Financial Reporting Standards* ("IFRS 1"). IFRS 1 provides guidance for an entity's initial adoption of IFRS and outlines that, in general, an entity applies the principles under IFRS retrospectively with adjustments arising on conversion from Canadian GAAP to IFRS 1 also requires companies adopting IFRS to reconcile equity and net earnings from the previously reported Canadian GAAP amounts to the restated IFRS amounts. Our reconciliation of equity under Canadian GAAP as at December 1, 2008, the date of transition, and as at November 30, 2009 to the restated IFRS amounts are included

in note 27 of the consolidated financial statements, as is the reconciliation of comprehensive income for the year-ended November 30, 2009.

IFRS 1 also provides certain optional exemptions from retrospective application of certain IFRS requirements as well as mandatory exceptions which prohibit retrospective application of standards.

We elected to apply the following optional exemptions from full retrospective application:

- (i) *IFRS 2 Share-based Payment:* IFRS 1 encourages the application of IFRS 2, *Share-based Payment* provisions to equity instruments granted on or before November 7, 2002, but permits the application only to equity instruments granted after November 7, 2002 that were not vested by the transition date. As permitted by this exemption, the Company applied IFRS 2 only to equity instruments granted after November 7, 2002 that were not vested by the transition date. As permitted by this exemption, the Company applied IFRS 2 only to equity instruments granted after November 7, 2002 that were not vested by December 1, 2008.
- (ii) Designation of financial assets and financial liabilities exemption: we elected to re-designate cash from the held for trading category to loans and receivables.
- We also followed the mandatory exemptions applicable to the Company as described below:

*Estimates* – Hindsight cannot be used to create or revise estimates. Estimates previously made under Canadian GAAP cannot be revised for application of IFRS except where necessary to reflect any difference in accounting policies.

## Impact of IFRS on the Company's Financial Statements

The adoption of IFRS resulted in some changes to our accounting policies that were applied in the recognition, measurement and disclosure of balances and transactions in our financial statements. However, none of the changes to our accounting policies resulted in significant changes to line items within our financial statements.

The following provides a summary of our evaluation of important changes to accounting policies in key areas:

# IFRS 2, Share-Based Payment ("IFRS 2")

Under IFRS, when stock option awards vest gradually, each tranche is to be considered as a separate award, while under Canadian GAAP, companies can make a policy choice to consider gradually vested tranches as a single award. Similarly, the IFRS standard requires that forfeiture estimates be established at the time of the initial fair value assessment of share-based payments rather than to account for the forfeitures as they occur. Therefore, the compensation expense will have to be recognized over the expected term of each tranche and take into account the impact of the differences in accounting for forfeitures. As a result of this change, an amount of \$175,000 was recorded to deficit at the transition date, with the counterpart to contributed surplus.

#### IAS 36, Impairment of Assets ("IAS 36")

Under Canadian GAAP impairment standards for non-financial assets, a write-down to estimated fair value is recognized if the estimated undiscounted future cash flows from an asset or group of assets are less than their carrying value. IAS 36 requires a write-down to be recognized if the recoverable amount, determined as the higher of the estimated fair value less costs to sell or value in use, is less than carrying value. We performed impairment testing as of December 1, 2008 and concluded that no impairment charge was required under IFRS. No impairment indicators were identified for the period between the transition date and November 30, 2009 and November 30, 2010. IAS 36 also permits the reversal of certain impairment charges where conditions have changed. We reviewed past impairment charges and concluded that there was no justification for reversal of past impairment charges.

# IAS 1, Presentation of Financial Statements ("IAS 1")

Financial statement presentation is addressed in conjunction with the related IFRS standards. Certain additional disclosures were required in the notes to the financial statements and the statement of comprehensive income was modified to reflect a presentation by function. The reclassifications required as a result of this change are described in note 27 (c) of the consolidated financial statements.

### Other Standards

Our examination of all other standards, including for example, IAS 21 – The Effects of Changes in Foreign Exchange Rates, IAS 37 – Provisions, Contingent Liabilities and Contingent Assets, and IAS 18 – Revenue, revealed no significant adjustment was necessary other than enhanced disclosures.



Note 27 of the consolidated financial statements for the year ended November 30, 2010 contains a detailed description of our conversion to IFRS, including a line-by-line reconciliation of our financial statements previously prepared under Canadian GAAP to those under IFRS as at November 30, 2009 and December 1, 2008.

## Impact on the Business

The impact of the conversion to IFRS on the Company was minimal and therefore resulted in a limited number of adjustments. Our systems easily accommodated the required changes. Our internal controls and disclosure controls and procedures did not require significant modification as a result of its conversion to IFRS. Furthermore, there was no impact on our contractual arrangements or compliance thereto.

# Impact on Information Systems and Technology

The transition had minimal impacts on our information systems. The areas where information systems were most impacted were minor modifications to certain general ledger accounts, sub-ledgers and end-user reports to accommodate IFRS accounting adjustments, recording, and heightened disclosures.

# Impact on Internal Control over Financial Reporting and Disclosure Controls and Procedures

Our internal controls over financial reporting were also not significantly affected by the transition to IFRS. The IFRS differences required presentation and process changes to report more detailed information in the notes to the financial statements, as well as certain changes to the recognition and measurement practices. Disclosure controls and procedures were adapted to take into consideration the changes in recognition, measurement and disclosure practices but the impact was minimal as well.

## Impact on Financial Reporting Expertise

Training and education was provided to all members of the finance team who are directly affected by the transition to IFRS. This training focused mainly on the process changes required and an overview of the reasons behind the changes from a standards perspective.

#### **New Accounting Policies**

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning after January 1, 2010 or later periods. Many of these updates are not applicable or are inconsequential to us and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on our results and financial position:

#### Annual Improvements to IFRS

The IASB's improvements to IFRS published in April 2009 contain fifteen amendments to twelve standards that result in accounting changes for presentation, recognition or measurement purposes largely for annual periods beginning on or after January 1, 2010, with early adoption permitted. These amendments were considered by the Company and deemed to be not applicable to the Company other than for the amendment to IAS 17 – Leases relating to leases which include both land and buildings elements. In this case, the Company early adopted this amendment.

The IASB's improvements to IFRS contain seven amendments that result in accounting changes for presentation, recognition or measurement purposes. The most significant features of the IASB's annual improvements project published in May 2010 are included under the specific revisions to standards discussed below.

(i) IFRS 3:

Revision to IFRS 3, Business Combinations:

Effective for annual periods beginning on or after July 1, 2010 with earlier adoption permitted.

Clarification on the following areas:

- the choice of measuring non-controlling interests at fair value or at the proportionate share of the acquiree's net assets applies only to instruments that represent present ownership interests and entitle their holders to a proportionate share of the net assets in the event of liquidation. All other components of non-controlling interest are measured at fair value unless another measurement basis is required by IFRS.
- application guidance relating to the accounting for share-based payments in IFRS 3 applies to all share-based payment
  transactions that are part of a business combination, including un-replaced awards (i.e., unexpired awards over the
  acquiree shares that remain outstanding rather than being replaced by the acquirer) and voluntarily replaced share-based
  payment awards.



(ii) IFRS 7:

Amendment to IFRS 7, Financial Instruments: Disclosures: Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted. Multiple clarifications related to the disclosure of financial instruments and in particular in regards to transfers of financial assets.

(iii) IAS 1:

Amendment to IAS 1, Presentation of Financial Statements: Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted. Entities may present the analysis of the components of other comprehensive income either in the statement of changes in equity or within the notes to the financial statements.

(iv) IAS 27:

Amendment to IAS 27, Consolidated and Separate Financial Statements:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted. The 2008 revisions to this standard resulted in consequential amendments to IAS 21, *The Effects of Changes in Foreign Exchange Rates*, IAS 28, *Investments in Associates*, and IAS 31, *Interests in Joint Ventures*. IAS 27 now provides that these amendments are to be applied prospectively.

(v) IAS 34:

Amendment to IAS 34, Interim Financial Reporting:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted.

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

# New or Revised Standards and Interpretations

In addition, the following new or revised standards and interpretations have been issued but are not yet applicable to the Company:

(i) IAS 24:

Amendments to IAS 24, Related Party Disclosures:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption is permitted. There are limited differences in the definition of what constitutes a related party; however, the amendment requires more detailed disclosures regarding commitments.

- (ii) IFRS 8:
  - IFRS 8, Operating Segments:

Effective for annual periods beginning on or after January 1, 2010. Requires purchase information about segment assets.

- (iii) IFRS 9:
  - New standard IFRS 9, Financial Instruments:

Effective for annual periods beginning on or after January 1, 2013 with earlier adoption permitted. As part of the project to replace IAS 39, *Financial Instruments: Recognition and Measurement*, this standard retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets. More specifically, the standard:

- · deals with classification and measurement of financial assets
- · establishes two primary measurement categories for financial assets: amortized cost and fair value
- classification depends on entity's business model and the contractual cash flow characteristics of the financial asset

• eliminates the existing categories: held to maturity, available for sale, and loans and receivables.

Certain changes were also made regarding the fair value option for financial liabilities and accounting for certain derivatives linked to unquoted equity instruments.

# **Outstanding Share Data**

At February 7, 2011, the common shares issued and outstanding were 60,515,764 while outstanding options granted under the stock option plan were 3,068,306.

# Disclosure Controls and Procedures and Internal Control Over Financial Reporting

As at November 30, 2010, an evaluation of the design and operating effectiveness of our disclosure controls and procedures, as defined in the rules of Canadian Securities Administrators, was carried out. Based on that evaluation, the President and Chief Executive Officer and the Senior Executive Vice-President and Chief Financial Officer concluded that the design and operating effectiveness of those disclosure controls and procedures were effective.

Also as November 30, 2010, an evaluation of the design and operating effectiveness of internal controls over financial reporting, as defined in the rules of the Canadian Securities Administrators, was carried out to provide reasonable assurance regarding the reliability of financial reporting and financial statement compliance with IFRS. Based on that evaluation, the President and Chief Executive Officer and the Senior Executive Vice-President and Chief Financial Officer concluded that the design and operating effectiveness of internal controls over financial reporting were effective.

These evaluations were based on the framework established in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, a recognized control model, and the requirements of Multilateral Instrument 52-109 of the Canadian Securities Administrators. A disclosure committee comprised of members of senior management assists the President and Chief Executive Officer and the Senior Executive Vice-President and Chief Financial Officer in their responsibilities.

All control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention or overriding of the controls or procedures. As a result, there is no certainty that our disclosure controls and procedures or internal control over financial reporting will prevent all errors or all fraud. There were no changes in our internal controls over financial reporting that occurred during the year ended November 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

#### OUR BUSINESS

#### Overview

We are a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on GRF peptides. Our strategy is to leverage our expertise in the field of metabolism and GRF peptides to address serious health disorders while remaining actively involved in the commercialization of our future products. Our first product, *EGRIFTA*<sub>TM</sub> (tesamorelin for injection), was approved by the FDA in November 2010. *EGRIFTA*<sub>TM</sub> is currently the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

We estimate that excess abdominal fat in HIV-infected patients affects approximately 29% of HIV-infected patients treated with antiretroviral therapies and approximately 12% of untreated patients. In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. Lipodystrophy is characterized by abnormalities in the production and storage of fat, which lead to excess abdominal fat, or lipohypertrophy, and the loss of fat tissue, or lipoatrophy, generally occurring in the limbs and facial area.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood (such as triglycerides and cholesterol), and hyperglycemia, an increase in the amount of sugar in the blood, characterized by insulin resistance, both of which lead to increased risks of cardiovascular disease and diabetes. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy.

*EGRIFTA*<sup>TM</sup> is currently marketed exclusively in the United States by EMD Serono, an affiliate of Merck KGaA, pursuant to a collaboration and licensing agreement. We have also recently entered into distribution and licensing agreements for *EGRIFTA*<sup>TM</sup> with Sanofi granting Sanofi the exclusive commercialization rights in Latin America, Africa and the Middle East and with Ferrer granting Ferrer the exclusive commercialization rights in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. Using data compiled by the CDC and WHO/UNAIDS, we estimate that in 2012, there will be approximately 190,000 HIV-infected patients treated with antiretroviral therapies with lipohypertrophy in the United States, 170,000 in Europe, and 180,000 in Latin America, or 540,000 patients in total. We also estimate that in 2012, there will be an additional 47,000 HIV-infected untreated patients with lipohypertrophy in the United States, 42,000 in Europe, and 28,000 in Latin America, or an additional 117,000 patients in total.

In January 2011, EMD Serono launched *EGRIFTA*<sub>TM</sub> in the United States. EMD Serono is executing a launch program that consists of medical education, advertising, marketing and promotion through their experienced sales force, and supporting market access through co-pay programs, reimbursement education and support for payors. We believe *EGRIFTA*<sub>TM</sub> will achieve a high degree of physician and payor acceptance driven by our product's safety and efficacy, the lack of approved alternative therapies for these patients and the prominent medical and social need to treat HIV/AIDS patients.

*EGRIFTA*<sup>TM</sup> is the trade name used for our first marketed product using our most advanced compound, tesamorelin. Tesamorelin is a GRF analogue that stimulates the synthesis and pulsatile release of endogenous growth hormone. Tesamorelin was synthesized using our internally-developed peptide stabilization method. This method increases a protein's resistance to enzymatic degradation, which prolongs its duration of action and enhances its effectiveness in clinical use. We believe this compound and future GRF analogues that we are developing can be used in a number of additional high-value indications. Clinical data have shown tesamorelin to have both lipolytic (fat-burning) and anabolic (muscle-building) properties. Our initial development of *EGRIFTA*<sup>TM</sup> focused on the lipolytic properties of the compound.

Tesamorelin's anabolic properties have led us to pursue its development for muscle wasting in COPD patients as our second indication. COPD is characterized by progressive airflow obstruction due to chronic bronchitis or emphysema leading in certain cases to muscle wasting, a decrease of muscle mass and deterioration in functionality. We have completed a Phase 2 trial which demonstrated a statistically significant increase in lean body mass. Based upon these trial results, we intend to randomize our first patient in a new Phase 2 clinical study in the second half of

2011. Based on available market data, we estimate that in 2009 the number of diagnosed COPD patients with muscle wasting was approximately 3.1 million in the United States, France, Germany, Italy, United Kingdom, Spain and Japan.

To solidify our leadership position in the field of GRF therapeutics, we have embarked on a program to discover new generations of GRF analogues. We believe that GRF compounds have the potential to improve patient outcome in many high-value indications, such as wasting in chronic heart failure and renal failure, as well as growth hormone deficiency with abdominal obesity. We also believe that we can improve the route of administration of GRF peptides to make them quicker and easier to use for patients. Our early-stage pipeline also includes compounds for the treatment of AKI and certain cancers.

# **Our Strategy**

Our goal is to leverage our expertise in the field of metabolism and GRF peptides to become a leading specialty pharmaceutical company with the necessary infrastructure to take innovative therapeutic products from research and development to full commercialization in worldwide markets. Key elements of this strategy include:

# Maximize the Global Commercial Potential of EGRIFTATM

In order to maximize the commercial potential of *EGRIFTA*<sub>TM</sub> we have entered into licensing agreements with EMD Serono, Sanofi and Ferrer for different territories around the world. We intend to continue to support our commercial partners to ensure the successful commercialization of *EGRIFTA*<sub>TM</sub> in their respective territories. This will include regulatory support, manufacture and supply of *EGRIFTA*<sub>TM</sub> and potential co-promotion.

We have developed a new presentation of *EGRIFTA*TM which is quicker and easier to use than its current presentation. We are also developing a new and more concentrated formulation of tesamorelin. Compared to our current formulation, this new formulation requires a smaller volume of injection and is expected to be stable at room temperature. In addition, this new formulation could potentially be used with a new delivery device such as a pen, to facilitate patient self-administration. We expect the new presentation and the new formulation will have a positive impact on our manufacturing capacity and will significantly reduce our unit costs.

## Develop Tesamorelin for Muscle Wasting in COPD

We will be conducting a new clinical program in muscle wasting in COPD. We have demonstrated in a first Phase 2 clinical trial that tesamorelin has increased muscle mass in COPD patients. We believe tesamorelin could improve patients' functionality in daily activities and address a significant unmet need in a large and potentially lucrative market.

# Solidify Our Position as a Leader in the Field of Novel GRF Products

We will leverage our expertise in peptide discovery, drug development and regulatory affairs to continue our development of new peptides, primarily GRF peptides, in order to expand our portfolio of product candidates and solidify our position as a leader in this field.

### Be Actively Involved in the Commercialization of Our Products

We intend to retain commercial rights to our future products for indications and territories where we believe we can effectively market them. We may also co-promote *EGRIFTA*<sub>TM</sub> in certain territories and tesamorelin in other indications.

#### Pursue External Growth Opportunities

In addition to developing products internally, we will opportunistically pursue in-licensing arrangements or acquisitions of complementary businesses, compounds or products. We will also identify and evaluate commercial growth opportunities that may include collaborations with drug delivery companies.

# **Our Product and Product Candidates**

The following table provides an overview of our product and product candidates and their current stages of development:

Development Programs	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Approved
EGRIFTA <sup>TM</sup> (tesamorelin for injection) for HIV-associated lipodystrophy						
Tesamorelin for muscle wasting in COPD						
TH0673 for acute kidney injury						
Novel GRF analogues						
Melanotransferrin peptides for cancer	$\rightarrow$					

## EGRIFTATM – Our Lead Product

*EGRIFTA*<sup>TM</sup> induces the release of growth hormone which causes a reduction in excess abdominal fat (lipohypertrophy) in HIVinfected patients without reducing or interfering with subcutaneous fat, and, as such, has no clinically significant effect on undesired loss of subcutaneous fat (lipoatrophy).

*EGRIFTA*<sup>TM</sup> is currently available in the United States as a once-daily two unit dose (two vials, each containing 1 mg of tesamorelin) of sterilized lyophilized powder to be reconstituted with sterile water for injection. To administer *EGRIFTA*<sup>TM</sup>, 1 ml is retrieved from each vial into one syringe to prepare a single 2 ml patient self-administered subcutaneous injection. *EGRIFTA*<sup>TM</sup> is injected under the skin into the abdomen once a day.

For the purposes of FDA approval, *EGRIFTA*<sup>TM</sup> was evaluated in two clinical trials involving 816 HIV-infected adult men and women with lipodystrophy and excess abdominal fat. In both studies, patients treated daily with *EGRIFTA*<sup>TM</sup> experienced greater reductions in abdominal fat as measured by CT scan and greater improvements in belly appearance distress, compared with patients receiving another injectable solution (placebo). Once the treatment was terminated, the patients' condition reversed to its status prior to the beginning of the treatment. The most commonly reported adverse effects in the studies included reactions due to the release of endogenous hormone, such as joint pain (arthralgia), pain in the extremities, swelling in the lower limbs and muscle pain (myalgia), injection site reactions such as skin redness (erythema), itching (pruritis) and pain and clinically manageable changes in blood sugar control. Our clinical trials did not seek to measure any potential cardiovascular benefits of *EGRIFTA*<sup>TM</sup> on cardiovascular events.

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

- to develop a single vial presentation of the existing formulation of EGRIFTA™. We have developed a new presentation of EGRIFTA™ which is quicker and easier to use than its current presentation. In the new presentation, EGRIFTA™ will be available as a single unit dose (one vial containing 2 mg of tesamorelin) of sterile, lyophilized powder to be reconstituted with sterile water for injection. The FDA requires that this new presentation be available by November 2013 and we expect it to be commercially available before that date. The development of the new presentation is complete and the dossier is ready for regulatory submission.
- to conduct a long-term observational safety study using EGRIFTATM. The purpose of the long-term observational study required by the FDA is to evaluate the safety of long-term administration of EGRIFTATM.
- to conduct a Phase 4 clinical trial using EGRIFTA™. The primary purpose of the Phase 4 clinical trial is to assess whether EGRIFTA™ increases the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat.

The FDA requires that the proposed protocols for the long-term observational safety study and Phase 4 clinical trial be submitted by the second quarter of 2011. Under the terms of our collaboration and licensing agreement, EMD Serono is responsible for finalizing and obtaining approval of such protocols. We will continue to support EMD Serono in developing and finalizing such protocols.

# Lipodystrophy

Lipodystrophy is characterized by abnormalities in the production and storage of fat. It has two components: lipohypertrophy, abnormal and excessive fat accumulation, and lipoatrophy, the noticeable, localized loss of fat tissue under the skin. In patients with lipohypertrophy, fat accumulation occurs mostly around the waist and may also occur in other regions, including breast tissue and in dorsocervical tissues in the neck, resulting in a "buffalo hump". Excess fat also appears as lipomas, or benign tumors composed of fat cells. In patients with lipoatrophy, the loss of fat tissue generally occurs in the limbs and facial area.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood (such as triglycerides and cholesterol), and hyperglycemia, an increase in the amount of sugar in the blood, characterized by insulin resistance, both of which lead to increased risks for cardiovascular disease and diabetes.

In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy. Recent data suggest that different pathophysiological mechanisms are involved in the development of lipohypertrophy and lipoatrophy. The most common statistically significant independent risk factors identified for lipohypertrophy are duration of antiretroviral therapy, markers of disease severity and protease inhibitor use. Other factors include age, genetics, and gender.

### Market Opportunity

Based on our analysis of 20 independent medical studies published from 2000 to 2004, we estimate that excess abdominal fat in HIV-infected patients affects approximately 29% of HIV-infected patients treated with antiretroviral therapies. According to a separate 2003 independent medical study, we estimate that an additional 12% of untreated HIV-infected patients are also affected by excess abdominal fat.

Based on the above-mentioned data, we have identified the following potential markets for EGRIFTATM.

- United States. The United States market represents the largest commercial opportunity for *EGRIFTA*™. We estimate the prevalence of HIV/AIDS in the United States will rise to 1.3 million people in 2012. Of this amount, approximately 650,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 190,000 will suffer from excess abdominal fat. In addition, approximately 47,000 untreated patients will suffer from excess abdominal fat.
- Europe. We estimate the prevalence of HIV/AIDS in Europe will rise to 1.4 million people in 2012. Of this amount, approximately 590,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 170,000 will suffer from excess abdominal fat. In addition, approximately 42,000 untreated patients will suffer from excess abdominal fat.
- Latin America. We estimate the prevalence of HIV/AIDS in Latin America will rise to 2.2 million people in 2012. Of this
  amount, approximately 630,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 180,000
  will suffer from excess abdominal fat. This number is proportionately lower than the other territories due to a lower
  percentage of diagnosed and treated patients. With approximately 60,000 treated patients who will suffer from excess
  abdominal fat, Brazil offers the largest market in Latin America for EGRIFTATM. In addition, approximately 28,000 untreated
  patients will suffer from excess abdominal fat.

We estimate that the total number of patients diagnosed with and treated for HIV/AIDS who will suffer from excess abdominal fat in our primary target markets will be 540,000 in 2012. We estimate that an additional 117,000 untreated patients may develop lipohypertrophy in such markets.

The foregoing information is based on historical data from the CDC for the United States, and WHO/UNAIDS for Europe and Latin America. We used the historical growth rates derived from that data to estimate the prevalence of HIV/AIDS in 2012.



# EGRIFTATM Commercialization Activities

We are working closely with EMD Serono to support the commercialization of *EGRIFTA*TM. We are also working closely with Sanofi and Ferrer to obtain regulatory approval for and the subsequent commercialization of *EGRIFTA*TM. Each of our commercial partners were chosen due to their commercial and regulatory capabilities in their respective territories.

#### EMD Serono Agreement – United States

On October 28, 2008, we entered into a collaboration and licensing agreement granting EMD Serono the exclusive commercialization rights to *EGRIFTA*<sub>TM</sub> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States.

Under the terms of the agreement, EMD Serono has the exclusive right to conduct *EGRIFTA*<sub>TM</sub> commercialization activities in the United States. We are responsible for the manufacturing and supply of *EGRIFTA*<sub>TM</sub> and for the development of a new formulation. The agreement also entitles us to conduct additional clinical programs to develop tesamorelin for potential additional indications. EMD Serono has the option to commercialize products resulting from such additional clinical programs in the United States. If EMD Serono exercises this option, it will pay half of the development and regulatory costs incurred and to be incurred by us in connection with such additional clinical programs. If EMD Serono decides not to exercise its option, we have the right to commercialize tesamorelin for such indications on our own or with third parties. We also have the option to co-promote any product resulting from such clinical programs under terms and conditions to be agreed with EMD Serono. This agreement extends until the expiration of the last valid claim based upon a patent right (including patent applications) controlled by us in the United States covering *EGRIFTA*<sub>TM</sub> or any other product based on an additional indication for tesamorelin that EMD Serono has elected to commercialize under the agreement.

We may receive up to US\$215 million in upfront and milestone payments in addition to royalties and revenues from the sale of *EGRIFTA*TM to EMD Serono. To date, we have received US\$65 million which includes an upfront payment and regulatory milestone payments of US\$57 million and an equity investment of US\$8 million. Future milestone payments will be made based on the achievement of certain sales milestones. We will also be entitled to receive royalties at an increasing rate based on achieving specified levels of annual net sales of *EGRIFTA*TM in the United States.

We made our first delivery of *EGRIFTA*<sup>TM</sup> to EMD Serono on December 13, 2010. In January 2011, EMD Serono launched *EGRIFTA*<sup>TM</sup> in the United States. EMD Serono is executing a launch program that consists of increasing disease awareness through medical education to doctors, patient advocacy and advertising, marketing and promotion through their experienced sales force, and supporting market access through patient support, co-pay programs, reimbursement education and support for payors.

EMD Serono is responsible for establishing the sale price of *EGRIFTA*<sub>TM</sub> in the United States. The wholesale acquisition cost has been set at US\$23,900 per patient per year. We expect to receive our first royalty payments in the second quarter of 2011.

### Sanofi Agreement -- Latin America, Africa and the Middle East

On December 6, 2010, we entered into a distribution and licensing agreement granting Sanofi, a subsidiary of Sanofi-aventis S.A., the exclusive commercialization rights to *EGRIFTA*™ for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East.

Under the terms of the agreement, we will sell *EGRIFTA*<sub>TM</sub> to Sanofi at a transfer price equal to the higher of a percentage of Sanofi's net selling price and a predetermined floor price. Sanofi will be responsible for conducting all regulatory and commercialization activities for *EGRIFTA*<sub>TM</sub> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTA*<sub>TM</sub> to Sanofi. We have retained all development rights to *EGRIFTA*<sub>TM</sub> for other indications and will be responsible for conducting development activities for any additional potential indications. We also granted Sanofi an option to commercialize tesamorelin for other indications in the territories mentioned above. If such option is not exercised, or is declined, by Sanofi, we may commercialize tesamorelin for such indications on our own or with a third party. The initial term of this agreement extends until December 2020.

Ferrer Agreement - Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries

On February 3, 2011, we entered into a distribution and licensing agreement granting Ferrer the exclusive commercialization rights to *EGRIFTA*<sub>TM</sub> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the agreement, we will sell *EGRIFTA*<sup>TM</sup> to Ferrer at a transfer price equal to the higher of a percentage of Ferrer's net selling price and a predetermined floor price. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTA*<sup>TM</sup> to Ferrer. We have retained all development rights to *EGRIFTA*<sup>TM</sup> for other indications and will be responsible for conducting development activities for any additional potential indications. We have the option to co-promote *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Ferrer has the option to enter into a co-development and commercialization agreement using tesamorelin for potential additional indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development. This agreement extends until the later of the expiration of the last valid claim based on a patent right (including patent applications) controlled by us covering a product licensed under the agreement or ten years from the date of the first commercial sale of *EGRIFTA*<sup>TM</sup> for each country covered by the agreement.

# Unpartnered Territories

We have retained full commercial rights for *EGRIFTA*<sub>TM</sub> in certain territories, including Canada. In territories where we do not currently have commercial partners, we may commercialize *EGRIFTA*<sub>TM</sub> directly or in collaboration with commercial partners.

# Tesamorelin - Our Lead Compound

Tesamorelin is a stabilized 44 amino acid human GRF analogue, which was synthesized in our laboratories in 1995 using our longacting peptide method. Although natural peptides have significant therapeutic potential, they are subject to enzymatic degradation which severely limits their effectiveness in clinical use. Our long-acting peptide method is a peptide stabilization process which increases the target protein's resistance to enzymatic degradation, while maintaining its natural specificity. This usually results in a more stable and efficient compound, which can thus prolong its duration of action. Tesamorelin induces growth hormone secretion in a natural and pulsatile way. The clinical results obtained to date using tesamorelin suggest a therapeutic potential in both anabolic and lipolytic indications. *EGRIFTA*TM has demonstrated the ability to significantly reduce visceral adipose tissue, increase muscle mass and reduce waist circumference.

#### Mechanism of Action

In vitro, tesamorelin binds and stimulates human GRF receptors with similar potency as the endogenous GRF. GRF is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone, which is both anabolic and lipolytic. Growth hormone exerts its effects by interacting with specific receptors on a variety of target cells, including chondrocytes, osteoblasts, myocytes, hepatocytes, and adipocytes, resulting in a host of pharmacodynamic effects. Some, but not all these effects, are primarily mediated by insulin-like growth factor one, IGF-1, produced in the liver and in peripheral tissues.

The effects of recombinant human growth hormone, or rhGH, and tesamorelin have been the subject of several clinical trials in the area of HIV-associated lipodystrophy. Based on these clinical trials, the safety profiles of rhGH and tesamorelin appear to be very different. The natural synthesis of growth hormone is regulated by a feedback mechanism preventing its overproduction. Tesamorelin induces optimal activity of the somatotrope function and retains the natural rhythm (pulsatility) of the physiological secretion of growth hormone without interfering with the feedback mechanism mentioned above. With the exogenous administration of rhGH, the feedback mechanisms are short-circuited, which gives rise to higher levels of growth hormone. The side effects associated with rhGH include nerve, muscle or joint pain, swelling due to fluid retention (edema), carpal tunnel syndrome, numbness and tingling of skin and increased risk of diabetes. These side effects are particularly frequent among older people. In addition, rhGH can cause hyperglycemia which makes it contraindicated for patients with diabetes or pre-diabetic conditions.

### Muscle Wasting in COPD - New Indication for Tesamorelin

We have selected COPD as our second clinical program with tesamorelin. We chose to consider muscle wasting in COPD patients with decreased functioning in daily activities for a clinical program based on the anabolic properties



of tesamorelin. The goal of the program is to show an improvement in functionality in daily activities in COPD patients with loss of muscle mass.

We completed a three-month Phase 2 clinical study involving 109 stable ambulatory COPD patients. Patients were randomized to receive either 1 mg or 2 mg doses of tesamorelin, or a placebo each day. Patients treated using 1 mg or 2 mg doses of tesamorelin experienced a statistically significant increase in lean body mass compared with patients receiving a placebo. In addition to the increase in lean body mass, such patients experienced improvements in three functional measures associated with tesamorelin, particularly for the 2 mg group. The three functional measures were:

- · Respiratory symptoms, as assessed by St. George's Respiratory Questionnaire;
- · Leg discomfort, as assessed by the Borg Scale following an exercise endurance test; and
- Breathing discomfort, as assessed by the Borg Scale following an exercise endurance test.

## COPD

COPD is characterized by progressive airflow obstruction due to chronic bronchitis or emphysema, two commonly co-existing lung diseases. COPD results in a limitation of the flow of air to and from the lungs resulting in a shortness of breath. In contrast to asthma, the limitation of airflow is not easily reversible and usually gets progressively worse over time.

Many COPD patients are affected by a systemic manifestation which may lead to muscle wasting. Muscle wasting (cachexia or involuntary weight loss), a decrease or thinning of the muscle mass, is associated with several abnormalities, including impaired exercise capacity and functioning and decreased muscle strength. Muscle wasting is an independent predictor of a COPD patient's functional deterioration and mortality, and it is a common symptom in patients with moderate to severe COPD. The importance of improving not only muscle strength, but other functional parameters and quality of life is well recognized in order to improve the well being of patients with COPD and decreased functionality. We are not aware of any treatment for muscle wasting in COPD approved by any regulatory authorities.

## Market Opportunity

According to independent research, 26 million adults aged 40 or over were diagnosed with COPD in the United States, France, Germany, Italy, the United Kingdom, Spain and Japan in 2009. The prevalence of COPD increases with age and is much higher in adult males. The diagnosed population is expected to increase at a compound annual growth rate of 2.5%.

Treatment varies across countries and region, however 17.9 million patients were receiving treatment for COPD management in 2009 in the United States, France, Germany, Italy, the United Kingdom, Spain and Japan. COPD can be classified using four levels of severity, from mild to very severe (stages I to IV) using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification. Our program will focus primarily on COPD patients in GOLD stage II and III. Based on available market data, we estimate that in 2009, the number of diagnosed COPD patients in GOLD stage II and III suffering from a muscle wasting condition, with a body mass index of under 25, was approximately 3.1 million in those markets.

#### Clinical Development Plan

Tesamorelin's anabolic properties have led us to pursue its development for muscle wasting in COPD patients as our second indication. This clinical development program will be conducted in stable ambulatory COPD patients, GOLD stage II and III, with muscle wasting experiencing decreased functionality in daily activities. It will include three studies:

• One Phase 2 study: This study will be a randomized, placebo-controlled study in approximately 200 COPD patients with muscle wasting. Patients will be randomized to receive either one of two different dosages of tesamorelin or placebo each day for six months. We intend to randomize our first patient in this Phase 2 clinical study in the second half of 2011. The Phase 2 study will evaluate the safety and efficacy of using tesamorelin in COPD patients, GOLD stage II and III, with muscle wasting. The primary endpoint will be an increase in lean body mass. Other efficacy endpoints will be measured, such as a six minute walking distance test, exercise endurance time, and quality of life (daily activities). Safety assessments will include monitoring of adverse events and laboratory evaluations.



• *Two Phase 3 studies:* If the Phase 2 study is successful, we anticipate there will be two 12-month Phase 3 studies (one pivotal and one confirmatory) to be conducted in parallel. We expect a total of approximately 1,200 patients will be included in this program.

We currently believe that the clinical trials will last approximately four years and that the program will cost between approximately \$55 and \$65 million. A significant portion of the costs will be borne by our commercial partners if they elect to exercise their option to commercialize under their respective agreements.

## Other Product Candidates

# Novel Growth Hormone-Releasing Factor Analogues

We are working on several novel analogues of GRF that have improved chemical stability compared to tesamorelin. To date, we have synthesized over 80 different compounds. We believe that GRF compounds have the potential to improve patient outcome in many high-value indications. We also believe we can improve the route of administration of GRF peptides to make them quicker and easier to use for patients.

# Compounds for Acute Kidney Injury

AKI is the acute deterioration of kidney function leading to increased urea waste products and electrolyte imbalance in blood. AKI is common among hospitalized patients and complicates the management of patients in intensive care units. According to a 2008 medical publication, AKI affected 3% to 7% of patients admitted to hospital and approximately 25% to 30% of patients in the intensive care unit within days of major surgery. The incidence of AKI was approximately 600,000 to 900,000 patients in the United States per year. Despite hospitalization and renal replacement, the mortality rate is 50% to 60% for dialyzed patients. We believe that hemodialysis is the only approved treatment for post-surgical AKI.

We have identified AKI as a potential clinical program for internal development. We have developed novel peptides specifically tailored for the prevention or treatment of AKI. One of these peptides, TH0673, is a peptide that is currently in preclinical development. We have tested TH0673 in animal models of AKI and have found that it increases creatinine clearance, improves excretion of nitrogenous waste compounds and limits kidney damage. We expect to have additional preclinical results in AKI in the first half of 2011.

### Other Discovery Activities – Melanotransferrin Peptides (Anti-Cancer Compounds)

In November 2010, we entered into a discovery and collaboration agreement with the Université du Québec à Montréal, Gestion Valeo and Transfert Plus in connection with research led by Dr. Richard Béliveau seeking to discover short peptide mimics of melanotransferrin for the development of a new cancer treatment.

Melanotransferrin is related to the transferrin family of proteins and is expressed normally in melanocytes, but also in several cancer cells. Dr. Béliveau's research has demonstrated that soluble melanotransferrin reduces cell migration, invasion and angiogenesis, which are hallmarks of tumorigenesis and metastasis. We have identified small peptides from the melanotransferrin protein which could replicate the functions of the full length protein. Currently, we are optimizing the peptides for better pharmaceutical properties so that the optimized peptides can be tested in animal models of cancer and tumor angiogenesis.

# **Intellectual Property**

# **Our Current Patent Portfolio**

Our current patent portfolio is comprised of patents and patent applications for the following compounds:

#### Tesamorelin

In the United States, we own a patent covering the composition of matter (tesamorelin), which is scheduled to expire in 2015. We have applied for a patent term extension requesting an extension of five years to this patent term. If our request for patent term extension for the entire five year term is granted, the patent protection for tesamorelin in the United States would be extended until 2020. In addition, we own an issued United States patent relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which is scheduled to expire in 2023. Because tesamorelin qualifies as a new chemical entity, we benefit from data protection for a five year period for *EGRIFTA*TM ending November 2015. See "– Regulatory Exclusivity".



- In Europe, tesamorelin is covered by granted patents scheduled to expire in 2016. In the event of receipt of marketing approval from the EMA, we intend to apply for supplementary protection certificates, or SPCs, in certain countries which, if granted, could extend the patents covering tesamorelin in the countries where SPCs are approved until 2021. We have also filed two patent applications relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy where, if such patents were granted, they would be scheduled to expire in 2023 and 2025, respectively. As discussed below, the first time a new product is approved in Europe, the regulation provides for a 10 year exclusivity period. Assuming approval in 2012, we would benefit from protection until 2022. See "— Regulatory Exclusivity".
- We have obtained a patent covering the composition of matter (tesamorelin) in Brazil that expires in 2019.
- We have filed patent applications for the therapeutic indication of muscle wasting in COPD in several countries, including the United States, where, if such patents were granted, they would be scheduled to expire in 2024, with the exception of a recently-granted patent application in the United States, which benefits from a patent term adjustment extending its term to 2027.
- We have filed patent applications in several countries, including the United States, for the new formulation of tesamorelin where, if such patents were granted, they would be scheduled to expire in 2028.
- We have filed United States and international Patent Cooperation Treaty applications relating to combination therapies of tesamorelin with certain drugs indicated for the treatment of HIV which, if patents issued from these applications were granted, would be scheduled to expire in 2030.

Novel GRF Peptides

- We have recently filed a United States provisional patent application relating to new GRF analogues. Patents claiming
  priority from this application may be pursued and if such patents were granted, they would be scheduled to expire in 2032.
- AKI
  - We have filed patent applications in several countries, including the United States, relating to our peptide TH0673 and related peptides, and their use in the treatment of AKI, where, if such patents were granted, they would be scheduled to expire in 2028.

# **Our Trademarks & Other Intellectual Property**

*EGRIFTA*<sup>TM</sup> is the trademark used for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. Trademark registration in the United States necessitates a prior commercial use in the territory in order to be granted. We are in the process of filing the declaration of use to obtain trademark registration.

We have obtained registration for *EGRIFTA*™ in Europe, Japan, Australia, Norway, Switzerland, Mexico and Lebanon and have filed trademark applications for this trademark in other countries. The use of the trademark in each jurisdiction generally requires the approval of the regulatory authorities in such jurisdictions.

Other trademarks related to tesamorelin have been filed as part of our business strategy. We have also reserved certain domain names in order to support future activities.

# **Our Policy on Intellectual Property**

Our intellectual property practice is to keep all information relating to proprietary compounds, inventions, improvements, trade secrets, know-how and continuing technological innovation confidential and, where practicable, file patent and trademark applications. In particular, as part of our intellectual property protection practice, we:

- perform surveillance of third party patents and patent applications in order to identify any third party patent or third party patent application which, if granted, could be infringed by our activities;
- where practicable, file patent applications for any new and patentable invention, development or improvement in the United States and in other countries;
- prosecute all pending patent applications in conformity with applicable patent laws and in a manner that efficiently covers our activities;
- file trademark applications in countries of interest for our trademarks;
- · register domain names in countries of interest; and



maintain our intellectual property rights by paying government fees as may be necessary to ensure such rights remain in force.

# **Regulatory Exclusivity**

The regulatory regimes of the United States and Europe may provide market exclusivity for a pharmaceutical product. Data protection and patent term extension provide a patent holder with additional protection against third parties who may wish to commercialize a product similar to an approved product.

### Data Protection

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, awards, in certain circumstances, non-patent marketing exclusivities to pioneer drug manufacturers. The Hatch-Waxman Act provides five years of non-patent marketing exclusivity within the United States to an applicant who gains approval of a New Drug Application, or NDA, for a "new chemical entity," a drug for which the FDA has not previously approved any other new drug with the same active moiety, which is the molecule or ion responsible for the action of the drug. This marketing exclusivity prevents the FDA from approving, in certain circumstances, any abbreviated new drug application for a generic drug or any 505(b)(2) NDA. See "Government Regulation—United States–FDA Process" below.

In Europe, when a product based on a new compound is approved, the European Medicines Agency, or EMA, grants a 10 year exclusivity period beginning on the date of such approval. When the same compound is approved for a second indication within the first eight years of this 10 year period, the exclusivity period is extended by one year, providing a total exclusivity period of 11 years for the compound.

#### Patent Term Extension

In the United States, the Hatch-Waxman Act permits patent term extension for one patent per approved drug of up to five years for patent term lost during product development and the FDA regulatory review process. However, patent term extension cannot extend the remaining patent term beyond a total of 14 years from the product's approval date. The patent term extension period is generally one-half the time between the effective date of an Investigational New Drug Application, or IND, and the submission date of an NDA plus the time between the submission date of an NDA and the NDA. We have applied for a patent term extension with respect to tesamorelin.

In the European Union, SPCs for medicinal products are governed by Regulation 469/2009 with effect from May 2009. An SPC has the effect of extending the term of a patent relating to protection of a particular medicinal product by compensating the patentee for some lost patent protection caused by the length of time taken to obtain marketing authorisation for the product in question. An SPC is a national right, available in member states of the European Union, by application to the national patent office of each state for which a certificate is desired. The SPC must be based on a patent but since an SPC is only granted in respect of a very specific active ingredient in a product, it is generally of rather more limited scope than the patent on which it is based. Typically, the term of the SPC is equal to the period which has elapsed between filing of the patent application and grant of the first European Union marketing authorisation less five years. The term of the SPC may not, generally, exceed five years. However, some European Union legislation regarding pediatric medicines provides for a six-month extension of the basic SPC term in certain circumstances. The SPC takes effect on expiry of the basic patent. In each country for which SPC protection is sought, a separate SPC application must be filed within six months of the grant of the first marketing authorisation in that country for the active ingredient(s) in question.

# Manufacturing

We do not own or operate commercial scale manufacturing facilities for the production of our product or any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished product for clinical trials and commercial sale.

We are responsible for the manufacture and supply of tesamorelin to ensure the commercialization of *EGRIFTA*<sub>TM</sub> under our agreements with EMD Serono, Sanofi and Ferrer. As part of our agreement with EMD Serono, we are required to maintain certain levels of inventory. In order to fulfill these contractual obligations, we have negotiated and entered into various third-party supply agreements.



# Bachem

We have an agreement with Bachem, Inc., an American subsidiary of Swiss-based Bachem AG, providing for the manufacturing and supply of the active pharmaceutical ingredient of tesamorelin for clinical programs and *EGRIFTA*<sub>TM</sub> for commercial sale in the United States.

# Draxis

We have an agreement with Draxis Pharma, a division of Draxis Specialty Pharmaceuticals, Inc., or Draxis, providing for the manufacture and supply of the finished form of tesamorelin for clinical programs and *EGRIFTA*<sub>TM</sub> for commercial sale. Under our agreement, Draxis must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions.

We have identified and initiated discussions with possible secondary suppliers of these products. We believe that there are alternate sources of supply for these products that will be able to satisfy our needs and will be able to receive FDA qualification. We expect our new presentation as well as our new formulation of tesamorelin will significantly increase our production capacity for *EGRIFTA*TM due to the smaller quantity of vials, shorter manufacturing process times and increased batch sizes.

## Competition

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions, many of whom have greater financial, technical and human resources than us. We believe the key competitive factors that will affect the development and commercial success of *EGRIFTA*<sub>TM</sub> and our product candidates are efficacy, safety and tolerability profile, reliability, product acceptance by physicians and other healthcare providers, convenience of dosing, price and reimbursement. Also, the development of new treatment methods for the indications we are targeting could render our drugs non-competitive or obsolete. We are not aware of other GRF products being commercialized or in development for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy although we may face indirect competition for *EGRIFTA*<sub>TM</sub> from other drugs that may be prescribed by physicians. The use of these other drugs for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy has not been approved by the FDA nor any other regulatory authority.

We believe that competition in the area of muscle wasting in COPD patients is limited. We are aware of one other compound which has completed a Phase 1 clinical study in COPD muscle wasting (GOLD stage I and II). We may face indirect competition from other drugs such as anabolic steroids, testosterone and growth hormone that may be prescribed by physicians. However, these drugs have not been approved by the FDA for muscle wasting in COPD.

#### **Government Regulation**

## Overview

The research, development, manufacture and marketing of pharmaceutical products are governed by various governmental authorities throughout the world to ensure efficacy and safety.

Governmental authorities in the United States at the federal, state and local level, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products, such as *EGRIFTA*TM and other product candidates that we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States or foreign requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. Sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

On November 10, 2010, the FDA approved *EGRIFTA*™ as the first approved treatment for excess abdominal fat in HIV-infected patients with lipodystrophy. Our other product candidates must receive regulatory approval from the



FDA or other relevant foreign regulatory authorities before they may legally be marketed in the United States or other countries.

In Canada, these activities are governed by the provisions of the Food and Drugs Act and its regulations, which is enforced by the Therapeutic Products Directorate of the Health Products and Food Branch of Health Canada. We have not yet applied to market *EGRIFTA*TM in Canada.

## **United States – FDA Process**

Before new pharmaceutical products may be sold in the United States, clinical trials of the product candidates must be conducted and the results submitted to the FDA for approval. The drug approval process requires, among other things, a demonstration of product safety and efficacy. Generally, a demonstration of safety and efficacy includes preclinical testing and clinical trials of product candidates. The testing, manufacture and marketing of pharmaceutical products in the United States requires the approval of the FDA. The FDA enforces laws and regulations which apply to preclinical testing, clinical trials, and manufacture of these products. The drug approval process in the United States is described in brief below.

Pre-Clinical Testing: Before testing of any compounds with potential therapeutic value in human subjects may begin in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes laboratory evaluations of product pharmacology and toxicity in animal studies of the drug candidates. In parallel, the chemistry of the drug candidates must be elucidated and their manufacturing, including formulation and stability, clearly defined and controlled.

Investigational New Drug Application: Among other things, pre-clinical testing results obtained from animal studies and in vitro studies, are submitted to the FDA as part of an IND application and are reviewed by the FDA prior to the commencement of human clinical trials. An IND sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. Unless the FDA objects to an IND (referred to as a clinical hold), the IND becomes effective 30 days following its receipt by the FDA. Once trials have commenced, the FDA may stop the trials at any time by placing them on "clinical hold" because of safety concerns or noncompliance. If the FDA issues a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Accordingly, we cannot be sure that submission of a IND will result in the FDA allowing clinical trials to begin or that, once began, issues will not arise that suspend or terminate such trials.

Clinical Trials: Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator pursuant to an FDA-approved protocol. Each clinical trial must be conducted under the auspices of an Institutional Review Board, or IRB, that considers, among other things, ethical factors, the safety of human subjects and approves the patient informed consent, which must be agreed to by all participants prior to participation in the clinical trial. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another.

All phases of clinical trials must be conducted in conformance with Good Clinical Practices, which are ethical and scientific quality standards for conducting, recording, and reporting clinical trials to assure that the rights, safety, and well-being of trial participants are protected, and the FDA's regulations for the protection of human subjects.

Phase 1 Clinical Trials: Phase 1 clinical trials represent the initial administration of the investigational drug to a small group of healthy human subjects or, more rarely, to a group of select patients with the targeted disease or disorder. The goal of Phase 1 clinical trials is typically to test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.

Phase 2 Clinical Trials: Phase 2 clinical trials involve a small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.



Phase 3 Clinical Trials: Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase 3 clinical trials are initiated to establish further clinical safety and efficacy of the investigational drug in a broader sample of the patient population with the target disease or disorder at geographically dispersed study sites in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for regulatory approval and product labeling.

New Drug Application: All data obtained from a comprehensive development program including research and product development, manufacturing, pre-clinical and clinical trials and related information are submitted in an NDA to the FDA. In addition to reports of the trials conducted under the IND, the NDA includes information pertaining to the preparation of the new drug, chemistry manufacturing and controls, or CMC, analytical methods, details of the manufacture of finished products and proposed product packaging and labeling. The submission of an application is no guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. The re-submitted application is also subject to review before the FDA accepts it for filing. Once an application is accepted for filing, an FDA review team – medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts – evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use and whether the applicant's manufacturing is GMP-compliant to assure and preserve the product's identity, strength, quality and purity. As part of the approval process, the FDA will inspect the facility or facilities where the product is manufactured. The FDA review process may be extended by FDA requests for additional information or clarification. In some cases, the FDA may decide to expedite the review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs.

As part of its review, the FDA may refer the application to an advisory committee for evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Under legislation enacted in 2007, the FDA may determine that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks. If required, a REMS may include various elements, such as publication of a medication guide, patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

In reviewing an NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. The FDA may require larger or additional clinical trials, leading to unanticipated delay or expense. Even if such additional information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials may be subject to different interpretation, and the FDA may interpret data differently than the applicant. The receipt of regulatory approval often takes a number of years, involving the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, or restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies may be minor, for example, requiring labeling changes, or major, for example, requiring additional studies. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. In addition, changes in FDA approval policies or requirements may occur, or new regulations may be promulgated, which may result in delay or failure to receive FDA approval.

Changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components requires review and approval of the FDA.

Under the Hatch-Waxman Act, the U.S. Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. The Hatch-Waxman Act requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the FDA's publication, "Approved Drug Products

with Therapeutic Equivalence Evaluations", commonly known as the Orange Book. The Hatch-Waxman Act allows for, under certain circumstances, an abbreviated NDA, or ANDA, where an applicant seeks to determine that its proposed product is biologically equivalent to the reference drug. ANDA applicants do not have to conduct extensive clinical trials to prove the safety or efficacy of the drug product; rather, they are required to conduct less rigorous bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug. In addition, in certain cases, an application for marketing approval may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant and for which the applicant has not obtained a specific right to reference those studies. Such applications, known as a 505(b)(2) NDA, are permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approval on literature or on a finding by the FDA of safety and/or efficacy for a previously approved drug product. In addition, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA's finding of safety and efficacy of the previously approved product coupled with new clinical information needed by FDA to support the change. FDA approval of the NDA or ANDA is required before marketing of the product may begin in the United States.

The Pediatric Research Equity Act, or PREA, requires NDAs (or NDA supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain data assessing the safety and efficacy for the claimed indication in all relevant pediatric subpopulations. Data to support dosing and administration also must be provided for each pediatric subpopulation for which the drug is safe and effective. FDA may grant deferrals for the submission of data, or full or partial waivers from the PREA requirements. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation, as described below, has been granted.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Post-Approval Studies and Registries: Post-approval studies, also referred to as Phase 4 clinical trials are studies that are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies be conducted post-approval, and in these cases these Phase 4 studies are called post-marketing commitments.

Adverse Event Reporting: Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal or suspension of the product from the market. Furthermore, in September 2007 the Food and Drug Administration Amendments Act of 2007 was enacted, which provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance including, among other things, the authority to require additional post-approval studies or clinical trials and mandate label changes as a result of safety findings, including the development and implementation of a REMS.

### Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a "rare disease or condition," which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales in the United States of the drug. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan

use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in, or shorten the duration of the regulatory review and approval process.

If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different drugs for the indication for which the orphan product has exclusivity or may obtain approval for the same drug but for a different indication for which the orphan product has exclusivity or may obtain approval for the same drug but for a different indication for which the orphan product has exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug designated as an orphan drug receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

# Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for market, including a fast track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval but may expedite the development or approval process.

#### Non-U.S. Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations governing clinical studies and commercial sales and distribution of our products in other jurisdictions around the world. Whether or not we obtain FDA approval for a product, we must obtain approvals from the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In some international markets, additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

In the European Union, medicinal products must be authorized either through the decentralized procedure by the competent authorities of the European Union Member States, or through the centralized procedure by the European Commission following an opinion by the EMA. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the



treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products, and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized approval procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state objects to approval of the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states. In many European Union countries, pricing and reimbursement negotiations must also take place before the product is sold in their national market between the company marketing the product and the competent national authorities.

In order to obtain approval for commercializing new drugs in Canada, we must satisfy many regulatory conditions. We must complete preclinical studies in order to file a Clinical Trial Application, CTA, in Canada. We then receive different clearance authorizations to proceed with Phase 1 clinical trials, which can then lead to Phase 2 and Phase 3 clinical trials. Once all three phases of trials are completed, we file a registration file named a New Drug Submission, or NDS, in Canada. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities' rules, regulations and guidelines and demonstrates favourable safety, efficacy and receives a risk/benefit analysis, then the regulatory authorities issue a notice of compliance, which allows us to market the product.

# **Good Manufacturing Practices**

The FDA, the EMA, the competent authorities of the European Union Member States and other foreign regulatory agencies regulate and inspect equipment, facilities, and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. Among the conditions for NDA or equivalent foreign approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures adhere to the FDA's or other competent authorities' current GMP. Before approval of an NDA or equivalent foreign approval, the FDA or other competent authority may perform a pre-approval inspection of a manufacturing facility to determine its compliance with GMP and other rules and regulations. In complying with GMP, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Similarly, NDA or equivalent foreign approval may be delayed or denied due to GMP non-compliance or other issues at contract sites or suppliers included in the NDA or equivalent foreign approval, and the correction of these shortcomings may be beyond our control. Facilities are also subjected to the requirements of other government bodies, such as the U.S. Occupational Safety & Health Administration and the U.S. Environmental Protection Agency.

If, after receiving clearance from regulatory agencies or competent authorities, a company makes certain changes in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Our third-party suppliers must adhere to GMP and product-specific regulations enforced by the FDA or other competent authorities following product approval. The FDA, the European Union and other national competent authorities and regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our suppliers' equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against them, including the suspension of manufacturing operations.

# **Good Clinical Practices**

The FDA, the EMA and other competent authorities promulgate regulations and standards, commonly referred to as Good Clinical Practices, or GCP, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the European Union and other foreign national competent authorities and regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. We rely on third-party service providers to conduct our clinical trials. If our study sites fail to comply with applicable GCP, the clinical data

generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications.

# **Good Laboratory Practices**

The FDA and other regulatory authorities promulgate regulations and standards, commonly referred to as Good Laboratory Practices, or GLP, for the conduct of non-clinical, commonly referred to as "preclinical," non-human studies to provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. Compliance with GLP is intended to assure regulatory authorities of the quality and integrity of the results obtained during the preclinical studies. Before we may test our product candidates on humans in clinical trials, we must first conduct preclinical testing, including animal studies, in accordance with GLP. The FDA or other regulatory authorities may inspect the testing facilities where our pre-clinical studies are conducted. The results of preclinical studies in the United States, Europe or other countries, not conducted in accordance with GLP, might be inadmissible in support of an NDA in the United States, or comparable applications in other countries.

## United States Sales and Marketing

Our commercial partner, EMD Serono, will be subject to various United States regulations relating to the sales and marketing of *EGRIFTA*™ in the United States. The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA actively enforces the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The FDA does not regulate the practice of medicine by physicians in their choice of treatment, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

Marketing of *EGRIFTA*TM within the United States is also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our commercial partners' practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent.

In addition, several states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. The recently enacted health care reform legislation will require record-keeping and disclosure to the federal government of payments to physicians commencing in 2012. Any activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege or convict our commercial partner of violating these laws, our business could be harmed. In addition, there is ability for private individuals to bring similar actions.

Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

## **Pharmaceutical Pricing and Reimbursement**

In the United States and in other countries, sales of *EGRIFTA*<sub>TM</sub> and our other product candidates will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities (such as the Centers for Medicare & Medicaid Services in the United States), managed care providers, private health insurers and other organizations. We believe *EGRIFTA*<sub>TM</sub> will achieve a high degree of



physician and payor acceptance, driven by our product's safety and efficacy, the lack of approved alternative therapies for these patients and the prominent medical and social need to treat HIV/AIDS patients.

However, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We, or our commercial partners, may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of *EGRIFTA*<sub>TM</sub> or our other product candidates. *EGRIFTA*<sub>TM</sub> or our other product candidates may not be considered cost-effective. It is time consuming and expensive for us, and our commercial partners, to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell *EGRIFTA*<sub>TM</sub> or our other product candidates on a competitive and profitable basis.

# **United States**

Pursuant to our agreement with EMD Serono, they are responsible for identifying and obtaining possible reimbursements under such government programs in the United States. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products and biologic agents. Substantial new provisions affecting compliance also have been enacted, which may require us, or EMD Serono, to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and also may increase our regulatory burdens and operating costs.

The MMA imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and included a major expansion of the prescription drug benefit under a new Medicare Part D. Medicare Part D went into effect on January 1, 2006. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

It is not clear what effect the MMA will have on the prices paid for *EGRIFTA*<sup>TM</sup> and our other product candidates. Some studies indicate that Part D lowered the average price and increased the utilization of prescription drugs by Medicare beneficiaries. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

There are also laws that govern a company's eligibility to participate in Medicare and Medicaid reimbursements. For example, a company may be debarred from participation if it is found to have violated federal anti-kickback laws, which could have a significant effect on a company's ability to operate its business.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Indeed, we expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. At the present time, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress is considering passing legislation that would lift the ban on federal negotiations. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could harm our business, financial condition and results of operations.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

# Europe and Other Countries Covered by Our Agreements

Outside of the United States, sales of *EGRIFTA*<sup>TM</sup> and our other product candidates will depend in part on the availability and level of reimbursement from third-party payers. Third-party payers can be public or private or a combination of both. In order to obtain public reimbursement, prescription drugs are often evaluated by specialized bodies in a country. This process is in many cases independent of marketing approval and the time to carry out the evaluation differs in each country, often extending beyond the initial regulatory approval date of the drug.

The requirements and aspects considered during the assessment of a new prescription drug are not necessarily the same in each country and are given different weight depending on the countries' attitudes towards providing public healthcare and the government's willingness to pay for these new drugs. We or our commercial partners could be required to conduct specific health economic and other studies or analyses in order to satisfy such requirements. The decision to comply with such requirements will depend on the prospects of obtaining a positive opinion and the costs involved in the process and the profitability of the market.

In many jurisdictions, pricing plays an important role in the evaluation of prescription drugs for reimbursement and in most cases, there are price controls that can include, but are not limited to, reference pricing to drugs sold within the country and in other countries, the evaluation of what a fair price would be based on the condition that is being treated and innovative quality of the new drug.

Many countries, particularly in Europe, have initiated cost-cutting measures which have been reflected in reduced budgets for drugs, higher discounts imposed on manufacturers and price negotiations between authorities and manufacturers among other actions. We expect the current reimbursement evaluation process and pricing policies to keep evolving in ways that we may not foresee.

In Latin America, Brazil has a formal price procedure through Agência Nacional de Vigilância Sanitoria (ANVISA) which determines the price of a pharmaceutical based on five reference countries, including the United States. However, there is uncertainty in pricing of pharmaceutical drugs in Latin America in general.

Pursuant to our agreements with Sanofi and Ferrer, each is responsible for identifying and obtaining possible reimbursements under such government programs in their respective territories.

## Employees

As at November 30, 2010, we had 99 employees, all of whom were employed in Canada. All of our employees are engaged in administration, finance, research and development, regulatory and business development functions. None of our employees are unionized. We believe the relations with our employees are good.

## Facilities

We carry out our activities at 2310 Alfred-Nobel Boulevard in the Technoparc Montréal in Ville Saint-Laurent, Québec, Canada. We lease a 36,400 square-foot building, which houses both offices and laboratories which enable us to conduct small-scale peptide manufacturing, discovery and manage preclinical and clinical research.

# Legal Proceedings

On July 26, 2010, we received a motion for authorization to institute a class action lawsuit against us, our chairman and our former chief executive officer. This motion was filed in the Superior Court of Québec, district of Montreal. The applicant is seeking to initiate a class action suit and to certify and represent a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. This applicant alleges that we did not comply with our continuous disclosure obligations as a reporting issuer by failing to disclose certain alleged adverse effects relating to the administration of *EGRIFTA*™. We are of the view that the allegations contained in the motion are entirely without merit and intend to take all appropriate actions to vigorously defend our position. The Motion has not yet been heard by the Superior Court of Québec and no date has been set for the hearing. We have subscribed for insurance covering our potential liability and the potential liability of our directors and officers in the performance of all their duties for us subject to a \$200,000 deductible and standard terms, conditions and exclusions.

We are not otherwise currently subject to any material legal proceedings.

#### MANAGEMENT

# **Directors and Executive Officers**

The following table sets forth information about our executive officers and directors.

NAME AND PLACE OF RESIDENCE	AGE	POSITION WITH THE CORPORATIO
Paul Pommier (1)(2)(3)(4)(5)	68	Chairman of the Board
Québec, Canada		
John-Michel T. Huss <sup>(4)</sup>	46	President and Chief Executive Officer and Director
Québec, Canada		
Gilles Cloutier <sup>(3)(5)</sup>	66	Director
North Carolina, United States		
A. Jean de Grandpré (2)(3)(4)(5)	89	Director
Québec, Canada		
Robert G. Goyer <sup>(3)</sup>	72	Director
Québec, Canada		
Gérald A. Lacoste (1)(3)(5)	67	Director
Québec, Canada		
Bernard Reculeau <sup>(2)</sup>	60	Director
Paris, France		
Jean-Denis Talon (1)(2)(4)	69	Director
Québec, Canada		
Luc Tanguay (4)	52	Senior Executive Vice President and Chief Financial Officer and
Québec, Canada		Director
Marie-Noël Colussi	42	Vice President, Finance
Québec, Canada		
Chantal Desrochers	56	Vice President, Business Development and Commercialization
Québec, Canada		
Andrea Gilpin	41	Vice President, Investor Relations and Communications
Québec, Canada		
Jocelyn Lafond	43	Vice President, Legal Affairs, and Corporate Secretary
Québec, Canada		
Christian Marsolais	48	Vice President, Clinical Research and Medical Affairs
Québec, Canada		
Martine Ortega	55	Vice President, Compliance and Regulatory Affairs
Québec, Canada		
Pierre Perazzelli	59	Vice President, Pharmaceutical Development
Québec, Canada		
Krishna Peri	56	Vice President, Research
Québec, Canada		

#### Notes:

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.
 (3) Member of the Nominating and Corporate Governance Committee.

(4) Member of the Finance Committee.

<sup>(5)</sup> Member of the Strategic Review Committee.

Paul Pommier, MBA. Chairman of the Board. Mr. Paul Pommier worked for more than 25 years at National Bank Financial Inc., his last position being Senior Executive Vice President, Corporate and Government Finance. Throughout his career, he oversaw public and private financings, mergers and acquisitions, as well as the marketing

of investment offerings. Under his leadership, National Bank Financial Inc. developed notable expertise in tax-shelter financings.

John-Michel T. Huss, MBA. *President & Chief Executive Officer.* John-Michel T. Huss brings more than 20 years of global experience in the pharmaceutical industry to Theratechnologies. He began his career at Merck & Co., occupying various sales and marketing positions in the United States and in Europe. In 1996, he accepted an International Product Manager position at the headquarters of F. Hoffman-La Roche, in Basel, Switzerland. Mr. Huss joined Sanofi-Synthelabo GmbH in 1999, where he held positions in Germany and in Canada. He was appointed General Manager of the Swiss subsidiary at Sanofi in 2007 (Sanofi-Synthelabo merged with Aventis in 2004), and in 2009 was promoted to the position of Chief of Staff, Office of the CEO, in Paris.

**Gilles Cloutier, Ph.D.** *Corporate Director.* Dr. Gilles Cloutier has over 30 years of experience in the pharmaceutical industry including five years with contract research organizations, providing strategic support to biotechnology and pharmaceutical companies. Dr. Cloutier has also held key positions with large North-American pharmaceutical companies, where he developed expertise in the field of clinical research. His experience includes the development and approval of several drugs in Canada, the United States and Europe. Dr. Cloutier sits on our board of directors and is also Chairman of the Fondation André Delambre for amyotrophic lateral sclerosis (ALS).

**A. Jean de Grandpré, C.C., Q.C.** *Corporate Director.* A. Jean de Grandpré contributed to Bell Canada's significant growth as Chairman of the Board and Chief Executive Officer, and went on to become the founding Chairman of the Board and Chief Executive Officer of BCE. In recognition of these achievements, he was inducted into the Canadian Business Hall of Fame. Mr. de Grandpré also served on the boards of directors of other important Canadian and US corporations, namely Northern Telecom Limited, Chrysler Corporation, Sun Life Financial Inc. and Toronto Dominion Bank, and as a member of the international advisory boards of Chemical Bank and Goldman Sachs. He has been a member of our board of directors since our founding in October 1993 and was appointed Chairman in 1996. He resigned his position as Chairman in March 2007.

**Robert G. Goyer, Ph.D.** *Emeritus professor, Faculty of Pharmacy of the Université de Montréal.* Dr. Goyer has more than 40 years of experience in the pharmaceutical field. Dr. Goyer is the former president of Jouveinal Canada and is also a former dean of the Faculty of Pharmacy of Université de Montréal. Recognized for his broad expertise in drug development, he has served on the boards of several companies and governmental organizations. He was notably Chairman of the Advisory Committee on drug approval procedures of Health Canada's Therapeutic Products Directorate and a member of the board of directors of the Régie de l'assurance maladie du Québec. He was Chairman of the Conseil du médicament du Québec from 2003 to 2005.

**Gérald A. Lacoste, Q.C.** *Corporate Director.* Gérald A. Lacoste is a lawyer with extensive experience in the fields of securities regulation, financing and corporate governance. He was previously Chairman of the Québec Securities Commission (now known as the Autorité des marchés financiers) and was also President and CEO of the Montreal Stock Exchange. During his career, Mr. Lacoste acted as legal counsel to the Canadian Standing Senate Committee on Banking, Trade and Commerce, he chaired the Québec Advisory Committee on Financial Institutions, and was a member of the task force on the capitalization of life insurance companies in Québec. Mr. Lacoste is currently a corporate director, actively involved in the biotechnology industry, and is a member of the North American Free Trade Agreement (NAFTA) arbitration panel.

**Bernard Reculeau.** *Corporate Director.* Mr. Bernard Reculeau brings over 25 years of pharmaceutical industry experience to Theratechnologies. From September 2006 to December 2009, he was the President of CIS Bio International, a French company specializing in nuclear medicine and biomedical technologies. Prior to joining CIS Bio International, Mr. Reculeau was Senior Vice President Pharmaceutical Operations of Sanofi for the InterContinental Region. In his previous functions, he was responsible for product development and commercialization in numerous countries around the world. Mr. Reculeau has close to 25 years in pharmaceutical operations, notably in France where he ran the pharmaceutical operations for Rhône-Poulenc and Rhône-Poulenc Rorer as well as in other countries in the European Union. Mr. Reculeau retired in early 2010.

**Jean-Denis Talon.** *Chairman of the Board, AXA Canada.* Mr. Jean-Denis Talon had a successful career with AXA Insurance over a period of more than 20 years, ultimately becoming President and Chief Executive Officer. He is currently Chairman of the Board of AXA Canada. Mr. Talon is also former President of the Financial Affairs Committee at the Insurance Bureau of Canada.

Luc Tanguay, M.Sc., CFA. Senior Executive Vice President and Chief Financial Officer of the Company. Mr. Luc Tanguay has been active in the biotechnology industry for over 15 years. As a member of our senior management since 1996, he has contributed to our growth by facilitating access to public and private capital funding. A member of the board of directors since 1993, he has held various management positions since joining the Company. Prior to joining us, Mr. Tanguay had a career in investment banking at National Bank Financial Inc.

**Marie-Noël Colussi, CA.** *Vice President, Finance.* Ms. Marie-Noël Colussi is a graduate of Université du Québec à Montréal in business administration. Prior to joining us, Ms. Colussi worked for eight years with KPMG, a major accounting firm. Ms. Colussi has experience in accounting, auditing, control and taxation, particularly in research and development. She joined us in March 1997, and prior to her appointment as Vice President, Finance in February 2002, she held the positions of Director, Accounting and Internal Control and Controller.

**Chantal Desrochers, B.Ph., MBA.** *Vice President, Business Development and Commercialization.* Ms. Chantal Desrochers obtained her degrees in pharmacy and business from the Université de Montréal. She began her career at Schering-Plough in sales and ultimately became a Product Director. After obtaining her M.B.A., Ms. Desrochers joined Bristol-Myers Squibb Company in Canada as Marketing Director, Pharmaceuticals and became Vice President, Institutional Business in 1995. In 1997, Ms. Desrochers was promoted to European Franchise Marketing Director, Cardiovascular, in France where she contributed to the commercial development of cardiovascular products. This led to her appointment as International Marketing Director, Cardiovascular, at Bristol-Myers Squibb in Princeton, New Jersey. Prior to joining us in 2005, Ms. Desrochers offered consulting services in business development and product development strategies.

Andrea Gilpin, Ph.D., MBA. Vice President, Investor Relations and Communications. Prior to joining us in 2007, Dr. Gilpin was Director, Investor Relations at MethylGene Inc. and held various positions at biotechnology companies. Dr Gilpin has a Ph.D. (Genetics/Biochemistry) from the University of Toronto and an MBA from the Asper School of Business.

**Jocelyn Lafond, LL.B., LL.M.** *Vice President, Legal Affairs, and Corporate Secretary.* Mr. Lafond has over 15 years of experience in the fields of corporate and securities law. Mr. Lafond holds a law degree from Université Laval and a Masters Degree in Law from the University of Toronto. He has been a member of the Barreau du Québec since 1992. Prior to joining us in 2007, Mr. Lafond was a partner with the international law firm of Fasken Martineau DuMoulin LLP.

**Christian Marsolais, Ph.D.** *Vice President, Clinical Research and Medical Affairs.* Dr. Christian Marsolais has over 15 years of experience in clinical research for large pharmaceutical companies, such as Sandoz Canada Inc. and BioChem Therapeutics Inc. Before joining us in 2007, Dr. Marsolais held various positions at Pfizer Global Pharmaceuticals, where he was appointed Director of Medical Affairs, Therapeutic Areas, in 2004. In this position, Dr. Marsolais was responsible for the clinical program and scientific initiatives development, as well as the integration of the Scientific Affairs and Clinical Research for the oncology and HIV Franchise. Dr. Marsolais holds a Ph.D. in Biochemistry from the Université de Montréal.

**Martine Ortega, Pharm. D.** *Vice President, Compliance and Regulatory Affairs.* Ms. Martine Ortega joined us in 2006. A graduate in pharmacy from the Université d'Aix-Marseille II, she holds a postdoctoral degree in dermatology. Ms. Ortega has close to 20 years of experience in the pharmaceutical industry, where she has gained knowledge of the drug development process. During her career, she has acquired broad expertise in GLP, GCP and GMP practices and procedures as well as in computerized systems validation. She is also experienced in relations with US, European and Canadian regulatory agencies. Prior to joining us, she held senior management positions at Ventana Clinical Research Corporation, MDS Pharma Services and Sandoz Canada Inc.

**Pierre Perazzelli, B. Sc.** *Vice President, Pharmaceutical Development.* A graduate of Université Laval, Mr. Perazzelli has been working in the pharmaceutical manufacturing industry for over 20 years. Throughout his career, he has held various positions in large pharmaceutical companies, including Bristol Myers Squibb and Abbott Laboratories, Ltd. He was Director of the LAB Laboratory, a research centre specializing in pharmaceutical formulation. He is also experienced in the production of generic drugs. Mr. Perazzelli joined us in May 2000.

**Krishna Peri, Ph.D.** *Vice President, Research.* Co-inventor of the ExoPep<sub>TM</sub> technology and a founder of Pharma-G, Dr. Krishna Peri holds a Ph.D. in biochemistry from the University of Saskatchewan, Canada. He pursued post-doctoral research in cancer as an NCI fellow at McGill University and at Ste. Justine Hospital Research Center. After

our acquisition of Pharma-G in 2000, he served as director of discovery research, and was subsequently appointed Vice-President, Research, in June 2004.

# **Term of Our Executive Officers**

Each of our executive officers has been appointed by our board of directors and serves until his or her successor is duly appointed and qualified.

# Term of Our Board of Directors

Our directors are elected at the annual meeting of shareholders for one-year terms and remain in office until the next annual meeting of shareholders, unless a director resigns or a director's position becomes vacant following his death or removal or for any other reason before the next annual meeting of shareholders. Our articles of incorporation provide that the board of directors must have a minimum of three and a maximum of 20 directors. Our board of directors currently consists of nine directors.

# **Committees of Our Board of Directors**

Our board of directors has established an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee, a Finance Committee and a Strategic Review Committee to assist the directors in carrying out their responsibilities.

## Audit Committee

Our board of directors has established an Audit Committee composed of three members: Paul Pommier, its chairman, Jean-Denis Talon and Gérald A. Lacoste. All three are independent within the meaning of applicable securities laws and as "independence" is defined by Nasdaq and financially literate. Each member of the Audit Committee has acquired in-depth financial expertise giving each the ability to read and understand a set of financial statements which present the breadth and level of complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised in our financial statements.

The Audit Committee is responsible for assisting our board of directors in overseeing the following:

- the integrity of our financial statements and related information;
- our internal control systems;
- the appointment and performance of the external auditor; and
- · the supervision of our risk management.

# **Compensation Committee**

Our board of directors has established a Compensation Committee composed of four members: Jean-Denis Talon, its chairman, A. Jean de Grandpré, Paul Pommier and Bernard Reculeau. All four are independent within the meaning of applicable securities laws and as "independence" is defined by Nasdaq.

The Compensation Committee is responsible for assisting our board of directors in overseeing the following:

- · compensation of senior management;
- assessment of senior management;
- compensation of directors;
- stock option and deferred share unit grants; and
- overall increase in total compensation.

#### Nominating and Corporate Governance Committee

Our board of directors has established a Nominating and Corporate Governance Committee composed of five members: Gérald A. Lacoste, its chairman, Gilles Cloutier, Jean de Grandpré, Robert G. Goyer and Paul Pommier.

All five are independent within the meaning of applicable securities laws and as "independence" is defined by the Nasdaq.

The Nominating and Corporate Governance Committee is responsible for assisting our board of directors in overseeing the following:

- recruitment of candidates for the board;
- review of the size of the board;
- composition of the board;
- function of the board;
- orientation and education of board members; and
- governance.

# **Finance Committee**

Our board of directors has established a Finance Committee composed of five members: Paul Pommier, its chairman, A. Jean de Grandpré, John-Michel T. Huss, Jean-Denis Talon and Luc Tanguay.

The responsibilities of the Finance Committee are to study, analyze and present recommendations to our board of directors on financing matters.

# Strategic Review Committee

Our board of directors has established a Strategic Review Committee composed of four members: Paul Pommier, its chairman, Gilles Cloutier, Jean de Grandpré and Gérald A. Lacoste.

The responsibilities of the Strategic Review Committee are to oversee, analyze and recommend to our board of directors our business strategies.

# **Employment Agreements**

Each of our executive officers has entered into an employment agreement with us. Each employment agreement has an indefinite term. Each employment agreement determines the annual salary of the executive officer subject to annual review by the Compensation Committee. In addition to his/her respective base salary, each executive officer is entitled to our benefits program and is eligible to receive an annual bonus based on the attainment of annual objectives. If we terminate the employment of any of our executive officers without just and sufficient cause, or, except in the case of Christian Marsolais, Andrea Gilpin, Chantal Desrochers, Pierre Perazzelli, Krishna Peri and Marie-Noël Colussi, in the event of a change of control, the executive officer in guestion is entitled to receive an amount equal to between 6 and 24 months of his or her annual base salary.

On August 31, 2010, we entered into an employment agreement with Mr. John-Michel T. Huss, our President and Chief Executive Officer. Under the terms of the employment agreement, Mr. Huss is entitled to an annual base salary of \$600,000 (to be reviewed annually) and is eligible to receive an annual bonus representing 100% of his base salary. He is also entitled to receive 250,000 stock options vesting in equal tranches over four years, which were granted to him as of the effective date of his employment, and to receive a number of share units redeemable for an amount equivalent to the value of a common share, equal in value to \$250,000 for each of the first four years of his employment.

In his employment agreement, Mr. Huss agreed to customary non-competition, non-solicitation, non-disclosure and assignment of intellectual property provisions. If we terminate Mr. Huss's employment without just cause, he will be entitled to receive an indemnity payment of \$1.5 million. Furthermore, in the event of a change of control of Theratechnologies, if Mr. Huss's employment is terminated or he resigns, his employment agreement provides for an indemnity payment equal to twice his base salary and twice his last bonus entitlement (the bonus entitlement for 2011 until he has been with us for a full year). Mr. Huss is also entitled to a number of relocation-related benefits in 2011.

# **Related Party Transactions**

We are not aware that any of our directors, officers, other insiders or any persons associated with or otherwise related to any of the foregoing has had an interest in any material transaction carried out since the beginning of the



most recently completed financial year or in any proposed transaction which has materially affected or is likely to materially affect us or any of our subsidiaries.

# PRINCIPAL SHAREHOLDERS

The following table shows information known to us with respect to the beneficial ownership of our common shares by:

- each of our directors;
- each of our chief executive officer, chief financial officer and our three other most highly compensated executive officers during our last completed fiscal year, or Named Executive Officers; and
- all of our directors and executive officers as a group. •

To our knowledge, no person or group or affiliated persons known by us is the beneficial owner of more than 10% of our common shares other than Stewardship Partners Investment Counsel Inc. who, based exclusively on a report filed on the Canadian System for Electronic Document Analysis and Retrieval, or SEDAR, on July 6, 2010, holds approximately 10.1%.

NAME OF BENEFICIAL OWNER	NUMBER OF COMMON SHARES BENEFICIALLY OWNED <sup>(1)</sup>
Directors and Named Executive Officers	
Paul Pommier	190,100
John-Michel T. Huss	_
Gilles Cloutier	71,000
A. Jean de Grandpré	200,000
Robert G. Goyer	10,000
Gérald A. Lacoste	11,000
Bernard Reculeau	18,100
Jean-Denis Talon	60,000
Luc Tanguay	83,000
Chantal Desrochers	16,300
Christian Marsolais	8,597
Martine Ortega	3,000
All directors and executive officers as a group (17 persons)	723,972

Does not include any options held.

## **DESCRIPTION OF SHARE CAPITAL**

We are authorized to issue an unlimited number of common shares and an unlimited number of preferred shares issuable in series.

Subject to the priority rights of holders of preferred shares, holders of common shares are entitled to any dividend declared by the board of directors, to one vote per share at meetings of our shareholders and, in the event of our liquidation or dissolution, to participate in the distribution of the assets.

Preferred shares carry no voting rights. Preferred shares may be issued at any time in one or more series. Our articles of incorporation give our board of directors the power to fix the number of preferred shares and the consideration per share, as well as to determine the provisions attached to the preferred shares of each series (including dividends, redemption and conversion rights, if any). The shares of every series of preferred shares will have priority over all of our other shares, including common shares, with respect to the payment of dividends and return of capital in the event of our liquidation or dissolution.

The common shares issued represent the total voting rights pertaining to our securities.

#### **Shareholder Rights Plan**

On February 10, 2010, we entered into a shareholder rights plan agreement, or Rights Plan. The Rights Plan entitles a holder of rights (other than the Acquiring Person, as defined below, or any affiliate or associate of an Acquiring Person or any person acting jointly or in concert with an Acquiring Person or any affiliate or associate of an Acquiring Person) to purchase our common shares at a discount of 50% to the market price upon a person becoming an "Acquiring Person", subject to certain exceptions and the terms and conditions set out in the Rights Plan. An "Acquiring Person" is defined in the Rights Plan as a beneficial owner of 20% or more of our common shares. The Rights Plan will expire at the close of our annual meeting of shareholders in 2013.

In order to implement the Rights Plan, we issued one right in respect of each common share outstanding as of 6:00 p.m. (Montreal time) on February 9, 2010, the "Effective Date". One right will also be issued and attached to each subsequently issued common share, including the common shares issued pursuant to this offering. The rights will separate and trade separately from the common shares to which they are attached and will become exercisable after the "Separation Time", as defined below:

The "Separation Time" is the close of business on the tenth business day following the earliest of:

- (a) the date of the first public announcement made by us or an Acquiring Person that a person has become an Acquiring Person;
- (b) the date of the commencement of, or first public announcement of the intent of any Person to commence, a take-over bid (other than a Permitted Bid (as defined in the Rights Plan) or a Competing Permitted Bid (as defined in the Rights Plan)) by any person for our common shares;
- (c) the date upon which a Permitted Bid or Competing Permitted Bid ceases to be such; or
- (d) such later date as may be determined by the board of directors.

After the time at which a person becomes an Acquiring Person, and subject to the terms and conditions set out in the shareholder rights plan agreement, each right would, upon exercise, entitle a rights holder, other than the Acquiring Person and related persons, to purchase common shares at a 50% discount to the market price at the time.

Under the Rights Plan, a "Permitted Bid" is a bid made to all holders of the common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties, have been tendered, the offeror may take up and pay for the common shares but must extend the bid for a further 10 days to allow other shareholders to tender.

# **PRIOR SALES**

During the 12-month period prior to the date of this prospectus, we issued the following common shares and granted the following options. Unless otherwise indicated, all common shares were issued upon exercise of stock options and all options were granted under our compensation plans.

DATE	TYPE OF SECURITY	PRICE PER SECURITY (\$)	NUMBER OF SECURITIES
February 2, 2010	Common shares	1.80	500
February 3, 2010	Common shares	1.80	1,000
February 12, 2010	Common shares	1.80	666
February 23, 2010	Common shares	1.80	666
March 11, 2010	Common shares	1.80	333
March 23, 2010	Common shares	1.80	166
March 31, 2010	Common shares	1.80	666
April 1, 2010	Common shares	1.85	6,667
April 1, 2010	Common shares	1.20	6,667
April 7, 2010	Common shares	1.80	666
April 14, 2010	Common shares	1.80	5,833
April 28, 2010	Common shares	1.80	1,000
May 10, 2010	Common shares	1.80	500
May 10, 2010	Common shares	1.20	7,500
May 11, 2010	Common shares	1.80	2,332
May 11, 2010	Common shares	1.85	1,667
May 11, 2010	Common shares	5.00	2,880 (1)
June 8, 2010	Stock options	4.75 (2)	70,000 (3)
June 14, 2010	Common shares	1.84	10,000
June 29, 2010	Common shares	1.80	500
July 15, 2010	Common shares	1.80	1,666
July 15, 2010	Common shares	1.42	10,000
July 30, 2010	Common shares	1.80	166
September 1, 2010	Common shares	1.80	166
September 20, 2010	Common shares	1.80	1,666
November 16, 2010	Common shares	1.80	166
November 19, 2010	Common shares	1.80	500
November 24, 2010	Common shares	1.80	500
December 1, 2010	Stock options	5.65 (2)	250,000 (3)
December 23, 2010	Common shares	1.80	667
January 11, 2011	Common shares	1.80	667
January 13, 2011	Common shares	1.80	1,000
January 24, 2011	Common shares	1.80	666

Notes:

(1) Number of common shares issued under our employee stock purchase plan.

(2) Exercise price per common share.
 (3) Number of common shares issuable upon the exercise of outstanding options.

## CERTAIN MATERIAL INCOME TAX CONSIDERATIONS

## **Certain Canadian Federal Income Tax Considerations**

The following summary fairly describes the principal Canadian federal income tax considerations generally applicable to a purchaser who acquires as a beneficial owner common shares pursuant to this offering and who, at all relevant times, for the purposes of the Income Tax Act (Canada) and the Income Tax Regulations (collectively the "Tax Act"), (i) deals at arm's length with Theratechnologies, (ii) is not affiliated with Theratechnologies, and (iii) holds his, her or its common shares as capital property (a "Holder"). Common shares will generally be considered to be capital property to a purchaser provided the purchaser does not acquire or hold the shares in the course of carrying on a business or as part of an adventure or concern in the nature of trade.

This summary does not apply to a purchaser (i) that is a "specified financial institution", (ii) that is a "financial institution" for purposes of certain rules referred to as the mark-to-market rules, (iii) an interest in which is a "tax shelter investment", or (iv) that reports its "Canadian tax results" in a currency other than Canadian currency, each as defined in the Tax Act. Such a holder should consult his, her or its own tax advisors to the purchase of common shares pursuant to this offering.

This summary is based on the current provisions of the Tax Act and an understanding of the current administrative policies and assessing practices of the Canada Revenue Agency published in writing prior to the date hereof. This summary takes into account all specific proposals to amend the Tax Act that have been publicly announced by, or on behalf of, the Minister of Finance (Canada) prior to the date hereof (the "Proposed Amendments"). This summary assumes that the Proposed Amendments will be enacted in the form proposed. This summary does not otherwise take into account or anticipate any other changes in law or administrative policy or assessing practice, whether by way of judicial, legislative or administrative action, nor does it take into account provincial, territorial or foreign tax legislation or considerations, which may differ from those discussed in this summary. No assurance can be given that the Proposed Amendments will be enacted in the form proposed or at all.

This summary is of a general nature only and is not exhaustive of all possible Canadian federal income tax considerations. This summary is not intended to constitute legal or tax advice to any particular shareholder. Accordingly, prospective purchasers should consult their own tax advisors regarding their own particular circumstances.

Generally, for the purposes of the Tax Act, all amounts relating to the acquisition, holding and disposition of the common shares must be converted into Canadian dollars based on the exchange rates as determined in accordance with the Tax Act. The amount of dividends required to be included in the income of, and capital gains or capital losses realized by, a Holder may be affected by fluctuations in the Canadian / U.S dollar exchange rate.

# **Taxation of Resident Holders**

This portion of the summary is applicable to Holders who, at all relevant times, for the purposes of the Tax Act, are, or are deemed to be, resident in Canada (the "Resident Holders").

Certain Resident Holders may, in certain circumstances, be entitled to make or may have already made the irrevocable election under subsection 39(4) of the Tax Act to have the common shares and every other Canadian security (as defined in the Tax Act) owned by them in the taxation year of the election and in all subsequent taxation years deemed to be capital property. Resident Holders whose common shares might not otherwise be considered to be capital property should consult their own tax advisors for advice concerning this election.

In the case of a Resident Holder who is an individual (other than certain trusts), any dividends received or deemed to be received on the common shares will be included in computing the individual's income for a taxation year and will be subject to the gross-up and dividend tax credit rules applicable to taxable dividends paid by taxable Canadian corporations. Provided that appropriate designations are made by us at the time a dividend is paid, such dividend will be treated as an eligible dividend for the purposes of the Tax Act and a Resident Holder will be entitled to an enhanced gross up and dividend tax credit in respect of such dividend.

In the case of a Resident Holder that is a corporation, any dividends received or deemed to be received on the common shares will be included in computing the corporation's income and will generally be deductible in computing its taxable income. A Resident Holder that is a "private corporation" as defined in the Tax Act or a

corporation that is controlled, whether because of a beneficial interest in one or more trusts or otherwise, by or for the benefit of an individual (other than a trust) or a related group of individuals (other than trusts) will generally be liable to pay a refundable tax of 33<sup>1</sup>/<sub>3</sub>% of the dividends received on the common shares to the extent that such dividends are deductible in computing the corporation's taxable income for the taxation year.

Generally, a Resident Holder who disposes of, or is deemed to have disposed of, a common share will realize a capital gain (or a capital loss) equal to the amount by which the proceeds of disposition of the common share, net of any reasonable costs of disposition, exceed (or are exceeded by) the adjusted cost base of the common share. The adjusted cost base of a common share acquired pursuant to this offering will be determined by averaging the cost of such common share with the adjusted cost base of all other common shares owned by the Resident Holder as capital property at that time.

Generally, one-half of any capital gain (a "taxable capital gain"), realized by a Resident Holder in a taxation year must be included in the Resident Holder's income for the year and one-half of any capital loss (an "allowable capital loss"), realized by a Resident Holder in a taxation year may be deducted from taxable capital gains realized in the year. Allowable capital losses in excess of taxable capital gains for that year may be carried back three years or forward indefinitely, in the circumstances and to the extent provided by the Tax Act. The amount of any capital loss realized by a Resident Holder that is a corporation on a disposition or deemed disposition of common shares may be reduced by the amount of dividends previously received or deemed to be received thereon, to the extent and under the circumstances prescribed in the Tax Act. Analogous rules apply where a Resident Holder that is a corporation is, directly or through a trust or partnership, a member of a partnership or a beneficiary of a trust which owns common shares. Such Resident Holder should consult their own advisors.

A Resident Holder that throughout a relevant taxation year is a Canadian-controlled private corporation, as defined in the Tax Act, may be liable to pay an additional refundable tax of 6<sup>2</sup>/<sub>3</sub>% on certain investment income, including taxable capital gains and dividends received or deemed to be received in respect of the common shares (but not dividends that are deductible in computing taxable income).

## Taxation of Non-Resident Holders

This portion of the summary is applicable to Holders who, at all relevant times, are not, and are not deemed to be, resident in Canada for the purposes of the Tax Act and who do not use or hold, and are not deemed to use or hold, the common shares in connection with carrying on business in Canada (each a "Non-Resident Holder"). Special rules, which are not discussed in this summary, may apply to a Non-Resident Holder that is an insurer that carries on an insurance business in Canada and elsewhere.

Amounts paid or credited to a Non-Resident Holder as dividends or deemed dividends on the common shares will be subject to withholding tax at a rate of 25%, subject to any reduction of such rate of withholding to which the Non-Resident Holder is entitled under any applicable income tax treaty. For example, the rate of withholding tax on dividends is generally reduced to 15% under the Convention Between Canada and the United States of America with Respect to Taxes on Income and Capital, signed September 26, 1980, as amended, (the "U.S. Treaty") if the beneficial owner of the dividends is resident in the United States for purposes of the U.S. Treaty.

A Non-Resident Holder will not be subject to tax on a capital gain realized on the disposition of a common share unless, at the time of disposition, the common share constitutes taxable Canadian property to the Non-Resident Holder and the Non-Resident Holder is not entitled to relief under an applicable income tax convention between Canada and the country in which the Non-Resident Holder at a particular time provided that the common share will not constitute taxable Canadian property to a Non-Resident Holder at a particular time during the 60-months period that ends at that time, (1) the Non-Resident Holder, persons with whom the Non-Resident Holder did not deal at arm's length (within the meaning of the Tax Act), or the Non-Resident Holder together with such persons, has owned 25% or more of the issued shares of any class or series of our capital stock and (2) more than 50% of the fair market value of the common share was derived directly or indirectly from one or any combination of: (i) real or immovable properties situated in Canada, (ii) "Canadian resource properties" (as defined in the Tax Act), (iii) "timber resource properties" (as defined in the Tax Act), and (iv) options in respect of, or interests in, or for civil law rights in, property in any of the foregoing whether or not the property exists. Notwithstanding the foregoing, in certain circumstances set out in the Tax Act, common shares could be deemed to

be taxable Canadian property. Non-Resident Holders whose common shares may constitute taxable Canadian property should consult their own tax advisors.

# Certain U.S. Federal Income Tax Considerations

The following is a general summary of certain U.S. federal income tax considerations with respect to the acquisition, ownership and disposition of common shares by a U.S. Holder (as defined below). This summary applies to U.S. Holders who acquire common shares in the Offering and hold those common shares as a capital asset within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). This summary is based upon the Code, regulations promulgated under the Code, the U.S. Treaty, administrative rulings and judicial decisions as in effect on the date of this prospectus, all of which are subject to change, possibly with retroactive effect, and to differing interpretations, which could result in U.S. federal income tax considerations different from those summarized below. No ruling from the Internal Revenue Service (the "IRS") has been requested or will be obtained regarding the U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares. There can be no assurance that the IRS will not challenge any of the conclusions described herein or that a U.S. court will not sustain such a challenge.

This summary is for general information purposes only, and does not purport to be a complete analysis or listing of all potential U.S. federal income tax considerations that may apply to a U.S. Holder relating to the acquisition, ownership and disposition of common shares. It does not address the effects of any state or local taxes, or the tax consequences in jurisdictions other than the United States nor any U.S. federal estate, gift or generation-skipping transfer tax. In addition, it does not address tax consequences that may be relevant to a U.S. Holder in light of such holder's particular circumstances, including alternative minimum tax consequences, nor does it address the special tax rules that apply to certain classes of taxpayers, including but not limited to the following:

- a person that owns, or is treated as owning under applicable ownership attribution rules, 10% or more of the voting power of Theratechnologies;
- a broker or dealer in securities or currencies;
- a trader in securities that elects to use a mark-to-market method of accounting;
- a bank, mutual fund, life insurance company or other financial institution;
- · a real estate investment trust, regulated investment company or grantor trust;
- a tax-exempt organization;
- a qualified retirement plan or individual retirement account;
- a person that holds common shares as part of a straddle, hedge, constructive sale or other integrated transaction for tax purposes;
- a partnership, S corporation or other pass through entity;
- an investor in a partnership, S corporation or other pass through entity;
- a person who received common shares in connection with the performance of services;
- a person whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- U.S. tax expatriates and certain former citizens and long-term residents of the United States;
- a person that has been, is or will be a resident or deemed to be a resident in Canada for purposes of the Tax Act;
- a person whose common shares constitute "taxable Canadian property" under the Tax Act; and
- a person who has a permanent establishment in Canada for purposes of the U.S. Treaty or who uses or holds, or is deemed to use or hold, the common shares in connection with carrying on business in Canada.

For purposes of this discussion, a "U.S. Holder" is any beneficial owner of common shares that is:

- an individual citizen or resident of the United States;
- a corporation (or other entity classified as a corporation for U.S. federal income tax purposes) that is created or organized in
  or under the laws of the United States or any political subdivision thereof;
- an estate the income of which is subject to U.S. federal income taxation regardless of the source of such income; or
- a trust (1) that validly elects to be treated as a U.S. person for U.S. federal income tax purposes, or (2) the administration
  over which a U.S. court can exercise primary supervision and all of the substantial decisions of which one or more
  U.S. persons have the authority to control.



This summary does not address the U.S. federal income tax considerations with respect to non-U.S. Holders arising from the acquisition, ownership and disposition of common shares. A "non-U.S. Holder" is a beneficial owner of common shares that is not a U.S. Holder.

If a partnership or other pass-through entity (including for this purpose any entity or arrangement treated as a partnership or passthrough entity for U.S. federal income tax purposes) holds common shares, the tax treatment of a partner or owner will generally depend upon the status of such partner or owner and upon the activities of the partnership or other pass-through entity. U.S. Holders who are partners or owners of a partnership or other pass-through entity that owns or may acquire common shares should consult their tax advisors regarding the specific tax consequences of the acquisition and ownership of common shares.

U.S. HOLDERS SHOULD CONSULT THEIR OWN ADVISORS REGARDING THE TAX CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE COMMON SHARES IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES.

# **Distributions With Respect to Common Shares**

Theratechnologies has never declared or paid dividends and does not anticipate paying dividends in the foreseeable future. However, subject to the discussion under "– Passive Foreign Investment Company" below, the gross amount of distributions (including constructive distributions), if any, paid on the common shares generally would be treated as dividend income to the extent paid out of Theratechnologies's current or accumulated earnings and profits (as determined for U.S. federal income tax purposes). A U.S. Holder would be required to include the amount of such distribution in gross income as a dividend (without reduction for any Canadian income tax withheld from such distribution) on the day actually or constructively received. Distributions to a U.S. Holder in excess of earnings and profits will be treated first as a return of capital that reduces a U.S. Holder's tax basis in such common shares (thereby increasing the amount of gain or decreasing the amount of loss that a U.S. Holder would recognize on a subsequent disposition of common shares), and then as gain from the sale or exchange of such common shares. A corporate U.S. Holder generally will not be entitled to a dividends-received deduction that is otherwise available upon the receipt of dividends distributed by U.S. corporations.

For taxable years beginning before January 1, 2013, a dividend paid by Theratechnologies generally will be taxed at the preferential tax rates applicable to long-term capital gains if (a) Theratechnologies is a "qualified foreign corporation" (as defined below), (b) the U.S. Holder receiving such dividend is an individual, estate, or trust, and (c) certain holding period requirements are met. Theratechnologies generally will be a "qualified foreign corporation" under Section 1(h)(11) of the Code (a "QFC") if it is eligible for the benefits of a comprehensive income tax treaty with the United States that the U.S. Treasury Department determines to be satisfactory for these purposes. The U.S. Treasury has determined that the U.S. Treaty qualifies as such a treaty under the Code and Theratechnologies believes that it is eligible for the benefits of the U.S. Treaty qualifies as such a treaty under the Code and Theratechnologies believes that it is eligible for the benefits of the U.S. Treaty qualifies as such a treaty under the Code and Theratechnologies believes that it is eligible for the benefits of the U.S. Treaty. Furthermore, even if Theratechnologies is not otherwise a QFC under this definition, Theratechnologies would still be treated as a QFC with respect to any dividend paid by Theratechnologies if the common shares with respect to which such dividend is paid are readily tradable on an established securities market in the United States. However, a dividend paid by Theratechnologies will not be eligible for the preferential tax rates applicable to long-term capital gains if Theratechnologies is a passive foreign investment company (a "PFIC") for the taxable year during which such dividend is paid or for the preceding taxable year. See below under "– Passive Foreign Investment Company" for a discussion of Theratechnologies's status under the PFIC rules.

The amount of a distribution paid to a U.S. Holder of common shares in foreign currency generally will be equal to the U.S. dollar value of such distribution based on the exchange rate applicable on the date of receipt. A U.S. Holder that does not convert foreign currency received as a distribution into U.S. dollars on the date of receipt generally will have a tax basis in such foreign currency equal to the U.S. dollar value of such foreign currency on the date of receipt. Such a U.S. Holder generally will recognize ordinary income or loss on the subsequent sale or other taxable disposition of such foreign currency (including an exchange for U.S. dollars).

# Sale or Other Disposition of Common Shares

Subject to the discussion under "- Passive Foreign Investment Company" below, in general, a U.S. Holder that sells or otherwise disposes of common shares in a taxable disposition:

- will recognize gain or loss equal to the difference (if any) between the U.S. dollar value of the amount realized on such sale or other taxable disposition and such U.S. Holder's adjusted tax basis in such common shares;
- any gain or loss will be capital gain or loss and will be long-term capital gain or loss if the holding period for the common shares sold or otherwise disposed of is more than one year at the time of such sale or other taxable disposition; and
- any gain or loss will generally be treated as U.S.-source income for U.S. foreign tax credit purposes.

Long-term capital gains of non-corporate taxpayers are taxed at reduced rates. There are currently no preferential tax rates for long-term capital gains of a U.S. Holder that is a corporation. The deductibility of capital losses is subject to limitations.

In the case of a cash-basis U.S. Holder (or an accrual-basis U.S. Holder that makes an election referred to in the following paragraph) who receives foreign currency, such as Canadian dollars, in connection with a sale or other taxable disposition of common shares, the amount realized will be based on the U.S.-dollar value of the foreign currency received with respect to such common shares, as determined on the settlement date of such sale or other taxable disposition.

In the case of an accrual-basis U.S. Holder who receives foreign currency, such as Canadian dollars, in connection with a sale or other taxable disposition of common shares, the amount realized generally will be based on the U.S.-dollar value of the foreign currency received with respect to such common stock as determined on the trade date. An accrual-basis U.S. Holder generally will recognize a foreign currency gain or loss for U.S. federal income tax purposes to the extent of difference between the U.S.-dollar value of the foreign currency on the trade date and the date of payment. Any such currency gain or loss generally will be treated as ordinary income or loss and would be in addition to gain or loss, if any, recognized on the sale (or other taxable disposition) of such common shares. An accrual-basis U.S. Holder may generally elect the same treatment required of a cash-basis taxpayer with respect to a sale or other taxable disposition of such common shares, provided the election is applied consistently from year to year. The election may not be changed without the consent of the IRS.

# Foreign Tax Credit Considerations

A U.S. Holder who pays (whether directly or through withholding) Canadian or other foreign income tax with respect to the common shares may be entitled, at the election of such U.S. Holder, to receive either a deduction or a credit for such Canadian or other foreign income tax paid. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Generally, the credit cannot exceed the proportionate share of a U.S. Holder's U.S. federal income tax liability that such U.S. Holder's "foreign source" taxable income bears to such U.S. Holder's worldwide taxable income. In applying this limitation, a U.S. Holder's various items of income and deduction must be classified, under complex rules, as either "foreign source" or "U.S. source." This limitation is calculated separately with respect to specific categories of income. Dividends paid by Theratechnologies on the common shares generally would constitute "foreign source" income for foreign tax credit purposes. However, all or a portion of the dividends paid by a foreign corporation that is more than 50% owned by U.S. persons will be treated as U.S. source income for foreign tax credit purposes if the foreign corporation itself has more than a small amount of U.S. source income. The effect of this rule may be to treat a portion of any dividends we pay as U.S.-source income. Treatment of the dividends as U.S. source income in whole or in part may limit a U.S. Holder's ability to claim a foreign tax credit for the Canadian withholding taxes payable in respect of the dividends. Similar limitations may apply if Canada imposes income tax on a U.S. Holder's gain. Subject to certain limitations, the Code may permit a U.S. Holder entitled to benefits under the U.S. Treaty to elect to treat any dividends or Canadian-taxed gain as foreign source income for foreign tax credit purposes. In addition, the amount of a distribution with respect to the common shares that is treated as a "dividend" may be lower for U.S. federal income tax purposes than it is for Canadian income tax purposes, potentially resulting in a reduced foreign tax credit for the U.S. Holder. The rules governing the foreign tax credit are complex and their application



depends on each taxpayer's particular circumstances. Accordingly, each U.S. Holder should consult its own tax advisors regarding the foreign tax credit rules in light of their particular circumstances.

# Passive Foreign Investment Company

*PFIC Rules Generally.* Special and generally unfavourable U.S. federal income tax rules may apply to a U.S. Holder if its holding period in the common shares includes any period during which Theratechnologies is a PFIC. In general terms, Theratechnologies will be a PFIC for any tax year in which, after applying relevant look-through rules with respect to the income and assets of its subsidiaries, either (i) 75% or more of its gross income is passive income or (ii) the average percentage, by fair market value, of its assets that produce or are held for the production of passive income is 50% or more. "Passive income" includes, among other items, dividends, interest, certain rents and royalties, certain gains from the sale of stock and securities and certain gains from commodities transactions. Under attribution rules, if Theratechnologies is a PFIC, U.S. Holders will be deemed to own their proportionate share of the stock of any subsidiaries of Theratechnologies that are also PFICs (each, a "Subsidiary PFIC"), and will be subject to the U.S. tax rules described below with respect to their proportionate share of (a) a distribution on the stock of a Subsidiary PFIC and (b) a disposition or deemed disposition of the stock of a Subsidiary PFIC, both as if such U.S. Holders directly held the shares of such Subsidiary PFIC.

As described above, PFIC status for a taxable year depends upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. Therefore, the status of Theratechnologies and each of its subsidiaries as PFICs depends upon the financial results for each year and upon relative valuations, which are subject to change and beyond our ability to predict or control. In addition, the application of the relevant rules is subject to legal uncertainties. Given the most recent available information regarding Theratechnologies's 2010 financial position, results of operations and its projections for the fiscal year ending November 30, 2011, Theratechnologies does not expect to be classified as a PFIC for the fiscal year ended November 30, 2010 and does not expect to become a PFIC in the foreseeable future. However, there can be no assurance that the IRS will not challenge the determination made by Theratechnologies concerning its PFIC status or that Theratechnologies will not be a PFIC for any taxable period because PFIC classification is fundamentally factual in nature, is determined annually and generally cannot be determined until the close of the taxable year in question. As described below in greater detail (see " —QEF Election"), on an annual basis, Theratechnologies and of any subsidiary in which Theratechnologies owns more than 50% of such subsidiary's total voting power. The PFIC rules are complex, and each U.S. Holder should consult its own financial advisor, legal counsel or accountant regarding the PFIC rules.

If Theratechnologies is a PFIC for any year, subject to the special rules applicable to a U.S. Holder who makes a Mark-to-Market Election or a QEF Election (each as defined below), a U.S. Holder who disposes or is deemed to dispose of common shares at a gain or who receives a distribution treated as an "excess distribution" on common shares generally would be required to allocate such gain and distribution ratably to each day in the U.S. Holder's holding period for such common shares. The portion of such amounts allocated to the current tax year or to a year prior to the first year in which Theratechnologies was a PFIC would be includible as ordinary income in the current tax year. The portion of any such amounts allocated to the first year in the U.S. Holder's holding period in which Theratechnologies was a PFIC and any subsequent year or years (excluding the current year) would be taxed at the highest marginal rate applicable to ordinary income for each year (regardless of the U.S. Holder's actual marginal rate for that year and without reduction by any losses or loss carryforwards) and would be subject to interest charges to reflect the value of the U.S. federal income tax deferral.

In accordance with the rules above, if Theratechnologies is or was a PFIC at any time during the U.S. Holder's holding period, none of the gain recognized on the sale or other disposition of common shares would be eligible for the preferential long-term capital gains rate (see "– Sale or Other Disposition of Common Shares" above). In addition, dividends generally will not be qualified dividend income if Theratechnologies is a PFIC in the year of payment or the preceding year.

Certain elections (including the Mark-to-Market Election and the QEF Election, as defined and discussed below) may sometimes be used to reduce the adverse impact of the PFIC rules on U.S. Holders, but these elections may accelerate the recognition of taxable income and have other adverse results.

*Mark-to-Market Election.* A U.S. Holder of common shares in a PFIC would not be subject to the PFIC rules discussed above if the U.S. Holder had made a timely and effective election to mark the PFIC common shares to market (a "Mark-to-Market Election").

A U.S. Holder may make a Mark-to-Market Election with respect to the common shares only if such shares are marketable stock. Such shares generally will be "marketable stock" if they are regularly traded on a "qualified exchange," which is defined as (a) a national securities exchange that is registered with the SEC, (b) the national market system established pursuant to section 11A of the Exchange Act, or (c) a foreign securities exchange that is regulated or supervised by a governmental authority of the country in which the market is located, provided that (i) such foreign exchange has trading volume, listing, financial disclosure, and other requirements, and the laws of the country in which such foreign exchange is located, together with the rules of such foreign exchange of such foreign exchange ensure that such requirements are actually enforced and (ii) the rules of such foreign exchange ensure active trading of listed stocks. Theratechnologies common shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of common shares is traded on a qualified exchange for at least 15 days during each calendar quarter. Each U.S. Holder should consult its own tax advisor with respect to the availability of a Mark-to-Market Election with respect to the common shares.

In general, a U.S. Holder that makes a timely Mark-to-Market Election with respect to the common stock will include in ordinary income, for each taxable year in which Theratechnologies is a PFIC, an amount equal to the excess, if any, of (a) the fair market value of the common shares as of the close of such taxable year over (b) such U.S. Holder's tax basis in such shares. A U.S. Holder that makes a Mark-to-Market Election will be allowed a deduction in an amount equal to the lesser of (a) the excess, if any, of (i) such U.S. Holder's adjusted tax basis in the common shares over (ii) the fair market value of such shares as of the close of such taxable year or (b) the excess, if any, of (i) the amount included in ordinary income because of such Mark-to-Market Election for prior taxable years over (ii) the amount allowed as a deduction because of such Mark-to-Market Election for prior taxable years. If a U.S. Holder makes a Mark-to-Market Election after the first taxable year in which Theratechnologies is a PFIC and such U.S. Holder has not made a timely QEF Election with respect to Theratechnologies, the PFIC rules described above will apply to certain dispositions of, and distributions on, the common shares, and the U.S. Holder's mark-to-market income for the year of the election. If Theratechnologies were to cease being a PFIC, a U.S. Holder that marked its common shares to market would not include mark-to-market gain or loss with respect to its common shares for any taxable year that Theratechnologies was not a PFIC.

A U.S. Holder that makes a Mark-to-Market Election generally will also adjust such U.S. Holder's tax basis in his common shares to reflect the amount included in gross income or allowed as a deduction because of such Mark-to-Market Election. In addition, upon a sale or other taxable disposition of the common shares subject to a Mark-to-Market Election, any gain or loss on such disposition will be ordinary income or loss (to the extent that such loss does not to exceed the excess, if any, of (a) the amount included in ordinary income because of such Mark-to-Market Election for prior taxable years over (b) the amount allowed as a deduction because of such Mark-to-Market Election for prior taxable years). A Mark-to-Market Election applies to the taxable year in which such Mark-to-Market Election is made and to each subsequent taxable year, unless the common shares cease to be "marketable stock" or the IRS consents to revocation of such election. Each U.S. Holder should consult its own tax advisor regarding the availability of, and procedure for making, a Mark-to-Market Election with respect to the common shares.

Special adverse rules apply to U.S. Holders of common shares for any year in which Theratechnologies is a PFIC and holds stock in a Subsidiary PFIC. Although a U.S. Holder may be eligible to make a Mark-to-Market Election with respect to the common shares if Theratechnologies is a PFIC, no such election may be made with respect to the stock of any Subsidiary PFIC that a U.S. Holder is treated as owning if such stock is not marketable. Hence, the Mark-to-Market Election will not be effective to eliminate the deferred tax and interest charge described above with respect to a disposition or a deemed disposition of Subsidiary PFIC stock or a distribution from a Subsidiary PFIC.

*QEF Election.* A U.S. Holder of common shares in a PFIC generally would not be subject to the PFIC rules discussed above if the U.S. Holder had made a timely and effective election (a "QEF Election") to treat Theratechnologies as a "qualified electing fund" (a "QEF"). Instead, such U.S. Holder would be subject to U.S. federal income tax on its pro rata share of Theratechnologies's (i) net capital gain, which would be taxed as long-term capital gain to such U.S. Holder, and (ii) ordinary earnings, which would be taxed as ordinary income to such U.S. Holder, in each case regardless of whether such amounts are actually distributed to such U.S. Holder.

However, a U.S. Holder that makes a QEF Election may, subject to certain limitations, elect to defer payment of current U.S. federal income tax on such amounts, subject to an interest charge. If such U.S. Holder is not a corporation, any such interest paid will be treated as "personal interest," which is not deductible.

A U.S. Holder that makes a timely and effective QEF Election generally (a) may receive a tax-free distribution from Theratechnologies to the extent that such distribution represents Theratechnologies's "earnings and profits" that were previously included in income by such U.S. Holder because of such QEF Election and (b) will adjust such U.S. Holder's tax basis in the common shares to reflect the amount included in income or allowed as a tax-free distribution because of such QEF Election. In addition, for U.S. federal income tax purposes, a U.S. Holder that makes a QEF Election generally will recognize capital gain or loss on the sale or other taxable disposition of the common shares.

A QEF Election will be treated as "timely" if such QEF Election is made for the first taxable year in the U.S. Holder's holding period for the common shares in which Theratechnologies is a PFIC. A U.S. Holder may make a timely QEF election by filing the appropriate QEF Election documents at the time such U.S. Holder files a U.S. federal income tax return for such first year. If a U.S. Holder makes a QEF Election after the first taxable year in the U.S. Holder's holding period for the common shares in which Theratechnologies is a PFIC, then, in addition to filing the QEF Election documents, a U.S. Holder may elect to recognize gain (which will be taxed under the rules discussed under "– PFIC Rules Generally") as if the common shares were sold on the qualification date. The "qualification date" is the first day of the first taxable year in which Theratechnologies is a QEF with respect to such U.S. Holder. The election to recognize such gain can only be made if such U.S. Holder will be deemed to have made a timely QEF Election. In addition, under very limited circumstances, it may be possible for a U.S. Holder to make a QEF Election for the first taxable year in the U.S. Holder taxable year in the U.S. Holder is a PFIC and does not the first taxable year in the U.S. Holder is a PFIC and does not at imely manner. If a U.S. Holder taxable year in the U.S. Holder's holding period for the common shares a query limited circumstances, it may be possible for a U.S. Holder tails to make a QEF Election for the first taxable year in the U.S. Holder's holding period for the common shares a query limited circumstances in a timely manner. If a U.S. Holder tails to make a A QEF Election for the first taxable year in the U.S. Holder's holding period for the common shares in which Theratechnologies is a PFIC and does not the first taxable year in the U.S. Holder's holding period for the common shares in which Theratechnologies is a PFIC and does not the first taxable year in the U.S. Holder's holding period for the common shares

A QEF Election will apply to the taxable year for which such QEF election is made and to all subsequent taxable years, unless such QEF Election is invalidated or terminated or the IRS consents to revocation of such QEF Election. If a U.S. Holder makes a QEF Election and, in a subsequent taxable year, Theratechnologies ceases to be a PFIC, the QEF Election will remain in effect (although it will not be applicable) during those taxable years in which Theratechnologies is not a PFIC. Accordingly, if Theratechnologies becomes a PFIC in another subsequent taxable year, the QEF Election will be effective and the U.S. Holder will be subject to the rules described above during any such subsequent taxable year in which the Theratechnologies qualifies as a PFIC.

A QEF Election applies only to the non-U.S. corporation for which it is made. If Theratechnologies is a PFIC, a U.S. Holder would remain subject to the excess distribution rules discussed above under "– PFIC Rules Generally" in respect of its indirectly owned shares in each PFIC Subsidiary unless such U.S. Holder has made a timely and effective QEF Election in respect of such PFIC Subsidiary.

A U.S. Holder cannot make and maintain a valid QEF Election unless Theratechnologies provides certain U.S. tax information necessary to make such an election. On an annual basis, Theratechnologies intends to make available to U.S. Holders, upon their written request: (a) timely information as to the PFIC status of Theratechnologies and of any subsidiary in which Theratechnologies owns more than 50% of such subsidiary's total voting power, and (b) for each year in which Theratechnologies is a PFIC, all information and documentation that a U.S. Holder making a QEF Election is required to obtain for U.S. federal income tax purposes with respect to Theratechnologies and any such Subsidiary PFIC in which Theratechnologies owns more than 50% of the total aggregate voting power. Because Theratechnologies may hold 50% or less of the aggregate voting power of one or more Subsidiary PFICs at any time, U.S. Holders should be aware that there can be no assurance that Theratechnologies will satisfy record keeping requirements that apply to such Subsidiary PFICs, or that Theratechnologies will supply U.S. Holders with information that such U.S. Holders require to report under the QEF rules, in the event that Theratechnologies is a PFIC and a U.S. Holder wishes to make a QEF Election with respect to any such Subsidiary PFIC. With respect to Subsidiary PFICs for which Theratechnologies does not or that U.S. Holders do not obtain the required information, U.S. Holders will be subject to the default PFIC rules discussed above under the heading entitled "– PFIC

Rules Generally." Each U.S. Holder should consult its own tax advisor regarding the availability of, and procedure for making, a QEF Election with respect to Theratechnologies and any Subsidiary PFIC.

*Reporting.* A U.S. Holder's ownership of common shares in a PFIC generally must be reported by filing Form 8621 with the U.S. Holder's annual U.S. federal income tax return. Every U.S. Holder who is a shareholder in a PFIC must file an annual report containing such information as may be required by the U.S. Department of Treasury.

U.S. HOLDERS SHOULD CONSULT THEIR OWN ADVISORS REGARDING THE TAX CONSEQUENCES OF THERATECHNOLOGIES'S POTENTIAL STATUS AS A PFIC, INCLUDING THE AVAILABILITY OF, CONSEQUENCES OF AND PROCEDURE FOR MAKING A MARK-TO-MARKET ELECTION OR A QEF ELECTION, IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES.

# **Recent Legislative Developments**

Newly enacted legislation requires certain U.S. Holders that are individuals, estates or trusts to pay up to an additional 3.8% tax on dividends and capital gains for taxable years beginning after December 31, 2012. In addition, for taxable years beginning after March 18, 2010, new legislation requires certain U.S. Holders who are individuals that hold certain foreign financial assets (which may include common shares of Theratechnologies) to report information relating to such assets, subject to certain exceptions. Failure to provide such information could result in significant additional taxes and penalties. U.S. Holders should consult their own tax advisors regarding the effect, if any, of this legislation on acquisition, ownership and disposition of common shares.

# U.S. Information Reporting and Backup Withholding

Under U.S. federal income tax law and Treasury Regulations, certain categories of U.S. Holders must file information returns with respect to their investment in, or involvement in, a foreign corporation. Penalties for failure to file certain of these information returns are substantial. U.S. Holders should consult with their own tax advisors regarding the requirements of filing information returns.

U.S. Holders of common shares may be subject to information reporting and may be subject to backup withholding on distributions on common shares or on the proceeds from a sale or other disposition of common shares paid within the United States or by U.S.-related financial intermediaries. Backup withholding will generally not apply, however, to a U.S. Holder who:

- furnishes a correct taxpayer identification number and certifies that the U.S. Holder is not subject to backup withholding on IRS Form W-9, Request for Taxpayer Identification Number and Certification (or substitute form) and otherwise complies with the backup withholding rules; or
- is otherwise exempt from backup withholding.

Backup withholding is not an additional tax. Any amounts withhold from a payment to a holder under the backup withholding rules may be credited against the holder's U.S. federal income tax liability, and a holder may obtain a refund of any excess amounts withheld by filing the appropriate claim for refund with the IRS in a timely manner. Each U.S. Holder should consult its own tax advisor regarding the information reporting and backup withholding rules.

# UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement dated \_\_\_\_\_, 2011, between us and Jefferies & Company, Inc., as representative for the several underwriters, we have agreed to sell to the underwriters and the underwriters have severally agreed to purchase from us, the number of common shares indicated in the table below:

	NUMBER OF COMMON SHARES
Jefferies & Company, Inc.	
Stifel, Nicolaus & Company, Inc.	
RBC Dominion Securities Inc.	
BMO Nesbitt Burns Inc.	
Desjardins Securities Inc.	
National Bank Financial Inc.	
Total	

The underwriters are offering the common shares subject to their acceptance of the common shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares if any of them are purchased. However, the underwriters are not obligated to purchase any shares covered by the underwriters' over-allotment option described below. If an underwriter defaults, the underwriting agreement may be terminated. The obligations of the underwriters under the underwriters may be increased or the underwriting agreement may be terminated. The obligations of the underwriters under the underwriters of the discretion of the representative of the underwriters on the basis of its assessment of the effect that certain changes in the United States' or international political, financial or economic conditions may have on the market for the common shares. The obligations of the underwriters may also be terminated upon the occurrence of certain stated events.

We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under applicable securities legislation, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that they currently intend to make a market in the common shares. However, the underwriters are not obligated to do so and may discontinue any market-making activities at any time without notice. No assurance can be given as to the liquidity of the trading market for the common shares.

The underwriters are offering the common shares subject to their acceptance of the shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

The Offering is being made concurrently in the United States and Canada pursuant to the MJDS implemented by the securities regulatory authorities in the United States and Canada. The common shares will be offered in the United States through the U.S. underwriters and in each of the provinces of Canada through the Canadian underwriters either directly or through their respective broker-dealer affiliates or agents, as applicable. No securities will be offered or sold in any jurisdiction except by or through brokers or dealers duly registered under the applicable securities laws of that jurisdiction, or in circumstances where an exemption from such registered dealer requirements is available. Subject to applicable law, the underwriters may offer the common shares outside of the United States and Canada pursuant to prospectus exemptions.

The offering price of the common shares for investors will be payable in U.S. dollars.

# **Commission and Expenses**

The underwriters have advised us that they propose to offer the common shares to the public at the offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of US\$ per common share. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of US\$ per common share to certain brokers and dealers. After the offering, the offering price, concession and reallowance to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The offering price has been determined by negotiation between us and the underwriters.

We offer no assurances that the offering price will correspond to the price at which the common shares will trade in the public market subsequent to the offering or that an active trading market for the common shares will develop and continue after the offering.

For purposes of the offering in Canada, if all of the common shares have not been sold after the Canadian underwriters have made a reasonable effort to sell the common shares at the offering price disclosed in this prospectus, the Canadian underwriters may from time to time decrease or change the offering price and the other selling terms provided that the price for the common shares shall not exceed the offering price and further provided that the compensation that is realized by the Canadian underwriters will be decreased by the amount that the aggregate price paid by the purchasers for the common shares is less than the gross proceeds paid by the Canadian underwriters to us.

The following table shows the offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		тс	DTAL
	WITHOUT	WITH	WITHOUT	WITH
	OPTION TO	OPTION TO	OPTION TO	OPTION TO
	PURCHASE	PURCHASE	PURCHASE	PURCHASE
	ADDITIONAL	ADDITIONAL	ADDITIONAL	ADDITIONAL
	SHARES	SHARES	SHARES	SHARES
Public offering price	US\$	US\$	US\$	US\$
Underwriting discounts and commissions paid by us	US\$	US\$	US\$	US\$
Proceeds to us, before expenses	US\$	US\$	US\$	US\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$

## **Determination of Offering Price**

Prior to the offering, there has not been a public market for our common shares in the United States. However, our common shares are listed on the TSX. The offering price for our common shares will be determined by negotiations between us and the underwriters. Among the factors to be considered in these negotiations will be prevailing market conditions, the current trading price of our common shares on the TSX, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

# Listing

Our common shares are listed on the TSX under the trading symbol "TH". We have applied to have our common shares approved for listing on Nasdaq under the trading symbol "THER" and to have our common shares offered hereby listed on the TSX.

## **Option to Purchase Additional Shares**

We have granted to the underwriters an option, exercisable for 30 days from the date of the underwriting agreement, to purchase up to an aggregate of 1,650,000 additional common shares at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares



proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of the prospectus. If purchased, the additional shares will be sold by the underwriters on the same terms as those on which the other shares are sold. We will pay the expenses associated with the exercise of this option.

# No Sales of Similar Securities

We, our officers and directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-I(h) under the Securities Exchange Act of 1934, as amended; or
- otherwise dispose of any common shares, options or warrants to acquire common shares, or securities exchangeable or exercisable for or convertible into common shares currently or hereafter owned either of record or beneficially; or
- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of Jefferies & Company, Inc.

This restriction terminates after the close of trading of the common shares on and including the 90th day after the date of the underwriting agreement. However, subject to certain exceptions, in the event that either:

- during the last 17 days of the 90-day restricted period, we issue an earnings release or material news or a material event relating to us occurs, or
- prior to the expiration of the 90-day restricted period, we announce that we will release earnings results during the 16-day
  period beginning on the last day of the 90-day restricted period,

then in either case the expiration of the 90-day restricted period will be extended until the expiration of the 18-day period beginning on the date of the issuance of an earnings release or the occurrence of the material news or event, as applicable, unless Jefferies & Company, Inc. waives, in writing, such an extension.

Jefferies & Company, Inc. may, in its sole discretion and at any time or from time to time before the termination of the 90-day period, without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our officers, directors or shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

## Stabilization

In connection with the sale of our common shares in the United States, the Underwriters may sell more common shares than they are required to purchase in this offering or effect transactions which stabilize or maintain the market price of the common shares at levels other than those which otherwise might prevail on the open market. The underwriters have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in transactions, including over-allotment, stabilizing bids, syndicate covering transactions or the imposition of penalty bids, which may have the effect of stabilizing or maintaining the market price of the common shares at a level above that which might otherwise prevail in the open market. Over-allotment involves syndicate sales in excess of the offering size, which creates a syndicate short position.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional common shares in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional common shares or purchasing common shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional common shares. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to

be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of common shares on behalf of the underwriters for the purpose of fixing or maintaining the price of the common shares. A syndicate covering transaction is the bid for or the purchase of common shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common shares originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

In accordance with a rule of the Ontario Securities Commission and the Universal Market Integrity Rules for Canadian Marketplaces administered by the Investment Industry Regulatory Organization of Canada, the underwriters may not, at any time during the period of distribution, bid for or purchase common shares. This restriction is, however, subject to exceptions where the bid or purchase is not made for the purpose of creating actual or apparent active trading in, or raising the price of, the common shares. These exceptions include a bid or purchase permitted under the Universal Market Integrity Rules for Canadian Marketplaces relating to market stabilization and passive market making activities and a bid or purchase made for and on behalf of a customer where the order was not solicited during the period of distribution.

Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common shares. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

# **Electronic Distribution**

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of common shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

# Affiliations

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

National Bank Financial Inc. is a subsidiary of a lender that has made a \$1,800,000 revolving credit facility available to us. Accordingly, under applicable securities laws in Canada, we may be considered a "connected issuer" of this underwriter. As at November 30, 2010, we did not have any borrowings outstanding under this credit facility and we were in full compliance with all debt covenants it contains. The revolving credit facility will remain unsecured provided we continue to hold investments in an account with this underwriter equivalent to 150% of the amounts drawn under the facility. The terms, structure and pricing of this offering were determined solely by arm's-length negotiations between us and Jefferies & Company, Inc., Stifel, Nicolaus & Company, Inc., RBC Dominion Securities Inc. and BMO Nesbitt Burns Inc. and this underwriter will not receive any benefit in connection with this offering other than as described in this prospectus.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities)

and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer.

The underwriters and certain of their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

# NASDAQ QUORUM REQUIREMENT

Nasdaq Marketplace Rule 5615(a)(3) permits a foreign private issuer to follow its home country practice in lieu of certain of the requirements of the Rule 5600 Series. A foreign private issuer that follows a home country practice in lieu of one or more provisions of the Rule 5600 Series shall disclose in its registration statement related to its initial public offering or first U.S. listing on Nasdaq, or on its website, each requirement of the Rule 5600 Series that it does not follow and describe the home country practice followed by the issuer in lieu of those requirements.

We do not follow Rule 5620(c), but instead follow our home country practice. The Nasdaq minimum quorum requirement under Rule 5620(c) for a meeting of shareholders is 33.33% of the outstanding common shares. In addition, Rule 5620(c) requires that an issuer listed on Nasdaq state its quorum requirement in its bylaws. On February 8, 2006, as permitted by Part IA of the Companies Act (Québec), our directors approved a by-law amendment, which amendment was ratified by our shareholders on March 30, 2006, providing that one or more persons present in person or duly represented and holding not less than 10% of our common shares shall constitute a quorum at a meeting of our shareholders. The foregoing is consistent with the laws, customs, and practices in Canada.

# LEGAL MATTERS

Certain legal matters relating to this offering are being passed upon on our behalf by Fasken Martineau DuMoulin LLP, Montréal, Québec, with respect to Canadian legal matters and Goodwin Procter LLP, Boston, Massachusetts, with respect to U.S. legal matters. Certain legal matters relating to this offering are being passed upon on behalf of the underwriters by Osler, Hoskin & Harcourt LLP, Montréal, Québec and New York, New York, with respect to Canadian and U.S. legal matters.

As of February 18, 2011, the partners and associates of these firms beneficially owned, directly or indirectly, less than 1% of our issued and outstanding common shares.

# INTEREST OF EXPERTS

Our consolidated financial statements for the years ended November 30, 2010 and 2009 appearing and incorporated by reference in this prospectus and registration statement have been audited by KPMG LLP, independent auditors, as set forth in their report appearing elsewhere in this prospectus and incorporated by reference in this prospectus and registration statement, and are included and incorporated by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for the common shares in Canada is Computershare Trust Company of Canada at its principal offices in Montreal and Toronto and in the United States is Computershare Trust Company, Inc. at its principal office in Golden, Colorado.



## DOCUMENTS INCORPORATED BY REFERENCE

Information has been incorporated by reference in this prospectus from documents filed with securities commissions or similar authorities in Canada. Copies of documents incorporated by reference in this prospectus and not delivered with this prospectus may be obtained upon request without charge from our Secretary at 2310 Alfred-Nobel Blvd., Montreal, Québec, H4S 2B4, telephone: (514) 336-7800, or by accessing the disclosure documents available through the Internet on SEDAR, which can be accessed at www.sedar.com and on the SEC's website at www.sec.gov. The following documents, filed with the various securities commissions or similar authorities in each of the provinces of Canada, are specifically incorporated by reference and form an integral part of this prospectus:

- our annual information form dated February 22, 2011 for the fiscal year ended November 30, 2010;
- our consolidated statements of financial position as at November 30, 2010 and 2009 and December 1, 2008, and the
  consolidated statements of comprehensive income, changes in equity and cash flows for the years ended November 30,
  2010 and 2009, together with the notes thereto and the auditors' report thereon;
- our management's discussion and analysis of results and operations and financial condition for the fiscal year ended November 30, 2010;
- our management proxy circular dated February 23, 2010 in connection with our annual and special meeting of shareholders held on March 25, 2010;
- our material change report dated December 16, 2010 announcing the execution of a distribution and licensing agreement with Sanofi for the commercialization rights to EGRIFTA™ (tesamorelin for injection) in Latin America, Africa and the Middle East for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy;
- our material change report dated February 10, 2011 announcing the execution of a distribution and licensing agreement with Ferrer for the commercialization rights to *EGRIFTA*™ (tesamorelin for injection) in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy; and
- our material change report dated February 22, 2011 announcing a new clinical program for muscle wasting in COPD using tesamorelin.

Any documents of the type referred to in the preceding paragraph and any material change reports (excluding confidential material change reports) we filed with a securities commission or any similar authority in Canada or the SEC after the date of this prospectus and prior to the termination of the offering shall be deemed to be incorporated by reference into this prospectus.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for the purposes of this prospectus to the extent that a statement contained in this prospectus or in any subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes that statement. The modifying or superseding statement need not state that it has modified or superseded a prior statement or include any other information set forth in the document that it modifies or supersedes. The making of a modifying or superseding statement shall not be deemed an admission for any purposes that the modified or superseded statement, when made, constituted a misrepresentation, an untrue statement of a material fact or an omission to state a material fact that is required to be stated or that is necessary to make a statement not misleading in light of the circumstances in which it was made. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC under the U.S. Securities Act of 1933, as amended, a registration statement on Form F-10 (which, together with all amendments and supplements thereto, we refer to as the Registration Statement) with respect to our common shares offered hereby. This prospectus, which forms a part of the Registration Statement, does not contain all the information set forth in the Registration Statement, certain parts of which have been omitted in accordance with the rules and regulations of the SEC. For further information with respect to us, and the common shares offered hereby, reference is made to the Registration Statement and to the

schedules and exhibits filed therewith. Statements contained or incorporated by reference in this prospectus as to the contents of certain documents are not necessarily complete and, in each instance, reference is made to the copy of the document filed as an exhibit to the Registration Statement. Each such statement is qualified in its entirety by such reference. The Registration Statement can be found on the SEC's website, www.sec.gov.

Subsequent to the effectiveness of the Registration Statement, we will be subject to the information requirements of the Exchange Act, and in accordance therewith will file periodic reports and other information with the SEC. Under the MJDS, such reports and other information may be prepared in accordance with the disclosure requirements of Canada, which requirements are different from those of the United States. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Under the Exchange Act, we are not required to publish financial statements as frequently or as promptly as U.S. public companies. Any information filed with the SEC may be reviewed, printed and downloaded from the SEC's website (www.sec.gov) and inspected and copied at prescribed rates at the public reference room of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the public reference facilities may be obtained by calling the SEC at 1-800-SEC-0330.

## ENFORCEABILITY OF CIVIL LIABILITIES

We are incorporated under the laws of the Province of Québec, Canada. Most of our directors and officers, as well as some of the experts named in this prospectus, are residents of Canada, and a substantial portion of their assets and our assets are located outside of the United States. As a result, it may be difficult for U.S. investors to effect service of process within the United States upon us or those directors, officers and experts who are not residents of the United States or to enforce against us or them judgments obtained in the courts of the United States based upon the civil liability provisions of the federal securities laws or other laws of the United States. There is doubt as to the enforceability in Canada, or elsewhere, against us or against any of our directors, officers or experts who are not residents of the United States, in original actions or in actions for enforcement of judgments of United States courts, of liabilities based solely upon the civil liability provisions of the U.S. federal securities laws. Therefore, it may not be possible for U.S. investors to enforce those actions against us, our directors and officers or the experts named in this prospectus.

We have filed with the SEC, concurrently with the registration statement on Form F-10 relating to this offering, an appointment of agent for service of process on Form F-X. Under the Form F-X, we appointed CT Corporation System at its address at 111 8th Avenue New York, New York 10011 as our agent for service of process in the United States in connection with any investigation or administrative proceeding conducted by the SEC and any civil suit or action brought against or involving us in a United States court arising out of or related to or concerning this offering.

# CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED 2010 AND 2009



KPMG LLP Chartered Accountants 600 de Maisonneuve Blvd. West Suite 1500 Tour KPMG Montréal (Québec) H3A 03A

Telephone (514) 840-2100 Fax (514) 840-2187 Internet www.kpmg.ca

# AUDITORS' REPORT TO THE SHAREHOLDERS

We have audited the consolidated statements of financial position of Theratechnologies Inc. as at November 30, 2010 and 2009 and December 1, 2008, and the consolidated statements of comprehensive income, statements of changes in equity and statements of cash flows for the years ended November 30, 2010 and 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at November 30, 2010 and 2009 and December 1, 2008, and its financial performance and its cash flows for the years ended November 30, 2010 and 2009 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

KPMG LLP

**Chartered Accountants** 

Montreal, Canada February 8, 2011

# CONSOLIDATED FINANCIAL STATEMENTS YEARS ENDED NOVEMBER 30, 2010 AND 2009 AND AS AT DECEMBER 1, 2008

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# CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT NOVEMBER 30, 2010 AND 2009 AND DECEMBER 1, 2008

	<u>NOTE</u>	NOVEMBER 30, 2010 \$ (in thous	NOVEMBER 30, 2009 \$ sands of Canadian d	DECEMBER 1, 2008 \$ ollars)
Assets				
Current assets:				
Cash		26,649	1,519	133
Bonds	8	1,860	10,036	10,955
Trade and other receivables	9	161	375	610
Tax credits and grants receivable	10	332	1,333	1,451
Inventories	11	4,317	2,225	_
Prepaid expenses		1,231	630	739
Total current assets		34,550	16,118	13,888
Non-current assets:				
Bonds	8	36,041	51,807	35,249
Property and equipment	12	1,060	1,229	1,299
Other assets				2,776
Total non-current assets		37,101	53,036	39,324
Total assets		71,651	69,154	53,212
Liabilities				
Current liabilities:				
Accounts payable and accrued liabilities	13	4,977	5,568	6,865
Current portion of deferred revenue	4	6,847	6,847	
Total current liabilities		11,824	12,415	6,865
Non-current liabilities:				
Other liabilities	14	325	_	_
Deferred revenue	4	6,846	13,691	
Total non-current liabilities		7,171	13,691	
Total liabilities		18,995	26,106	6,865
Equity				
Share capital	15	279,398	279,169	269,219
Contributed surplus		7,808	6,757	5,760
Deficit		(235,116)	(244,160)	(229,004)
Accumulated other comprehensive income		566	1,282	372
Total equity		52,656	43,048	46,347
Contingent liability	18			
Commitments	23			
Subsequent events	26			
Total liabilities and equity		71,651	69,154	53,212

On behalf of the Board,

(signed) Paul Pommier Director

(signed) Jean-Denis Talon Director

See accompanying notes to the consolidated financial statements.

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME YEARS ENDED NOVEMBER 30, 2010 AND 2009

	NOTE	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
		(in thousands of except per sh	
Revenue:			
Research services:			
Milestone payments	4	25,000	10,884
Upfront payments and initial technology access fees	4	6,846	6,560
Royalties and license fees		22	24
Total revenue		31,868	17,468
Cost of sales		469	—
Research and development expenses, net of tax credits of \$934 (2009 – \$1,795)	10	14,064	20,810
Selling and market development expenses	6	2,670	6,862
General and administrative expenses		8,002	6,543
Total operating expenses		25,205	34,215
Results from operating activities		6,663	(16,747)
Finance income	7	1,888	2,252
Finance costs	7	493	(661)
Total net financial income		2,381	1,591
Net profit (loss) before income taxes		9,044	(15,156)
Income tax expense	16	114	
Net profit (loss)		8,930	(15,156)
Other comprehensive income (loss), net of tax:			
Net change in fair value available-for-sale financial assets, net of tax		(390)	1,039
Net change in fair value available-for-sale financial assets transferred to net profit (loss), net of			
tax		(326)	(129)
		(716)	910
Total comprehensive income (loss) for the year		8,214	(14,246)
Basic and diluted earnings (loss) per share	15	0.15	(0.25)

See accompanying notes to the consolidated financial statements.

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY YEARS ENDED NOVEMBER 30, 2010 AND 2009

	NOTE	SHARE CA NUMBER	PITAL DOLLARS \$	CONTRIBUTED SURPLUS \$ (in thousands of	UNREALIZED GAINS OR LOSSES ON AVAILABLE-FOR-SALE FINANCIAL ASSETS (I) \$ of Canadian dollars)	DEFICIT \$	TOTAL \$
Balance as at December 1, 2008		58,215,090	269,219	5,760	372	(229,004)	46,347
Total comprehensive income (loss) for the year:							
Net loss			_	_	_	(15,156)	(15,156)
Other comprehensive income (loss):							
Net change in fair value of available-for-sale financial assets, net of tax		_	_	_	1,039	_	1,039
Net change in fair value of available-for-sale financial assets transferred to net profit (loss), net of tax		_	_	_	(129)	_	(129)
Total comprehensive income (loss) for the year					910	(15,156)	(14,246)
Transactions with owners, recorded directly in equity:							
Issue of common shares	15(i)	2,214,303	9,950	_	_	_	9,950
Share-based compensation for stock option plan	15(iv)			997			997
Total contributions by owners	. ,	2,214,303	9,950	997			10,947
Balance as at November 30, 2009		60,429,393	279,169	6,757	1,282	(244,160)	43,048
Total comprehensive income (loss) for the year:							
Net profit		_	_	_	_	8,930	8,930
Other comprehensive income (loss):							
Net change in fair value of available-for-sale financial assets, net of tax		_	_	_	(390)	_	(390)
Net change in fair value of available-for-sale financial							
assets transferred to net profit (loss), net of tax					(326)		(326)
Total comprehensive income (loss) for the year					(716)	8,930	8,214
Transactions with owners, recorded directly in equity:							
Issue of common shares	15(i)	2,880	15	_	_	_	15
Income tax related to share issue costs		—	—	—	—	114	114
Share-based compensation plan:	. = 0 .						
Share-based compensation for stock option plan	15(iv)	—	—	1,133	—	—	1,133
Exercise of stock options: Monetary consideration	15(iv)	80.491	132	_			132
Attributed value	15(iv) 15(iv)	80,491	82	(82)	—	_	132
Total contributions by owners	T2(IV)	83,371	229	1,051		114	1,394
					566		
Balance as at November 30, 2010		60,512,764	279,398	7,808	566	(235,116)	52,656

(i) Accumulated other comprehensive income.

See accompanying notes to the consolidated financial statements.

# CONSOLIDATED STATEMENT OF CASH FLOWS YEARS ENDED NOVEMBER 30, 2010 AND 2009

	NOTE	NOVEMBER 30, 2010	NOVEMBER 30, 2009
		\$ (in thousands of	\$ Canadian dollars)
Operating activities:			
Net profit (loss)		8,930	(15,156)
Adjustments for:			
Depreciation of property and equipment	12	466	612
Share-based compensation		1,133	997
Income tax expense		114	_
Write-down of inventories	11	192	_
Lease inducements and amortization	17	325	_
Operating activities before changes in operating assets and liabilities		11,160	(13,547)
Change in accrued interest income on bonds		728	(923
Change in trade and other receivables		214	235
Change in tax credits and grants receivable		1,001	118
Change in inventories		(2,284)	(2,225
Change in prepaid expenses		(601)	109
Change in other assets			2,776
Change in accounts payable and accrued liabilities		(473)	(1,424
Change in deferred revenue		(6,845)	20,538
		(8,260)	19,204
Cash flows from operating activities		2,900	5,657
Financing activities:		,	
Proceeds from issue of share capital		15	9,950
Proceeds from exercise of stock options	15	132	
Share issue costs		_	(8)
Cash flows from financing activities		147	9,942
Investing activities:			
Acquisition of property and equipment	12	(415)	(407
Proceeds from sale of bonds		22,498	15,305
Acquisition of bonds		_	(29,111
Cash flows from (used in) investing activities		22,083	(14,213
Net change in cash		25.130	1.386
Cash as at December 1		1,519	133
Cash as at November 30		26,649	1,519
		20,040	1,515

See note 19 for supplemental cash flow information.

See accompanying notes to the consolidated financial statements.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS YEARS ENDED NOVEMBER 30, 2010 AND 2009 AND AS AT DECEMBER 1, 2008 (IN THOUSANDS OF CANADIAN DOLLARS, EXCEPT PER SHARE AMOUNTS)

## 1. Reporting Entity:

Theratechnologies Inc. is a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on growth hormone releasing factor peptides. Theratechnologies Inc. is leveraging its expertise in the field of metabolism to discover and develop products in specialty markets. Its commercialization strategy is to retain all or a significant portion of the commercial rights to its products. Its first product, *EGRIFTA*<sub>TM</sub> (tesamorelin for injection), was approved by the United States Food and Drug Administration ("FDA") in November 2010. To date, *EGRIFTA*<sub>TM</sub> is the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

The consolidated financial statements include the accounts of Theratechnologies Inc. and its wholly-owned subsidiaries (together referred to as the "Company" and individually as "the subsidiaries of the Company").

Theratechnologies Inc. is incorporated under Part 1A of the Québec *Companies Act* and is domiciled in Quebec, Canada. The Company is located at 2310 boul. Alfred-Nobel, Montreal, Quebec, H4S 2B4.

# 2. Basis of Preparation:

# (a) Statement of Compliance:

The consolidated financial statements of the Company have been prepared in accordance with IFRSs as issued by the International Accounting Standards Board ("IASB"). These are the Company's first consolidated financial statements prepared in accordance with International Financial Reporting Standards ("IFRSs"). The Company has applied IFRS 1, *First-time Adoption of International Financial Reporting Standards*, using December 1, 2008 as the date of transition to IFRSs.

An explanation of how the transition to IFRSs has affected the reported financial position, financial performance and cash flows of the Company is provided in note 27.

The consolidated financial statements were authorized for issue by the Board of Directors on February 8, 2011.

### (b) Basis of Measurement:

The Company's consolidated financial statements have been prepared on a going concern and historical cost basis, except for available-for-sale financial assets which are measured at fair value.

The methods used to measure fair value are discussed further in note 22.

# (c) Functional and Presentation Currency:

These consolidated financial statements are presented in Canadian dollars, which is the Company's functional currency. All financial information presented in Canadian dollars has been rounded to the nearest thousand.

### (d) Use of Estimates and Judgements:

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

Information about critical judgements in applying accounting policies and assumption and estimation uncertainties that have the most significant effect on the amounts recognized in the consolidated financial statements is included in the following notes:

- Note 4 Revenue and deferred revenue;
- Note 15 (iv) Stock option plan;



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

- Note 16 Income taxes;
- Note 18 Contingent liability.

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

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

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

# 3. Significant Accounting Policies:

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements and in preparing the opening IFRS statement of financial position at December 1, 2008, the date of transition to IFRSs.

The accounting policies have been applied consistently by the subsidiaries of the Company.

### (a) Basis of Consolidation:

The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases. Subsidiaries are entities controlled by the Company. Control is present where the Company has the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities. In assessing control, potential voting rights that are exercisable currently are taken into consideration. The accounting policies of subsidiaries are changed when necessary to align them with the policies adopted by the Company.

Reciprocal balances and transactions, revenues and expenses resulting from transactions between subsidiaries and with the Company are eliminated in preparing the consolidated financial statements.

# (b) Foreign Currency:

Transactions in foreign currencies are translated to the respective functional currencies of the subsidiaries of the Company at exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies at the reporting date are retranslated to the functional currency at the exchange rate at that date. The foreign currency gain or loss on monetary items is the difference between amortized cost in the functional currency at the beginning of the period, adjusted for effective interest and payments during the period, and the amortized cost in foreign currency translated at the exchange rate at the end of the reporting period.

Foreign currency differences arising on translation are recognized in net profit (loss), except for differences arising on the translation of available-for-sale equity instruments, which are recognized in other comprehensive income. Non-monetary assets and liabilities denominated in foreign currencies that are measured at fair value are translated to the functional currency at the exchange rate at the date on which the fair value was determined. Non-monetary items that are measured at historical cost in a foreign currency are translated using the exchange rate at the date of the transaction.

## (c) Revenue Recognition:

Collaboration agreements that include multiple deliverables are considered to be multi-element arrangements. Under this type of arrangement, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Payments received under the collaboration agreement may include upfront payments, milestone payments, research services, royalties and license fees. Revenues for each unit of accounting are recorded as described below:

#### (i) Sale of Goods:

Revenues from the sale of goods are recognized when the Company has transferred to the buyer the significant risks and rewards of ownership of the goods, there is no continuing management involvement with the goods, and the amount of revenue can be measured reliably.

(ii) Royalties and License Fees:

Royalties and license fees are recognized when conditions and events under the license agreement have occurred and collectibility is reasonably assured.

## (iii) Research Services:

Revenues from research contracts are recognized when services to be provided are rendered and all conditions under the terms of the underlying agreement are met.

(a) Upfront Payments and Initial Technology Access Fees:

Upfront payments and initial technology access fees are deferred and recognized as revenue on a systematic basis over the period during which the related products or services are delivered and all obligations are performed.

#### (b) Milestone Payments:

Revenues subject to the achievement of milestones are recognized only when the specified events have occurred and collectibility is reasonably assured.

# (d) Cost of Sales:

Cost of sales represents the cost of goods sold and includes the cost of raw materials, supplies, direct overhead charges, unallocated indirect costs related to production as well as write-down of inventories. Other direct costs, such as manufacturing start-up costs between validation and the achievement of normal production, are expensed as incurred.

# (e) Employee Benefits:

# Salaries and Short-Term Employee Benefits:

Salaries and short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided. A liability is recognized for the amount expected to be paid under short-term profit-sharing or cash bonus plans if the Company has a legal or constructive obligation to pay an amount as a result of past services rendered by an employee and the obligation can be estimated reliably.

# Post-Employment Benefits:

Post-employment benefits include a defined contribution plan under which an entity pays fixed contributions into a separate entity and will have no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution plans are recognized as an employee benefit expense when due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in future payments is available. The Company's defined contribution plan comprises the registered retirement savings plan, the Quebec Pension Plan and unemployment insurance.

## Termination Benefits:

Termination benefits are recognized as an expense when the Company is committed demonstrably, without realistic possibility of withdrawal, to a formal detailed plan to either terminate employment before the normal retirement date, or to provide termination benefits as a result of an offer made to encourage voluntary redundancy.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

# (f) Finance Income and Finance Costs:

Finance income comprises interest income on available-for-sale financial assets and gains (losses) on the disposal of available-for-sale financial assets. Interest income is recognized as it accrues in profit (loss), using the effective interest method.

Finance costs are comprised of bank charges, impairment losses on financial assets recognized in profit (loss) and of foreign currency gains and losses which are reported on a net basis.

### (g) Inventories:

Inventories are presented at the lower of cost, determined using the first-in first-out method, or net realizable value. Inventory costs include the purchase price and other costs directly related to the acquisition of materials, and other costs incurred in bringing the inventories to their present location and condition. Inventory costs also include the costs directly related to the conversion of materials to finished goods, such as direct labour, and a systematic allocation of fixed and variable production overhead, including manufacturing depreciation expense. The allocation of fixed production overheads to the cost of inventories is based on the normal capacity of the production facilities. Normal capacity is the average production expected to be achieved over a number of periods under normal circumstances.

Net realizable value is the estimated selling price in the Company's ordinary course of business, less the estimated costs of completion and selling expenses.

# (h) Property and Equipment:

#### Recognition and Measurement:

Items of property and equipment are recognized at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset and the costs of dismantling and removing the item and restoring the site on which it is located, if any.

When parts of an item of property and equipment have different useful lives, they are accounted for as separate items (major components) of property and equipment.

Gains and losses on disposal of an item of property and equipment are determined by comparing the proceeds from disposal with the carrying amount of property and equipment, and are recognized in net profit (loss).

#### Subsequent Costs:

The cost of replacing a part of an item of property and equipment is recognized in the carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to the Company, and its cost can be measured reliably. The carrying amount of the replaced part is derecognized. The costs of the day-to-day servicing of property and equipment are recognized in profit (loss) as incurred.

## Depreciation:

The estimated useful lives and the methods of depreciation for the current and comparative periods are as follows:

ASSET	METHOD	RATE/PERIOD
Computer equipment	Declining balance	50%
Laboratory equipment	Declining balance	20%
	and straight-line	5 years
Office furniture and equipment	Declining balance	20%
Leasehold improvements	Straight-line	Lower of term of lease
		or economic life

This most closely reflects the expected pattern of consumption of the future economic benefits embodied in the asset.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Estimates for depreciation methods, useful lives and residual values are reviewed at each reporting period-end and adjusted if appropriate.

# (i) Intangible Assets:

#### Research and Development:

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is expensed as incurred.

Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditure is capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete development and to use or sell the asset. These criteria are usually met when a regulatory filing has been made in a major market and approval is considered highly probable. The expenditure capitalized includes the cost of materials, direct labour, and overhead costs that are directly attributable to preparing the asset for its intended use. Other development expenditures are expensed as incurred. Capitalized development expenditures are measured at cost less accumulated amortization and accumulated impairment losses.

During the years ended November 30, 2010 and 2009 and as at December 1, 2008, no development expenditures were capitalized.

# (j) Financial Instruments:

The Company's financial instruments are classified into one of three categories: loans and receivables, available-for-sale financial assets and other financial liabilities. Loans and receivables and other financial liabilities are measured at amortized cost.

The Company has classified its bonds as available-for-sale financial assets. The Company has classified cash and trade and other receivables as loans and receivables, and accounts payable and accrued liabilities as other financial liabilities.

Available-for-sale financial assets are non-derivative financial assets that are designated as available-for-sale and that are not classified in any of the other categories. Subsequent to initial recognition, they are measured at fair value and changes therein, other than impairment losses and foreign currency differences on available-for-sale debt instruments, are recognized in other comprehensive income and presented within equity. When an investment is derecognized, the cumulative gain or loss in other comprehensive income is transferred to profit (loss).

## (k) Other Assets:

Other assets consist of prepaid expenses for research supplies that are not expected to be used within one year from the date of the consolidated statement of financial position.

Research supplies are purchased in advance, in accordance with specific regulatory requirements, to be used in connection with the Company's clinical trials.

### (I) Leases:

Operating lease payments are recognized in net profit (loss) on a straight-line basis over the term of the lease.

Lease inducements arising from leasehold improvement allowances and rent-free periods form an integral part of the total lease cost and are deferred and recognized in net profit (loss) over the term of the lease on a straight-line basis.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

#### (m) Impairment:

#### Financial Assets:

A financial asset not carried at fair value through profit or loss is assessed at each consolidated financial statement reporting date to determine whether there is objective evidence that it is impaired. The Company considers that a financial asset is impaired if objective evidence indicates that one or more loss events had a negative effect on the estimated future cash flows of that asset that can be estimated reliably.

An impairment test is performed, on an individual basis, for each material financial asset. Other individually non-material financial assets are tested as groups of financial assets with similar risk characteristics. Impairment losses are recognized in net profit (loss).

An impairment loss in respect of a financial asset measured at amortized cost is calculated as the difference between its carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses are recognized in net profit (loss) and reflected in an allowance account against the respective financial asset. Interest on the impaired asset continues to be recognized through the unwinding of the discount. When a subsequent event causes the amount of impairment loss to decrease, the decrease in impairment loss is reversed through net profit (loss).

Impairment losses on available-for-sale investment securities are recognized by transferring the cumulative loss that has been recognized in other comprehensive income, and presented in unrealized gains/losses on available-for-sale financial assets in equity, to net profit (loss). The cumulative loss that is removed from other comprehensive income and recognized in net profit (loss) is the difference between the acquisition cost, net of any principal repayment and amortization, and the current fair value, less any impairment loss previously recognized in net profit (loss). Changes in impairment provisions attributable to time value are reflected as a separate component of interest income.

If, in a subsequent period, the fair value of an impaired available-for-sale debt security increases and the increase can be related objectively to an event occurring after the impairment loss was recognized in net profit (loss), then the impairment loss is reversed, with the amount of the reversal recognized in net profit (loss). However, any subsequent recovery in the fair value of an impaired available-for-sale equity security is recognized in other comprehensive income.

#### Non-Financial Assets:

The carrying amounts of the Company's non-financial assets, other than inventories and deferred tax assets, are reviewed at each reporting date to determine whether there is any indication of impairment. If such an indication exists, the recoverable amount is estimated.

The recoverable amount of an asset or a cash-generating unit is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pretax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of cash inflows from other assets or groups of assets ("cash-generating unit"). Impairment losses recognized in prior periods are determined at each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. An asset's carrying amount, increased through reversal of an impairment loss, must not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

## (n) Provisions:

A provision is recognized if, as a result of a past event, the Company has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation. Provisions are assessed by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount on provisions is recognized in finance costs.

## Onerous Contracts:

A provision for onerous contracts is recognized when the expected benefits to be derived by the Company from a contract are lower than the unavoidable cost of meeting its obligations under the contract. The provision is measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract. Before a provision is established, the Company recognizes any impairment loss on the assets associated with that contract. There were no onerous contracts as at November 30, 2010 and 2009 and December 1, 2008.

#### Site Restoration:

Where there is a legal or constructive obligation to restore leased premises to good condition, except for normal aging on expiry or early termination of the lease, the resulting costs are provisioned up to the discounted value of estimated future costs and increase the carrying amount of the corresponding item of property and equipment. The Company amortizes the cost of restoring leased premises and recognizes an unwinding of discount expense on the liability related to the term of the lease.

#### Contingent Liability:

A contingent liability is a possible obligation that arises from past events and of which the existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Company; or a present obligation that arises from past events (and therefore exists), but is not recognized because it is not probable that a transfer or use of assets, provision of services or any other transfer of economic benefits will be required to settle the obligation, or the amount of the obligation cannot be estimated reliably.

#### (o) Income Taxes:

Income tax expense comprises current and deferred tax. Current tax and deferred tax are recognized in net profit (loss) except to the extent that they relate to items recognized directly in other comprehensive income or in equity.

#### Current Tax:

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous years. The Company establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

#### Deferred Tax:

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date.

A deferred tax liability is generally recognized for all taxable temporary differences.

A deferred tax asset is recognized for unused tax losses and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

## (p) Share-Based Compensation:

The Company records share-based compensation related to employee stock options granted using the fair value based method estimated using the Black-Scholes model. Under this method, compensation cost is measured at fair value at the date of grant and expensed, as employee benefits, over the period in which employees unconditionally become entitled to the award. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service conditions are expected to be met, such that the amount ultimately recognized as an expense is based on the number of awards that do meet the related service and non-market performance conditions at the vesting date.

Share-based payment arrangements in which the Company receives goods or services as consideration for its own equity instruments are accounted for as equity-settled share-based payment transactions, regardless of how the equity instruments are obtained by the Company.

As permitted by IFRS 1, the Company elected not to restate options that were granted before November 7, 2002 and those granted after November 7, 2002 that were fully vested prior to the date of transition to IFRS.

#### (q) Government Grants:

Government grants consisting of grants and investment tax credits, are recorded as a reduction of the related expense or cost of the asset acquired. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the approved grant program and there is reasonable assurance that the grant will be received.

#### (r) Share Capital:

#### Common Shares:

Common shares are classified as equity. Incremental costs directly attributable to the issue of common shares and share options are recognized as a deduction from equity, net of any tax effects.

## (s) Earnings Per Share:

The Company presents basic and diluted earnings per share ("EPS") data for its common shares. Basic EPS is calculated by dividing the net profit or loss attributable to common shareholders of the Company by the weighted average number of common shares outstanding during the period, adjusted for own shares held, if applicable. Diluted EPS is determined by adjusting the profit or loss attributable to common shareholders and the weighted average number of common shares outstanding, adjusted for own shares held if applicable, for the effects of all dilutive potential common shares, which consist of the stock options granted to employees.

## (t) New Standards and Interpretations not yet Applied:

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning on or after January 1, 2010 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on the Company's results and financial position:

## Annual Improvements to IFRS:

The IASB's improvements to IFRS published in April 2009 contain fifteen amendments to twelve standards that result in accounting changes for presentation, recognition or measurement purposes largely for annual periods beginning on or after January 1, 2010, with early adoption permitted. These amendments were considered by the Company and deemed to be not applicable to the Company other than for the amendment to IAS 17 – Leases relating to leases which include both land and buildings elements. In this case, the Company early adopted this amendment.

The IASB's improvements to IFRS contain seven amendments that result in accounting changes for presentation, recognition or measurement purposes. The most significant features of the IASB's annual

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

improvements project published in May 2010 are included under the specific revisions to standards discussed below.

(i) IFRS 3:

Revision to IFRS 3, Business Combinations:

Effective for annual periods beginning on or after July 1, 2010 with earlier adoption permitted.

Clarification on the following areas:

- <sup>n</sup> the choice of measuring non-controlling interests at fair value or at the proportionate share of the acquiree's net assets applies only to instruments that represent present ownership interests and entitle their holders to a proportionate share of the net assets in the event of liquidation. All other components of non-controlling interest are measured at fair value unless another measurement basis is required by IFRS.
- application guidance relating to the accounting for share-based payments in IFRS 3 applies to all share-based payment transactions that are part of a business combination, including unreplaced awards (i.e., unexpired awards over the acquiree shares that remain outstanding rather than being replaced by the acquirer) and voluntarily replaced share-based payment awards.
- (ii) IFRS 7:
  - Amendment to IFRS 7, Financial Instruments: Disclosures: Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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

(iii) IAS 1:

#### Amendment to IAS 1, Presentation of Financial Statements:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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

(iv) IAS 27:

Amendment to IAS 27, Consolidated and Separate Financial Statements:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

The 2008 revisions to this standard resulted in consequential amendments to IAS 21, *The Effects of Changes in Foreign Exchange Rates*, IAS 28, *Investments in Associates*, and IAS 31, *Interests in Joint Ventures*. IAS 27 now provides that these amendments are to be applied prospectively.

(v) IAS 34:

#### Amendment to IAS 34, Interim Financial Reporting:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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

#### New or revised standards and interpretations:

In addition, the following new or revised standards and interpretations have been issued but are not yet applicable to the Company:

(i) IAS 24:

Amendments to IAS 24, Related Party Disclosures:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

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

- (ii) IFRS 8:
  - IFRS 8, Operating Segments:

Effective for annual periods beginning on or after January 1, 2010.

Requires purchase information about segment assets.

(iii) IFRS 9:

New standard IFRS 9, Financial Instruments:

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

As part of the project to replace IAS 39, Financial Instruments: Recognition and Measurement, this standard retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets. More specifically, the standard:

- n deals with classification and measurement of financial assets
- establishes two primary measurement categories for financial assets: amortized cost and fair value
- n classification depends on entity's business model and the contractual cash flow characteristics of the financial asset
- n eliminates the existing categories: held to maturity, available for sale, and loans and receivables.

Certain changes were also made regarding the fair value option for financial liabilities and accounting for certain derivatives linked to unquoted equity instruments.

## 4. Revenue and Deferred Revenue:

On October 28, 2008, the Company entered into a collaboration and licensing agreement with EMD Serono Inc. ("EMD Serono"), an affiliate of the Group Merck KGaA, of Darmstadt, Germany, regarding the exclusive commercialization rights of tesamorelin in the United States for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy (the "Initial Product"). The Company retains all tesamorelin commercialization rights outside of the United States.

Under the terms of the agreement, the Company is responsible for the development of the Initial Product up to obtaining marketing approval in the United States, which was obtained on November 10, 2010. The Company is also responsible for product production and for developing a new formulation of the Initial Product. EMD Serono is responsible for conducting product commercialization activities.

At the closing of the agreement on December 15, 2008, the Company received US\$30,000 (C\$36,951), which includes an initial payment of US\$22,000 (C\$27,097) and US\$8,000 (C\$9,854) as a subscription for common shares in the Company by Merck KGaA at a price of US\$3.67 (C\$4.52) per share. The Company may receive up to US\$215,000, which amount includes the initial payment of US\$22,000, the equity investment of US\$8,000, as well as payments based on the achievement of certain development, regulatory and sales milestones. The Company will also be entitled to receive increasing royalties on annual net sales of tesamorelin in the United States, if applicable.

The initial payment of \$27,097 has been deferred and is being amortized on a straight-line basis over the estimated period for developing a new formulation of the Initial Product. This period may be modified in the future based on additional information that may be received by the Company. At November 30, 2010, an amount of \$6,846 (2009 – \$6,560) was recognized as revenue. As at November 30, 2010, the deferred revenue related to this transaction amounted to \$13,692 (2009 – \$20,537).

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

On August 12, 2009, the FDA accepted the New Drug Application ("NDA") made by the Company for tesamorelin. Under the terms of the Company's collaboration and licensing agreement with EMD Serono, the acceptance of the tesamorelin NDA resulted in a milestone payment of US\$10,000 (C\$10,884).

On November 10, 2010, the FDA approved *EGRIFTA*<sub>TM</sub> as the first approved treatment in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. By virtue of the collaboration and licensing agreement entered into in 2008 with EMD Serono, the Company received a milestone payment of US\$25,000 (C\$25,000) associated with the FDA-approval of *EGRIFTA*<sub>TM</sub>. This payment was received by the Company on November 30, 2010.

The Company may conduct research and development activities for additional indications. Under the collaboration and licensing agreement, EMD Serono will also have the option to commercialize additional indications for tesamorelin in the United States. If it exercises this option, EMD Serono will pay half of the development costs related to such additional indications. In such cases, the Company will also have the right, subject to an agreement with EMD Serono, to participate in promoting these additional indications.

#### 5. Personnel Expenses:

	NOTE	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Salaries and short-term employee benefits		11,577	10,779
Post-employment benefits		579	542
Termination benefits		20	275
Share-based compensation	15(iv)	1,133	997
Total personnel expenses		13,309	12,593

## 6. Selling and Market Development Expenses:

In 2008, the Company completed a formal review of the strategic alternatives regarding its operations which culminated in the signing of the collaborative licensing agreement with EMD Serono (note 4). As a result of this process, \$4,269 was recorded in 2009 for professional fees related to the closing of the agreement with EMD Serono.

#### 7. Finance Income and Finance Costs:

Recognized in net profit (loss):

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Interest income	1,562	2,123
Net gain on disposal of available-for-sale financial assets transferred from equity	326	129
Finance income	1,888	2,252
Bank charges	(18)	(26)
Net foreign currency gain (loss)	511	(635)
Finance costs	493	(661)
Net finance income recognized in net profit (loss)	2,381	1,591



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Recognized in other comprehensive income:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Net change in fair value of available-for-sale financial assets	(390)	1,039
Net change in fair value of available-for-sale financial assets transferred to net profit (loss)	(326)	(129)
Finance (costs) income recognized in other comprehensive income, net of tax	(716)	910

## 8. Bonds:

Bonds are interest-bearing available-for-sale financial assets, with a carrying amount of \$37,901 as at November 30, 2010 (\$61,843 in 2009, and \$46,204 as at December 1, 2008), have stated interest rates of 2.37% to 6.75% (2.37% to 6.75% in 2009 and 3.00% to 6.85% as at December 1, 2008) and mature in 1.9 year (2.16 in 2009 and 1.8 in 2008).

The Company's exposure to credit and interest rate risks related to bonds is presented in note 20.

#### 9. Trade and Other Receivables:

	NOTE	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$	DECEMBER 1, 2008 \$
Trade receivables		6	3	12
Sales tax receivable		100	190	419
Loans granted to employees under the share purchase plan	15(iii)	25	74	91
Loans granted to related parties under the share purchase plan	15(iii)	22	75	59
Other receivables		8	33	29
		161	375	610

The Company's exposure to credit and currency risks related to trade and other receivables is presented in note 20.

## 10. Tax Credits and Grants Receivable:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Balance at beginning of the year	1,333	1,451
Investment tax credits and grants received	(1,935)	(1,913)
Investment tax credits and grants recognized in net profit (loss)	934	1,795
	332	1,333

Tax credits and grants receivable comprise research and development investment tax credits receivable from the provincial government which relate to qualifiable research and development expenditures under the

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

applicable tax laws. The amounts recorded as receivable are subject to a government tax audit and the final amounts received may differ from those recorded. There are no unfulfilled conditions or contingencies associated with the government assistance received.

Unused federal tax credits may be used to reduce future income tax and expire as follows:

	<u> </u> \$
2023	452
2024	1,597
2025	1,863
2026	2,178
2027	3,000
2028	3,328
2029	2,250
2030	1,167
	_15,835

#### 11. Inventories:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$	DECEMBER 1, 2008 \$
Raw materials	3,395	2,225	_
Work in progress	922		
	4,317	2,225	

In 2010, \$123 of raw materials, and \$69 of work in progress were written down to their net realizable value (November 30, 2009 – nil and nil; December 1, 2008 – nil and nil). Consequently, a write-down of \$192 was recorded to cost of sales in 2010 (2009 – nil).

The write-down was due to unfavourable pricing related to raw materials that were not originally purchased under the conditions of the Company's current long-term procurement agreements.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

# 12. Property and Equipment:

	COMPUTER EQUIPMENT \$	LABORATORY EQUIPMENT \$	OFFICE FURNITURE AND EQUIPMENT \$	LEASEHOLD IMPROVEMENTS \$	<u>TOTAL</u> \$
Cost:					
Balance at December 1, 2008	682	1,824	1,015	1,846	5,367
Additions	222	125	188	8	543
Disposals	(30)	(4)	(79)	—	(113)
Balance at November 30, 2009	874	1,945	1,124	1,854	5,797
Additions	130	116	7	46	299
Disposals	(63)	(43)	(2)	_	(108)
Balance at November 30, 2010	941	2,018	1,129	1,900	5,988
Accumulated depreciation:					
Balance at December 1, 2008	500	1,427	700	1,441	4,068
Depreciation for the year	147	96	79	290	612
Disposals	(30)	(4)	(78)	—	(112)
Balance at November 30, 2009	617	1,519	701	1,731	4,568
Depreciation for the year	170	88	85	123	466
Disposals	(63)	(41)	(2)	_	(106)
Balance at November 30, 2010	724	1,566	784	1,854	4,928
Net carrying amounts:					
December 1, 2008	182	397	315	405	1,299
November 30, 2009	257	426	423	123	1,229
November 30, 2010	217	452	345	46	1,060

Depreciation expense for the year has been recorded in the following accounts in the consolidated statement of comprehensive income:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Cost of sales	8	
Research and development expenses	231	306
Selling and market development expenses	10	14
General and administrative expenses	217	292
	466	612



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

#### 13. Accounts Payable and Accrued Liabilities:

	NOTE	NOVEMBER 30, 2010	NOVEMBER 30, 2009	DECEMBER 1, 2008
		\$	\$	\$
Trade payables		1,001	1,984	284
Accrued liabilities and other payables		1,440	1,768	4,692
Salaries and benefits due to related parties	25	565	450	504
Employee salaries and benefits payable		1,971	1,366	1,385
		4,977	5,568	6,865

The Company's exposure to currency and liquidity risks related to accounts payable and accrued liabilities is presented in note 20.

## 14. Other Liabilities:

Other liabilities consist of deferred lease inducements relating to rent free periods amounting to \$325 as at November 30, 2010 (November 30, 2009 and December 1, 2008 – nil) (note 17).

#### 15. Share Capital:

Authorized in unlimited number and without par value:

#### Common shares

Preferred shares issuable in one or more series

All issued shares are fully paid, except for 33,524 (2009 – 90,298) issued under the share purchase plan and for which the loan has not been repaid in full (see note 15 (iii)).

Common shareholders are entitled to receive dividends as declared by the Company at its discretion and are entitled to one vote per share at the Company's annual general meeting.

No preferred shares are outstanding.

#### (i) 2010:

In 2010, the Company received subscriptions in the amount of \$15 for the issuance of 2,880 common shares in connection with its share purchase plan.

#### 2009:

Under the terms of the collaboration and licensing agreement with EMD Serono, the Company issued 2,179,837 common shares for a cash consideration of \$9,854 (see note 4).

In 2009, the Company also received subscriptions in the amount of \$96 for the issuance of 34,466 common shares in connection with its share purchase plan.

All shares issued were for cash consideration.

#### (ii) Shareholder Rights Plan:

On February 10, 2010, the Company's Board of Directors adopted a shareholder rights plan (the "Plan"), effective as of that date. The Plan is designed to provide adequate time for the Board of Directors and the shareholders, to assess an unsolicited takeover bid for the Company. In addition, the Plan provides the Board of Directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, as well as provide shareholders with an equal opportunity to participate in a takeover bid to receive full and fair value for their common shares. The Plan will expire at the close of the Company's annual meeting of shareholders in 2013.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

The rights issued under the Plan will initially attach to and trade with the common shares and no separate certificates will be issued unless a triggering event occurs. The rights will become exercisable only when a person, including any party related to it, acquires or attempts to acquire 20% or more of the outstanding shares without complying with the "Permitted Bid" provisions of the Plan or without approval of the Board of Directors. Should such an acquisition occur or be announced, each right would, upon exercise, entitle a rights holder, other than the acquiring person and related persons, to purchase common shares at a 50% discount to the market price at the time.

Under the Plan, a Permitted Bid is a bid made to all holders of the common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties, have been tendered, the offeror may take up and pay for the common shares, but must extend the bid for a further 10 days to allow other shareholders to tender.

## (iii) Share Purchase Plan:

The Share Purchase Plan entitles full-time and part-time employees of the Company who, on the participation date, are residents of Canada, are not under a probationary period and do not hold, directly or indirectly, five percent (5%) or more of the Company's outstanding common shares, to directly subscribe for common shares of the Company. Under the Share Purchase Plan, a maximum of 550,000 common shares may be issued to employees.

On May 1 and November 1 of each year (the "Participation Dates"), an employee may subscribe for a number of common shares under the Share Purchase Plan for an amount that does not exceed 10% of that employee's gross annual salary for that year. Under the Share Purchase Plan, the Board of Directors has the authority to suspend or defer a subscription of common shares, or to decide that no subscription of common shares will be allowed on a Participation Date if it is in the Company's best interest.

The Share Purchase Plan provides that the number of common shares that may be issued to insiders, at any time, under all share-based compensation arrangements of the Company, cannot exceed 10% of the Company's outstanding common shares, and the number of common shares issued to insiders, within any one-year period, under all security-based compensation arrangements, cannot exceed 10% of the outstanding common shares.

The subscription price for each new common share subscribed for under the Share Purchase Plan is equal to the weighted average closing price of the common shares on the Toronto Stock Exchange during a period of five days prior to the Participation Date. Employees may not assign the rights granted under the Share Purchase Plan.

An employee may elect to pay the subscription price for common shares in cash or through an interest-free loan from the Company. Loans granted by the Company under the Share Purchase Plan are repayable through salary withholdings over a period not exceeding two years. All loans may be repaid prior to the scheduled repayment at any time. The loans granted to any employee may at no time exceed 10% of that employee's current annual gross salary. All common shares purchased through an interest-free loan are hypothecated to secure full and final repayment of the loan and are held by a trustee until repayment in full. Loans are immediately due and payable on the occurrence of any of the following events: (i) termination of employment; (ii) sale or seizure of the hypothecated common shares; (iii) bankruptcy or insolvency of the employee; or (iv) suspension of the payment of an employee's salary or revocation of the employee's right to salary withholdings.

At November 30, 2010, \$47 (November 30, 2009 - \$149; December 1, 2008 - \$150) was receivable under these loans (see note 9).

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

## (iv) Stock Option Plan:

The Company has established a stock option plan under which it can grant to its directors, officers, employees, researchers and consultants non-transferable options for the purchase of common shares. The exercise date of an option may not be later than 10 years after the grant date. A maximum number of 5,000,000 options can be granted under the plan. Generally, the options vest at the date of the grant or over a period up to 5 years. As at November 30, 2010, 981,005 options could still be granted by the Company (2009 – 1,244,834).

All options are to be settled by physical delivery of shares.

Changes in the number of options outstanding during the past two years were as follows:

	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE PER OPTION \$
Options at December 1, 2008	2,161,800	6.52
Granted	680,500	1.83
Expired	(58,500)	5.16
Forfeited	(118,000)	9.92
Options at November 30, 2009	2,665,800	5.20
Granted	335,000	4.03
Expired	(32,500)	11.15
Forfeited	(38,671)	3.61
Exercised (weighted average share price: \$5.14)	(80,491)	1.66
Options at November 30, 2010	2,849,138	5.12
Exercisable at November 30, 2010	2,196,403	5.77

The following table provides stock option information as at November 30, 2010:

	OPTIC	OPTIONS OUTSTANDING		
PRICE RANGE (\$)	NUMBER OF OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING LIFE (YEARS)	WEIGHTED AVERAGE EXERCISE PRICE \$	
1.20 – 2.00	1,183,015	6.54	1.71	
2.01 – 2.75	141,459	3.85	2.59	
2.76 – 3.75	70,000	5.51	3.37	
3.76 – 4.60	265,000	9.03	3.84	
4.61 - 6.00	95,000	7.69	4.93	
6.01 - 9.00	570,664	4.82	8.17	
9.01 – 13.50	480,000	2.86	10.72	
13.51 – 15.30	44,000	0.36	15.12	
	2,849,138	5.59	5.12	

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

The fair value of options granted was estimated at the grant date using the Black-Scholes model and the following weighted average assumptions:

	NOVEMBER 30, 2010	NOVEMBER 30, 2009
Risk-free interest rate	2.49%	1.83%
Expected volatility	81.13%	79.50%
Average option life in years	7.5	7.5
Expected dividends	nil	nil
Grant-date share price	\$ 4.03	\$ 1.83
Option exercise price	\$ 4.03	\$ 1.83

The risk-free interest rate is based on the implied yield on a Canadian Government zero-coupon issue with a remaining term equal to the expected term of the option. The volatility is based solely on historical volatility equal to the expected life of the option. The life of the options is estimated considering the vesting period at the grant date, the life of the option and the average length of time similar grants have remained outstanding in the past. The dividend yield was excluded from the calculation since it is the present policy of the Company to retain all earnings to finance operations and future growth.

The following table summarizes the measurement date weighted average fair value of stock options granted during the years ended November 2010 and 2009:

	NUMBER OF OPTIONS	AVERAGE GRANT-DATE <u>FAIR VALUE</u> \$
2010	335,000	3.05
2009	680,500	1.36

The Black-Scholes model used by the Company to calculate option values was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differs from the Company's stock option awards. This model also requires four highly subjective assumptions, including future stock price volatility and average option life, which greatly affect the calculated values.

## (v) Earnings Per Share:

The calculation of basic earnings per share at November 30, 2010 was based on the net profit (loss) attributable to common shareholders of the Company of \$8,930 (2009 - (\$15,156)), and a weighted average number of common shares outstanding of 60,480,032 (2009 – 60,314,309), calculated as follows:

	NOVEMBER 30, 2010	NOVEMBER 30, 2009
Issued common shares at December 1	60,429,393	58,215,090
Effect of share options exercised	49,030	_
Effect of shares issued during the year	1,609	2,099,219
Weighted average number of common shares at November 30	60,480,032	60,314,309

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

The calculation of diluted earnings per share was based on a weighted average number of common shares calculated as follows:

NOVEMBER 30, 2010	NOVEMBER 30, 2009
60,480,032	60,314,309
842,959	
61,322,991	60,314,309
	2010 60,480,032 842,959

At November 30, 2010, 1,119,664 options (2009 – 1,371,167) were excluded from the diluted weighted average number of common shares calculation as their effect would have been anti-dilutive.

The average market value of the Company's shares for purposes of calculating the dilutive effect of share options was based on quoted market prices for the period during which the options were outstanding.

## 16. Income Taxes:

Current tax expense:

	NOVEMBER 30, 2010	NOVEMBER 30, 2009
	\$	\$
Current tax expense:		
Current tax expense for the year	3,285	_
Recognition of previously unrecognized tax losses	(3,171)	_
Current Income tax expense	114	
Deferred tax expense:		
Recognition and reversal of temporary differences	—	(4,031)
Change in unrecognized deductible temporary differences	—	4,031
Deferred income tax expense		
Total income tax expense	114	

Reconciliation between effective and applicable tax amounts:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Income taxes at domestic tax statutory rate	2,713	(4,683)
Change in unrecognized deductible temporary differences	(3,171)	4,031
Non-deductible expenses and other	572	652
	114	

Deferred tax assets:

Deferred tax asset of \$114 (2009 - nil) related to share issue costs was recognized directly in equity.

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Unrecognized deferred tax assets:

At November 30, 2010, temporary differences for which no deferred tax asset was recognized were as follows:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
_ong-term:		
Research and development expenses	30,143	29,380
Deferred non-capital losses	21,013	21,490
Property and equipment	609	674
Intellectual property and patent fees	9,230	12,307
Available deductions and other	4,648	4,963
	65,643	68,814

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

Given the Company's past losses, management does not believe that it is more probable than not that the Company can realize its deferred tax assets and therefore it has not recognized any amount in the statement of financial position.

At November 30, 2010, the amounts and expiry dates of tax attributes to be deferred for which no deferred tax asset was recognized were as follows:

		NOVEMBER 30, 2010		MBER 30, 2009
	FEDERAL \$	PROVINCIAL \$	FEDERAL \$	PROVINCIAL \$
Research and development expenses, without time limitation	103,324	123,062	103,346	115,686
Losses carried forward:				
2014	1,216	_	9,603	
2015	275	_	275	
2027	7,638	7,628	7,638	7,628
2028	46,316	32,174	46,316	46,271
2029	19,484	16,467	21,785	18,802
2030	11,440	11,436		
Other temporary differences, without time limitation:				
Excess of tax value of property and equipment over carrying value	2,773	1,666	3,121	1,785
Tax value of intellectual property and patent fees	34,301	34,289	45,735	45,718
Available deductions and other	57,343	1,412	58,415	2,732



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

## 17. Operating Leases:

The Company rents its headquarters and main office pursuant to an operating lease (the "Lease") expiring in April 2021. Under the terms of the Lease, the Company has also been granted two renewal options for periods of five years each. Lease payments will increase by 11% beginning on November 1, 2015.

During the year ended November 30, 2010, an amount of \$628 was recognized as an expense in respect of operating leases (2009 – \$805). Of the amount \$133 (2009 – \$176) is included in General and administrative expenses and \$495 (2009 – \$629) is included in Research and development expenses.

The Company's lease includes a lease of land and building. Since the land title does not pass, and the Company does not participate in the residual value of the building, it was determined that substantially all the risks and rewards of the building are with the lessor. As such, the Company determined that the lease is an operating lease.

The Company has committed to pay the lessor for its share of some operating expenses of the leased premises. This amount has been set at \$240 per year beginning May 1, 2010 and will be increased by 2.5% annually for the duration of the Lease. Refer to note 23 for the contractual commitments related to this lease.

The lessor granted the Company a monetary allowance in the amount of \$728 to make leasehold improvements. This amount had not been received as at November 30, 2010. Furthermore, the Company benefits from a 25-month rent free period which is deferred and recognized over the lease term. As at November 30, 2010, \$325 was included in Other liability (nil – November 30, 2009) in regards to the deferred free rent inducement (note 14 – Other liabilities).

The Company had issued an irrevocable letter of credit in favour of the lessor in the amount of \$323 under the terms of the Lease renewal, along with a first ranking movable hypothec in the amount of \$1,150 covering all the Company's tangible assets located in the rented premises. The letter of credit and the hypothec were cancelled on April 30, 2010.

#### 18. Contingent Liability:

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

The Motion had not yet been heard by the Superior Court of Quebec and a date has not been set for the hearing.

The Company has subscribed to insurance covering its potential liability and the potential liability of its directors and officers in the performance of their duties for the Company subject to a \$200 deductible. At November 30, 2010, an amount of \$96 in legal fees has been accrued and included in general and administrative expenses, of which \$61 was paid during the year and \$35 remained in accounts payable and accrued liabilities.

## 19. Statement of Cash Flows:

The Company entered into the following transactions which had no impact on the cash flows:

	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$	DECEMBER 1, 2008 \$
Additions to property and equipment included in accounts payable and accrued liabilities	65	183	48
Share issue costs included in accounts payable and accrued liabilities		—	8

In addition, interest received totalled \$2,290 (2009 - \$1,200).



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

## 20. Financial Instruments:

#### **Overview:**

This note provides disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk, currency risk and interest rate risk, and how the Company manages those risks.

#### (a) Credit Risk:

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

The Company's exposure to credit risk currently relates to accounts receivable with only one customer (see note 4). Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragovernmental and municipal bodies (\$37,542 as at November 30, 2010) as well as from companies with high credit ratings (\$359 as at November 30, 2010). As at November 30, 2010, the Company was not exposed to any credit risk over the carrying amount of the bonds.

#### (b) 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 the capital management section below, 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 to ensure the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

The following are amounts due on the contractual maturities of financial liabilities as at November 30, 2010 and 2009:

			NOVEMBER 30, 2	2010	
	TOTAL \$	CARRYING <u>AMOUNT</u> \$	LESS THAN <u>1 YEAR</u> \$	1 TO <u>5 YEARS</u> \$	MORE THAN <u>5 YEARS</u> \$
Accounts payable and accrued liabilities	4,977	4,977	4,977	_	_
					20. 0000

	NOVEMBER 30, 2009					
	TOTAL	CARRYING AMOUNT	LESS THAN <u>1 YEAR</u>	1 TO <u>5 YEARS</u> ¢	MORE THAN 5 YEARS	
	φ	φ	φ	φ	φ	
Accounts payable and accrued liabilities	5,568	5,568	5,568			

#### (c) 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 the Canadian dollar, primarily revenues from milestone payments and expenses for research and development incurred in US dollars, euros and



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

pounds sterling ("GBP"). The Company does not use derivative financial instruments to reduce its foreign exchange exposure.

The Company manages currency risk by maintaining cash in US dollars on hand to support US forecasted cash budgets for a maximum 12-month period. The Company does not currently view its exposure to the euro and GBP as a significant foreign exchange risk due to the limited volume of transactions conducted by the Company in these currencies.

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

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

	NOV	NOVEMBER 30, 2010			
	\$US	EURO	GBP		
Cash	26,424	_	1		
Trade and other receivables	—		_		
Accounts payable and accrued liabilities	(465)	(26)	(81)		
Items exposed to currency risk	25,959	(26)	(80)		

	NOVE	NOVEMBER 30, 2009		
	\$US	EURO	GBP	
Cash	1,471	—		
Trade and other receivables	_	4	_	
Accounts payable and accrued liabilities	(1,095)	_	(25)	
Items exposed to currency risk	376	4	(25)	

	DEC	<b>DECEMBER 1, 2008</b>			
	\$US	EURO	GBP		
Cash	1	_			
Trade and other receivables	_				
Accounts payable and accrued liabilities	(2,589)	(159)	(348)		
Items exposed to currency risk	(2,588)	(159)	(348)		



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

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

	NOVEMB	NOVEMBER 30, 2010		ER 30, 2009	DECEMBER 1, 2008	
	AVERAGE RATE	REPORTING DATE RATE	AVERAGE RATE	REPORTING DATE RATE	AVERAGE RATE	REPORTING DATE RATE
\$US – C\$	1.0345	1.0266	1.0594	1.0556	1.0479	1.2370
EURO – C\$	1.3848	1.3326	1.5808	1.5852	1.5440	1.5711
GBP – C\$	1.6051	1.5969	1.7597	1.7366	1.9767	1.9060

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

	NOVEN	NOVEMBER 30, 2010		NOVEMBER 30, 2009			
	\$US	EURO	GBP	\$US	EURO	GBP	
ase in net profit (loss)	1,298	(1)	(4)	19		(1)	

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

#### (d) 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 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 at November 30, 2010, 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 \$336; an assumed increase in interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

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

Based on the average value of variable interest-bearing cash during the year ended November 30, 2010 (\$3,219), an assumed 0.5% increase in interest rates during such period would have increased future cash flow and net profit by approximately \$16; an assumed decrease of 0.5% would have had an equal but opposite effect.

#### 21. Capital Management:

The Company's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and capital spending.

To fund its activities, the Company relied primarily on public offerings of common shares in Canada and private placements of its common shares as well as up-front payments and milestone payments primarily associated with EMD Serono. When possible, the Company optimizes its liquidity position using non-dilutive sources, including investment tax credits, grants and interest income.



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

The Company has a \$1,800 revolving credit facility for its short-term financing needs which was unused at November 30, 2010 (see note 23 (c)).

The capital management objectives remain the same as for the previous year.

At November 30, 2010, cash and bonds amounted to \$64,550 and tax credits and grants receivable amounted to \$332, for a total of \$64,882. The Company believes that its cash position will be sufficient to finance its operations and capital needs for the next year.

Currently, the Company's general policy on dividends is to retain cash to keep funds available to finance the Company's growth.

The Company is not subject to any externally imposed capital requirements.

#### 22. Determination of Fair Values:

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.

#### Financial Assets and Liabilities:

In establishing fair value, the Company uses a fair value hierarchy based on levels as defined below:

- <sup>n</sup> Level 1: defined as observable inputs such as quoted prices in active markets.
- n Level 2: defined as inputs other than quoted prices in active markets that are either directly or indirectly observable.
- Level 3: defined as inputs that are based on little or no observable market data, therefore requiring entities to develop its own assumptions.

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

Bonds are stated at estimated fair value, determined by inputs that are primarily based on broker quotes at the reporting date (Level 2).

## Share-Based Payment Transactions:

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



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

## 23. Commitments:

## (a) Leases:

At November 30, 2010 and 2009 and December 1, 2008, the minimum payments required under the terms of the non-cancellable lease are as follows:

	NOVEMBER 30, 	NOVEMBER 30, 2009 \$	DECEMBER 1, 2008 \$
Less than one year	55	340	816
Between one and five years	2,239	2,020	340
More than five years	3,943	4,216	
	6,237	6,576	1,156

#### (b) Long-term Procurement Agreements:

During and after the years ended November 30, 2010 and 2009, the Company entered into long-term procurement agreements with third-party suppliers in anticipation of the commercialization of *EGRIFTA*<sub>TM</sub>.

#### (c) Credit Facility:

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

As at November 30, 2010 and 2009, the Company did not have any borrowings outstanding under this credit facility.

## 24. Operating Segments:

The Company has a single operating segment. As described in note 4, all of the Company's revenues are generated from one customer, EMD Serono, which is domiciled in the United States.

All of the Company's non-current assets are located in Canada, the Company's headquarters.

#### 25. Related Parties:

The Company has a related party relationship with its wholly-owned subsidiaries. There are no transactions between the Company and its subsidiaries.

The key management personnel of the Company are the Directors.

Key management personnel compensation comprised:

	NOTE	NOVEMBER 30, 2010 \$	NOVEMBER 30, 2009 \$
Short-term employee benefits		1,891	1,647
Post-employment benefits		61	59
Share-based compensation	15(iv)	331	175
		2,283	1,881

Directors of the Company control 1.2 percent of the voting shares of the Company.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

On November 30, 2010, loans granted to key management personnel under share purchase plan (note 15 (iii)) amount to \$22 as at November 30, 2010 (\$75 as at November 30, 2009 and \$59 as at December 1, 2008).

#### 26. Subsequent Events:

#### **Distribution and Licensing Agreement:**

On December 6, 2010, the Company announced the signing of a distribution and licensing agreement with Sanofi-aventis ("Sanofi"), covering the commercial rights for *EGRIFTA*<sub>TM</sub> in Latin America, Africa, and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

Under the terms of the agreement, the Company will sell *EGRIFTA*TM to Sanofi at a transfer price equal to the higher of a percentage of Sanofi's net selling price and a predetermined floor price. The Company has retained all future development rights to *EGRIFTA*TM and will be responsible for conducting research and development for any additional potential indications. Sanofi will be responsible for conducting all regulatory activities for *EGRIFTA*TM in the aforementioned territories, including applications for approval in the different countries for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. The Company also granted Sanofi an option to commercialize tesamorelin for other indications in the territories mentioned above. If such option is not exercised, or is declined, by Sanofi, the Company may commercialize tesamorelin for such indications on its own or with a third party.

On February 3, 2011, the Company entered into a distribution and licensing agreement with Ferrer covering the commercial rights for *EGRIFTA*™ for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the Agreement, the Company will sell *EGRIFTA*TM to Ferrer at a transfer price equal to the higher of a significant percentage of the Ferrer's net selling price and a predetermined floor price. The Company has retained all development rights to *EGRIFTA*TM for other indications and will be responsible for conducting research and development for any additional programs. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with *EGRIFTA*TM for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. The Company will be responsible for the manufacture and supply of *EGRIFTA*TM to Ferrer. The Company has the option to co-promote *EGRIFTA*TM for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Ferrer has the option to enter into a co-development and commercialization agreement using tesamorelin relating to any such new indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development.

#### Deferred Share Unit Plan:

In December 2010, the Company adopted a deferred share unit plan ("Plan") to provide long-term incentive compensation for its directors and executive officers. Under the Plan, directors must receive their annual remuneration as a board member in fully vested deferred share units ("DSUs") until they reach a percentage of their annual remuneration and, once such percentage is attained, they have the option to elect to receive part or all of this annual remuneration in DSUs. Under the plan, executive officers have the option of receiving all or a portion of their annual bonus in the form of fully-vested DSUs. The units are only redeemable for cash when a participant ceases to be an employee or member of the Board of Directors. The Company manages the risk associated with the issuance of the DSU by entering into a yearly forward contract with a third party. As at February 7, 2011, all of the 99,912 DSU outstanding were covered by a prepaid forward contract.

## Stock Option Plan:

Between December 1, 2010 and February 7, 2011, the Company granted 250,000 options at an exercise price of \$5.65 per share. Also 27,832 options were forfeited and expired at a weighted exercise average price of \$12.06 per share. Furthermore, 3,000 options were exercised at a weighted exercise average price of \$1.80 per share for a cash consideration of \$5.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

### 27. Transition to IFRS:

As stated in note 2 (a), these are the Company's first consolidated financial statements prepared in accordance with IFRSs. The Company has applied IFRS 1 and the accounting policies set out in note 3 in preparing the financial statements for the year ended November 30, 2010, the comparative information presented in these financial statements for the year ended November 30, 2009 and in the opening IFRS statement of financial position at December 1, 2008 (the Company's date of transition).

In preparing these consolidated financial statements in accordance with IFRS 1, the Company has applied the mandatory exceptions and certain of the optional exemptions from full retrospective application of IFRSs.

The Company elected to apply the following optional exemptions from full retrospective application:

(i) Share-based payment transaction exemption:

The Company has elected to apply the share-based payment exemption. It applied IFRS 2 from December 1, 2008 to those stock options that were issued after November 7, 2002 but that had not vested by December 1, 2008. The application of the exemption is detailed below.

(ii) Designation of financial assets and financial liabilities exemption:

The Company elected to re-designate cash from the held-for-trading category to loans and receivables.

As required by IFRS 1, estimates made under IFRS at the date of transition must be consistent with estimates made for the same date under previous GAAP, unless there is evidence that those estimates were in error.

In preparing its opening IFRS consolidated statement of financial position, the Company has adjusted amounts reported previously in financial statements prepared in accordance with Canadian GAAP.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

An explanation of how the transition from previous Canadian GAAP to IFRS has affected the Company's financial position, financial performance and cash flows is set out in the following tables and accompanying notes.

## Reconciliation of equity as at December 1, 2008 and November 30, 2009:

		DECEMBER 1, 2008			NOVEMBER 30, 2009				
	NOTE	CANADIAN GAAP \$	IFRS ADJUST- <u>MENTS</u> \$	IFRS RECLASSI- <u>FICATIONS</u> \$	IFRS \$	CANADIAN GAAP \$	IFRS ADJUST- <u>MENTS</u> \$	IFRS RECLASSI- FICATIONS \$	IFRS \$
Assets									
Current assets:									
Cash		133	_	—	133	1,519		_	1,519
Bonds		10,955	_	_	10,955	10,036		_	10,036
Trade and other receivables		610	_	—	610	375		_	375
Tax credits and grants receivable	(a)	1,784	_	(333)	1,451	1,666	_	(333)	1,333
Inventories		—	—	—	—	2,225	—	_	2,225
Research supplies	(a)	301	—	(301)	—	287	—	(287)	_
Prepaid expenses	(a)	397		342	739	302		328	630
Total current assets	_	14,180		(292)	13,888	16,410		(292)	16,118
Non-current assets:									
Bonds		35,249	_	_	35,249	51,807	_	_	51,807
Property and equipment		1,299		_	1,299	1,229		_	1,229
Other assets	(a)	2,817		(41)	2,776	41		(41)	
Total non-current assets		39,365		(41)	39,324	53,077		(41)	53,036
Total assets	_	53,545		(333)	53,212	69,487		(333)	69,154
Liabilities									
Current liabilities:									
Accounts payable and accrued liabilities	(a)	7,198	_	(333)	6,865	5,901	_	(333)	5,568
Current portion of deferred revenue		_	_	_	_	6,847	_		6,847
Total current liabilities		7,198		(333)	6,865	12,748		(333)	12,415
Non-current liabilities:	-	<u> </u>			· <u> </u>				· · · · ·
Deferred revenue		_	_	_	_	13,691		_	13,691
Total non-current liabilities	-					13.691			13,691
Total liabilities	-	7,198		(333)	6,865	26,439		(333)	26,106
Equity	-	.,	. <u></u>	/			. <u></u>		
Share capital		269,219	_	_	269.219	279,169	_	_	279,169
Contributed surplus	(b)	5.585	175	_	5.760	6,484	273	_	6.757
Deficit	(b)	(228,829)	(175)	_	(229,004)	(243,887)	(273)	_	(244,160)
Accumulated other comprehensive income	(-)	372	(	—	372	1,282	(		1,282
Total equity		46,347			46,347	43,048			43,048
Total liabilities and equity	-	53,545		(333)	53,212	69,487		(333)	69,154

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

Reconciliation of comprehensive income for the year ended November 30, 2009:

	NOTE	CANADIAN GAAP \$	IFRS ADJUST- <u>MENTS</u> \$	IFRS RECLASSI- FICATION \$	IFRS \$
Revenue:					
Research services:					
Milestone payments	(C)	_	_	10,884	10,884
Upfront payments and initial technology access fees	(C)	_	_	6,560	6,560
Royalties and license fees	(C)	17,468	—	(17,444)	24
Interest	(C)	2,252		(2,252)	
Total revenue		19,720		(2,252)	17,468
Research and development expenses, net of tax credits	(b), (c)	20,431	33	346	20,810
Selling and market development expenses	(b), (c)	2,583	10	4,269	6,862
General and administrative expenses	(b), (c)	7,149	55	(661)	6,543
Patents	(C)	346	_	(346)	—
Fees associated with the collaboration and licensing agreement	(C)	4,269		(4,269)	
Total operating expenses		34,778	98	(661)	34,215
Results from operating activities		(15,058)	(98)	(1,591)	(16,747)
Finance income	(C)	_		2,252	2,252
Finance costs	(C)			(661)	(661)
Total net finance income			_	1,591	1,591
Net loss		(15,058)	(98)		(15,156)
Other comprehensive income:					
Net change in fair value of available-for-sale financial assets		1,039	—	—	1,039
Net change in fair value of available-for-sale financial assets transferred to net					
profit (loss)		(129)			(129)
Other comprehensive income for the year		910			910
Total comprehensive income for the year		(14,148)	(98)		(14,246)

Material adjustments to the consolidated statement of cash flows for 2009:

There are no material differences between the consolidated statement of cash flows presented under IFRS and the consolidated statement of cash flows presented under previous Canadian GAAP.

Notes to the reconciliations:

(a) Reclassification in the consolidated statement of financial position:

Certain corresponding figures as at December 1, 2008 and November 30, 2009 have been reclassified to conform to the new presentation under IFRS.

(b) Share-based compensation:

In certain situations, stock options granted vest in instalments over a specified vesting period. When the only vesting condition is service from the grant date to the vesting date of each tranche awarded, then each instalment should be accounted for as a separate share-based payment arrangement under IFRS,

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS - (CONTINUED)

otherwise known as graded vesting. Canadian GAAP permits an entity the accounting policy choice with respect to graded vesting awards. Each instalment can be considered as a separate award, each with a different vesting period, consistent with IFRS, or the arrangement can be treated as a single award with a vesting period based on the average vesting period of the instalments depending on the policy elected.

The Company's policy under Canadian GAAP was to treat graded vesting awards under the latter method and, as a result, an adjustment of \$175 was required on the application of IFRS 2 at the transition date, and an adjustment of \$98 was required for the restated 2009 comparative balances as shown below:

	DECEMBER 1, 2008 \$	NOVEMBER 30, 2009 \$
Consolidated statement of comprehensive income:		
Increase in research and development expenses	—	33
Increase in selling and market development expenses	_	10
Increase in general and administrative expenses	_	55
Adjustment to net loss and total comprehensive loss		98
Deficit	(175)	(273)
Increase in contributed surplus	175	273

(c) Reclassification in the consolidated statement of comprehensive income:

Under IFRS, the Company elected to present expenses using a classification based on their function and presents net finance income separately. The effect of these changes is summarized below:

	NOVEMBER 30, 2009 \$
Decrease in interest	(2,252)
Increase in finance income	2,252
Increase in research and development expenses	346
Decrease in patent fees	(346)
Decrease in general and administrative expenses	(661)
Increase in finance costs	661
Increase in selling and market development expenses	4,269
Decrease in fees associated with the collaboration and licensing agreement	(4,269)

Changes in presentation were also made to the revenue caption in order to conform with the new presentation under IFRS as noted below:

	NOVEMBER 30, 2009 \$
Decrease in royalties and license fees	(17,444)
Increase in upfront payments and initial technology access fees	6,560
Increase in milestone payments	10,884

# 11,000,000 Shares



# **Common Shares**

PRELIMINARY PROSPECTUS

Joint Book-Running Managers

# Jefferies Stifel Nicolaus Weisel RBC Capital Markets BMO Capital Markets

Co-Managers

# Desjardins Securities International Inc NBF Securities (USA) Corp

Until , 2011 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

, 2011

## PART II

## INFORMATION NOT REQUIRED TO BE DELIVERED TO OFFEREES OR PURCHASERS

## Indemnification

Under the Business Corporations Act (Québec) (the "Act"), except in respect of an action by or on behalf of the Registrant to procure a judgment in its favor, the Registrant shall indemnify against all costs, charges and expenses reasonably incurred by its mandatory (which covers directors and officers) prosecuted by a third person for an act done in the exercise of his duties and shall pay damages, if any, resulting from that act, unless such mandatory has committed a grievous offence or a personal offence separable from the exercise of his duties. However, in a penal or criminal proceeding, the Registrant shall indemnify against all costs, charges and expenses reasonable grounds to believe that his conduct was in conformity with the law. The Registrant may, with the approval of the court, assume the expenses of its mandatory if, having prosecuted him for an act done in the exercise of his duties, it loses its case. If the Registrant wins its case only in part, the court may determine the amount of the expenses it shall assume.

In addition, the By-laws of the Registrant provide in effect for the indemnification by the Registrant of each director and officer of the Registrant to the fullest extent permitted by applicable law.

The Registrant has purchased insurance for the benefit of all directors and officers of the Registrant and its subsidiaries against liability incurred by them in such capacity.

Under agreements which may be entered into by the Registrant, underwriters, dealers, placement agents and other intermediaries who participate in the distribution of securities may be entitled to indemnification by the Registrant against certain liabilities, including liabilities under applicable securities legislation. The underwriters, dealers, placement agents and other intermediaries with whom the Registrant enters into agreements may be customers of, engage in transactions with or perform services for the Registrant in the ordinary course of business.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

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EXHIBITS

Exhibit Number	Description
3.1*	Underwriting Agreement between the Registrant and Jefferies & Company, Inc., as Representative of the Several Underwriters.
4.1	Annual information form of the Registrant dated February 22, 2011 for the fiscal year ended November 30, 2010.
4.2	Audited consolidated statements of financial position of the Registrant as at November 30, 2010 and 2009 and December 1, 2008, and the consolidated statements of comprehensive income, changes in equity and cash flows for the years ended November 30, 2010 and 2009, together with the notes thereto and the auditors' report thereon.
4.3	Management's discussion and analysis of results and operations and financial condition for the fiscal year ended November 30, 2010.
4.4	Management proxy circular dated February 23, 2010 in connection with the Registrant's annual and special meeting of shareholders held on March 25, 2010.
4.5	Material change report dated December 16, 2010 announcing the execution of a distribution and licensing agreement with Sanofi-Aventis for the commercialization rights to <i>EGRIFTATM</i> (tesamorelin for injection) in Latin America, Africa and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.
4.6	Material change report dated February 10, 2011 announcing the execution of a distribution and licensing agreement with Ferrer for the commercialization rights to <i>EGRIFTATM</i> (tesamorelin for injection) in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.
4.7	Material change report dated February 22, 2011 announcing a new clinical program for muscle wasting in COPD using tesamorelin.
5.1	Consent of KPMG LLP.
5.2	Consent of Fasken Martineau Dumoulin LLP.
5.3	Consent of Goodwin Procter LLP.
6.1	Power of Attorney (included on the signature pages to the Registration Statement).

\* To be filed by amendment.

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## PART III

## UNDERTAKING AND CONSENT TO SERVICE OF PROCESS

#### Item 1. Undertaking

The Registrant undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the Commission staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to the securities registered pursuant to Form F-10 or to transactions in said securities.

## Item 2. Consent to Service of Process

(a) Concurrent with the filing of this Registrant Statement on Form F-10, the Registrant is filing with the Commission a written irrevocable consent and power of attorney on Form F-X.

(b) Any change to the name or address of the agent for service of the Registrant shall be communicated promptly to the Commission by amendment to Form F-X referencing the file number of the relevant registration statement.

#### III-1

## SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-10 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Montreal, Province of Québec, Country of Canada, on February 22, 2011.

#### THERATECHNOLOGIES INC.

By: /s/ John-Michel Huss John-Michel Huss President and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL MEN AND WOMEN BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints John-Michel Huss and Luc Tanguay and each of them, either of whom may act without the joinder of the other, the true and lawful attorney-in-fact and agent of the undersigned, with full power of substitution and resubstitution, to execute in the name, place and stead of the undersigned, in any and all such capacities, any and all amendments (including post-effective amendments) to this Registration Statement and registration statements filed pursuant to Rule 429 under the Securities Act of 1933, as amendment, and all instruments necessary or in connection therewith, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the United States Securities and Exchange Commission, and hereby grants to each such attorney-in-fact and agent, each acting alone, full power and authority to do and perform in the name and on behalf of the undersigned each and every act and thing whatsoever necessary or advisable to be done, as fully and to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities indicated and on the dates indicated.

Signature	Title	Date
/s/ John-Michel Huss John-Michel Huss	President and Chief Executive Officer and a Director (Principal Executive Officer)	February 22, 2011
/s/ Luc Tanguay Luc Tanguay	Senior Executive Vice President and Chief Financial Officer and a Director (Principal Financial and Accounting Officer)	February 22, 2011
/s/ Paul Pommier Paul Pommier	Director	February 22, 2011
/s/ Gilles Cloutier Gilles Cloutier	Director	February 22, 2011
	III-2	

Signature		Title	Date
/s/ A. Jean de Grandpré A. Jean de Grandpré	Director		February 22, 2011
/s/ Robert G. Goyer Robert G. Goyer	Director		February 22, 2011
/s/ Gérald A. Lacoste Gérald A. Lacoste	Director		February 22, 2011
/s/ Bernard Reculeau Bernard Reculeau	Director		February 22, 2011
/s/ Jean-Denis Talon	Director		February 22, 2011
Jean-Denis Talon	III-3		

## AUTHORIZED REPRESENTATIVE

Pursuant to the requirements of Section 6(a) of the Securities Act, the Authorized Representative certifies that it is the duly authorized United States representative of Theratechnologies Inc. and has duly caused this Registration Statement to be signed on its behalf by the undersigned, solely in its capacity as the duly authorized representative of Theratechnologies Inc. in the United States, in the State of North Carolina, United States of America on February 22, 2011.

## THERATECHNOLOGIES INC.

By: <u>/s/ Gilles Cloutier</u> Gilles Cloutier Director

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## EXHIBIT INDEX

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\* To be filed by amendment.

ANNUAL INFORMATION FORM Financial Year Ended November 30, 2010



February 22, 2011

## FORWARD-LOOKING STATEMENTS

This Annual Information Form, or AIF, contains forward-looking statements and forward-looking information within the meaning of applicable securities laws that are based on our management's belief and assumptions and on information currently available to our management, collectively, "forward-looking statements". In some cases, you can identify forward-looking statements by terms such as "may", "will", "should", "could", "would", "expect", "plan", "anticipate", "believe", "estimate", "project", "predict", "intend", "potential", "continue" and similar expressions intended to identify forward-looking statements. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements. Forward-looking statements include, but are not limited to, statements about:

- our ability, and the ability of our commercial partners, to commercialize EGRIFTATM in the United States and other territories;
- whether we will receive regulatory approvals for tesamorelin from regulatory agencies in territories other than the United States in which we wish to expand the commercialization of tesamorelin, and the timing and costs of obtaining such regulatory approvals;
- our recognition of milestones, royalties and other revenues from our commercial partners related to future sales of EGRIFTATM;
- our plans to conduct a new clinical program for tesamorelin in muscle wasting in chronic obstructive pulmonary disease, or COPD, including the timing and results of these clinical programs;
- the continuation of our collaborations and other significant agreements with our existing commercial partners and our ability to establish and maintain additional development collaborations;
- our estimates of the size of the potential markets for EGRIFTATM, tesamorelin and our other product candidates;
- the rate and degree of market acceptance of EGRIFTATM and our other product candidates;
- our success in obtaining, and the timing and amount of, reimbursement for EGRIFTATM and our other product candidates;
- the benefits of tesamorelin and our other product candidates as compared to others;
- the success and pricing of other competing drugs or therapies that are or may become available;
- our ability to maintain and establish intellectual property rights in tesamorelin and our other product candidates;
- the manufacturing capacity of third-party manufacturers, including the manufacturer of tesamorelin in commercial quantities;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes; and
- our need for additional financing and our estimates regarding our capital requirements and future revenues and profitability.

Such statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed in or implied by the forward-looking statements. Certain assumptions made in preparing the forward-looking statements include that:

- tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will receive approval in territories other than the United States covered in our commercialization agreements;
- no additional clinical studies will be required to obtain said regulatory approval of tesamorelin;
- EGRIFTATM will be accepted by the marketplace in the United States and will be on the list of reimbursed drugs by third-party payors;
- our relations with third-party suppliers of EGRIFTATM will be conflict-free and that such third-party suppliers will have the capacity to manufacture and supply EGRIFTATM to meet market demand and on a timely-basis;
- we will obtain positive results from our clinical program for the development of tesamorelin for muscle wasting in COPD patients; and
- our business plan will not be substantially modified.

Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these risks and uncertainties, the forward-looking events and circumstances discussed in this AIF may not occur, and you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors". Also, these forward-looking statements represent our estimates and assumptions only as of the date of this AIF. We undertake no obligation and do not intend to update or revise these forward-looking statements, unless required by law. We qualify all of the information presented in this AIF, and particularly our forward-looking statements, with these cautionary statements.

This AIF also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry and target indications. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

# **BASIS OF PRESENTATION**

We obtained the industry, market and competitive position data in this AIF from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. Certain statistical data and other information regarding the size of our potential markets are based on industry publications and/or derived from our own internal analysis of such industry publications. While we believe our internal company research and internal analysis are reliable and the market definitions, methodology and hypotheses we use are appropriate, such research, analysis, methodology or definitions have not been verified by an independent source. We cannot and do not provide any assurance as to the accuracy or completeness of such information. Market forecasts, in particular, are likely to be inaccurate, especially over long periods of time.

In this AIF, the use of *EGRIFTA*<sup>TM</sup> refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy regardless of the trade name used for such product in any particular territory. *EGRIFTA*<sup>TM</sup> is the trade name used in the United States for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*<sup>TM</sup> is our trademark. Other trademarks and service marks appearing in this AIF are the property of their respective holders.

All monetary amounts set forth in this AIF are expressed in Canadian dollars, except where otherwise indicated. References to "\$" and "C\$" are to Canadian dollars and references to "US\$" are to U.S. dollars.

In this AIF, references to "Theratechnologies", "we", "our" and "us" refer to Theratechnologies Inc. and its subsidiaries, unless the context otherwise states.

All information provided in this AIF is provided as of February 21, 2011, except where otherwise stated.

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# **ITEM 1 CORPORATE STRUCTURE**

#### 1.1 NAME, ADDRESS AND INCORPORATION

We were incorporated under the name Theratechnologies Inc. on October 19, 1993 under Part IA of the *Companies Act* (Québec) (now the *Business Corporations Act* (Québec)) by Certificate of Incorporation. We amended our articles on October 20, 1993 by repealing the restrictions applicable to private companies. On December 6, 1993, we again amended our articles to increase the number of directors and to modify our share capital. Finally, on March 26, 1997, we further modified our share capital to consist of an unlimited number of common shares and an unlimited number of preferred shares. Our common shares are listed on the Toronto Stock Exchange, or TSX, under the symbol "TH". See Item 6.1 for a complete description of our authorized share capital.

Our head office is located at 2310 Alfred-Nobel Boulevard, Montréal, Québec, Canada H4S 2B4. Our phone number is (514) 336-7800. Our website is www.theratech.com. The information contained on our website is not part of this AIF.

#### 1.2 SUBSIDIARIES

As of February 21, 2011, Theratechnologies had the following three wholly-owned subsidiaries:

- Theratechnologies Intercontinental Inc., a company incorporated under Part 1A of the Companies Act (Québec) and governed by the Business Corporations Act (Québec). Theratechnologies Intercontinental Inc., formerly Theratechnologies ME Inc., controls the worldwide rights to commercialize EGRIFTATM except in the United States, Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries, and Canada;
- Theratechnologies Europe Inc., a company incorporated under Part 1A of the Companies Act (Québec) and governed by the Business Corporations Act (Québec). Theratechnologies Europe Inc., formerly 9176-5057 Québec Inc., controls the rights to commercialize EGRIFTATM in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries; and
- **Pharma-G Inc.**, a company incorporated under Part 1A of the *Companies Act* (Québec) and governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.

Theratechnologies has retained the rights to commercialize *EGRIFTA*™ in the United States and in Canada.

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# **ITEM 2 OUR BUSINESS**

#### 2.1 OVERVIEW

We are a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on growthhormone releasing factor, or GRF, peptides. Our strategy is to leverage our expertise in the field of metabolism and GRF peptides to address serious health disorders while remaining actively involved in the commercialization of our future products. Our first product, *EGRIFTATM* (tesamorelin for injection), was approved by the United States Food and Drug Administration, or FDA, in November 2010. *EGRIFTATM* is currently the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

We estimate that excess abdominal fat in HIV-infected patients affects approximately 29% of HIV-infected patients treated with antiretroviral therapies and approximately 12% of untreated patients. In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. Lipodystrophy is characterized by abnormalities in the production and storage of fat, which lead to excess abdominal fat, or lipohypertrophy, and the loss of fat tissue, or lipoatrophy, generally occurring in the limbs and facial area.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood (such as triglycerides and cholesterol), and hyperglycemia, an increase in the amount of sugar in the blood, characterized by insulin resistance, both of which lead to increased risks of cardiovascular disease and diabetes. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy.

*EGRIFTATM* is currently marketed exclusively in the United States by EMD Serono Inc., or EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany, pursuant to a collaboration and licensing agreement. We have also recently entered into distribution and licensing agreements for *EGRIFTATM* with Sanofi Winthrop Industries S.A., or Sanofi, granting Sanofi the exclusive commercialization rights in Latin America, Africa and the Middle East and with Ferrer Internacional S.A., or Ferrer, granting Ferrer the exclusive commercialization rights in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. For a description of these agreements, see Item 2.5. Using data compiled by the United States Center for Disease Control, or CDC, and the World Health Organization and UNAIDS, or WHO/UNAIDS, we estimate that in 2012 there will be approximately 190,000 HIV-infected patients treated with antiretroviral therapies with lipohypertrophy in the United States, 170,000 in Europe, and 180,000 in Latin America, or 540,000 patients in total. We also estimate that in 2012, there will be an additional 47,000 HIV-infected untreated patients with lipohypertrophy in the United States, 42,000 in Europe, and 28,000 in Latin America, or an additional 117,000 patients in total.

In January 2011, EMD Serono launched *EGRIFTATM* in the United States. EMD Serono is executing a launch program that consists of medical education, advertising, marketing and promotion through their experienced sales force, and supporting market access through co-pay programs, reimbursement education and support for payors. We believe *EGRIFTATM* will achieve a high degree of physician and payor acceptance, driven by our product's safety and efficacy, the lack of approved alternative therapies for these patients and the prominent medical and social need to treat HIV/AIDS patients.

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*EGRIFTA*<sup>TM</sup> is the trade name used for our first marketed product using our most advanced compound, tesamorelin. Tesamorelin is a GRF analogue that stimulates the synthesis and pulsatile release of endogenous growth hormone. Tesamorelin was synthesized using our internally-developed peptide stabilization method. This method increases a protein's resistance to enzymatic degradation, which prolongs its duration of action and enhances its effectiveness in clinical use. We believe this compound and future GRF analogues that we are developing can be used in a number of additional high-value indications. Clinical data have shown tesamorelin to have both lipolytic (fat-burning) and anabolic (muscle-building) properties. Our initial development of *EGRIFTA*<sup>TM</sup> focused on the lipolytic properties of the compound.

Tesamorelin's anabolic properties have led us to pursue its development for muscle wasting in COPD patients as our second indication. COPD is characterized by progressive airflow obstruction due to chronic bronchitis or emphysema leading in certain cases to muscle wasting, a decrease of muscle mass and deterioration in functionality. We have completed a Phase 2 trial which demonstrated a statistically significant increase in lean body mass. Based upon these trial results, we intend to randomize our first patient in a new Phase 2 clinical study in the second half of 2011. Based on available market data, we estimate that in 2009, the number of diagnosed COPD patients with muscle wasting was approximately 3.1 million in the United States, France, Germany, Italy, United Kingdom, Spain and Japan.

To solidify our leadership position in the field of GRF therapeutics, we have embarked on a program to discover new generations of GRF analogues. We believe that GRF compounds have the potential to improve patient outcome in many high-value indications, such as wasting in chronic heart failure and renal failure, as well as growth deficiency with abdominal obesity. We also believe that we can improve the route of administration of GRF peptides to make them quicker and easier to use for patients. Our early-stage pipeline also includes compounds for the treatment of Acute Kidney Injury, or AKI, and certain cancers.

# 2.2 RECENT DEVELOPMENTS

Since the end of our most recently completed financial year, we have been engaged in the following activities:

- COPD indication for EGRIFTATM. On February 22, 2011, we announced a new clinical program in muscle wasting in COPD using tesamorelin. Tesamorelin's anabolic properties have led us to pursue the development of tesamorelin for muscle wasting in COPD patients for its second indication. The program will be conducted in stable ambulatory COPD patients with muscle wasting in the Global Initiative for Chronic Obstructive Lung Disease, or GOLD, stage II and III severity experiencing decreased functionality in daily activities.
- Execution of distribution and licensing agreement for EGRIFTATM for European market. On February 3, 2011, we announced the execution, through Theratechnologies Europe Inc., of a distribution and licensing agreement with Ferrer granting it the exclusive commercialization rights of tesamorelin in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. For a description of this agreement, see Item 2.5.
- Execution of distribution and licensing agreement for EGRIFTA<sup>TM</sup> for the Latin American, African and Middle Eastern Markets. On December 6, 2010, we announced the execution, through Theratechnologies Intercontinental Inc., of a distribution and licensing agreement with sanofi-aventis S.A., granting one of its subsidiaries, Sanofi Winthrop Industries, the exclusive distribution rights to EGRIFTA<sup>TM</sup> in Latin America, Africa and the Middle East for the reduction

of excess abdominal fact in HIV-infected patients with lipodystrophy. For a description of this agreement, see Item 2.5.

#### 2.3 THREE YEAR HISTORY

#### 2010

- FDA approval received for EGRIFTATM. On November 11, 2010, we announced that the FDA approved EGRIFTA™ as the first and only
  drug indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (abdominal lipohypertrophy). The FDA
  approval triggered a US\$25 million milestone payment pursuant to our collaboration and licensing agreement with EMD Serono.
- Appointment of new President and Chief Executive Officer. On September 1, 2010, we announced the appointment of Mr. John-Michel T. Huss as President and Chief Executive Officer of the Company, following the retirement of Mr. Yves Rosconi, effective November 30, 2010. Mr. Huss assumed his position on December 1, 2010.
- Execution of research collaboration agreement with UQAM, Gestion Valeo and Transfert Plus. On November 16, 2010, we entered into a research collaboration agreement with the Université du Québec à Montréal, or UQAM, Gestion Valeo, L.P., or Gestion Valeo, and Transfert Plus, L.P, or Transfert Plus, with the goal of discovering short peptide mimics of melanotransferrin with the hope of developing a novel cancer treatment. For a description of this agreement, see "Melanotransferrin peptides (Anti-cancer compounds)" at Item 2.5.
- Adoption of shareholder rights plan. On February 10, 2010, we announced that our board of directors had adopted a shareholder rights plan, effective as of such date. The plan was later ratified by our shareholders at our annual meeting held on March 23, 2010. The plan is designed to provide adequate time for the board of directors and the shareholders to assess an unsolicited takeover bid for Theratechnologies, to provide the board of directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, and to provide shareholders with an equal opportunity to participate in a takeover bid and receive full and fair value for their common shares. For a description of the plan, see Item 9.

#### 2009

- Advisory Committee reviews NDA for tesamorelin. On November 5, 2009, we announced that the Endocrinologic and Metabolic Drugs Advisory Committee of the FDA would be reviewing our New Drug Application, or NDA, for tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.
- *Filing of NDA for tesamorelin.* On June 1, 2009, we announced the filing of an NDA with the FDA for tesamorelin, an analogue of the growth hormone-releasing factor, proposed for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

#### 2008

Closing of transaction with EMD Serono. On December 16, 2008, we announced that we closed the transaction related to the collaboration and licensing agreement with EMD Serono. As part of this transaction, we received an upfront payment of US\$30 million which includes a license fee of US\$22 million from EMD Serono. In addition, Merck KGaA purchased US\$8 million of our common shares at a price of US\$3.67 per share.

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- 52-week confirmatory Phase 3 clinical trial results for tesamorelin. On December 15, 2008, we announced the 52-week results of our confirmatory Phase 3 clinical trial, evaluating the long-term safety profile of tesamorelin in patients with HIV-associated lipodystrophy. The results reported from both the 26-week confirmatory clinical study and 52-week confirmatory clinical study were consistent with the efficacy and safety profile observed in the first Phase 3 clinical study. This announcement concluded the Phase 3 clinical studies for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.
- Execution of collaboration and licensing agreement with EMD Serono for tesamorelin in the United States. On October 29, 2008, we announced the execution of a collaboration and licensing agreement with EMD Serono for the exclusive commercialization rights to tesamorelin in the United States for the reduction of excess abdominal fat in HIV patients with lipodystrophy. For a description of this collaboration and licensing agreement, see Item 2.5.
- 26-week confirmatory Phase 3 clinical trial results for tesamorelin. On June 18, 2008, we announced our 26-week results of our confirmatory Phase 3 clinical trial, evaluating the efficacy of tesamorelin in patients with HIV-associated lipodystrophy. The study was powered to detect an 8% reduction in visceral adipose tissue versus placebo. The study met its primary endpoint as well as important secondary endpoints confirming the positive results obtained in our initial Phase 3 study.
- Execution of strategic agreement with Dr. Grinspoon. On May 15, 2008, we announced our entering into an agreement with both the MGH and Dr. Grinspoon to explore the use of tesamorelin in relative growth hormone deficient abdominally obese, or GHDAO, subjects. MGH, under the direction of Dr. Grinspoon, is the sponsor and is conducting a Phase 2 clinical trial with tesamorelin in subjects who have excess visceral adipose tissue, or VAT, with a moderate growth hormone deficiency and who are abdominally obese. We accepted to provide tesamorelin for this study and the MGH will retain the rights to the results generated by this study, and we obtained an exclusive worldwide license to commercialize any results. Dr. Grinspoon completed subject enrolment in December 2010.
- Initiation of process to explore strategic options. On January 29, 2008, we announced that our board of directors initiated a process to explore strategic options available to the Company to further enhance shareholder value.
- US patent for tesamorelin issued. On January 8, 2008, we announced that the United States Patent and Trademark Office, or USPTO, issued Patent Number 7,316,997 entitled "GH Secretagogues and Uses Thereof" to Theratechnologies. This patent covers methods of treatment of HIV-associated lipodystrophy using tesamorelin. The granting of this patent extended the patent term protection of tesamorelin in HIV-associated lipodystrophy for eight additional years, until 2023.
- Phase 3 first clinical trial results for tesamorelin. On December 5, 2007, we announced that the results of our first Phase 3 clinical trial using tesamorelin were published in the December 6, 2007 New England Journal of Medicine (www.nejm.org). The study, entitled "Metabolic Effects of a Growth Hormone-Releasing Factor in Patients with HIV", outlines, in detail, the 26-week data of the trial. Top-line results of this Phase 3 trial were initially disclosed in December 2006.
- Preclinical work for AKI. We conducted some preclinical work on a molecule known as THG213.29 with the intent of pursuing a clinical
  program in AKI. Through our research and development, we discovered a new bifunctional peptide that appears to have favourable
  properties in the treatment of AKI in animal models of AKI. During our 2008 fiscal year, we

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replaced THG213.29 with the new bifunctional peptide TH0673 in the event we decide to develop a clinical program for AKI.

# 2.4 OUR STRATEGY

Our goal is to leverage our expertise in the field of metabolism and GRF peptides to become a leading specialty pharmaceutical company with the necessary infrastructure to take innovative therapeutic products from research and development to full commercialization in worldwide markets. Key elements of this strategy include:

### Maximize the global commercial potential of EGRIFTA™

In order to maximize the commercial potential of *EGRIFTA*TM we have entered into licensing agreements with EMD Serono, Sanofi and Ferrer for different territories around the world. We intend to continue to support our commercial partners to ensure the successful commercialization of *EGRIFTA*TM in their respective territories. This will include regulatory support, manufacture and supply of *EGRIFTA*TM, and potential co-promotion.

We have developed a new presentation of *EGRIFTATM* which is quicker and easier to use than its current presentation. We are also developing a new and more concentrated formulation of tesamorelin. Compared to our current formulation, this new formulation requires a smaller volume of injection and is expected to be stable at room temperature. In addition, this new formulation could potentially be used with a new delivery device such as a pen, to facilitate patient self-administration. We expect the new presentation and the new formulation will have a positive impact on our manufacturing capacity and will significantly reduce our unit costs.

# Develop tesamorelin for muscle wasting in COPD

We will be conducting a new clinical program in muscle wasting in COPD. We have demonstrated in a first Phase 2 clinical trial that tesamorelin has increased muscle mass in COPD patients. We believe tesamorelin could improve patients' functionality in daily activities and address a significant unmet need in a large and potentially lucrative market.

# Solidify our position as a leader in the field of novel GRF products

We will leverage our expertise in peptide discovery, drug development and regulatory affairs to continue our development of new peptides, primarily GRF peptides, in order to expand our portfolio of product candidates and solidify our position as a leader in this field.

#### Be actively involved in the commercialization of our products

We intend to retain commercial rights to our future products for indications and territories where we believe we can effectively market them. We may also co-promote *EGRIFTATM* in certain territories and tesamorelin in other indications.

#### Pursue external growth opportunities

In addition to developing products internally, we will opportunistically pursue in-licensing arrangements or acquisitions of complementary businesses, compounds or products. We will also identify and evaluate commercial growth opportunities that may include collaborations with drug delivery companies.

# 2.5 OUR PRODUCT AND PRODUCT CANDIDATES

The following table provides an overview of our product and product candidates and their current stages of development:

Development Programs	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Approved
EGRIFTA <sup>TM</sup> (tesamorelin for injection) for HIV-associated lipodystrophy						
Tesamorelin for muscle wasting in COPD				$\rightarrow$		
TH0673 for acute kidney injury						
Novel GRF analogues						
Melanotransferrin peptides for cancer	-					

### EGRIFTA™ — Our Lead Product

*EGRIFTATM* induces the release of growth hormone which causes a reduction in excess abdominal fat (lipohypertrophy) in HIV-infected patients without reducing or interfering with subcutaneous fat, and, as such, has no clinically significant effect on undesired loss of subcutaneous fat (lipoatrophy).

*EGRIFTATM* is currently available in the United States as a once-daily two unit dose (two vials, each containing 1 mg of tesamorelin) of sterilized lyophilized powder to be reconstituted with sterile water for injection. To administer *EGRIFTATM*, 1 ml is retrieved from each vial into one syringe to prepare a single 2 ml patient self-administered subcutaneous injection. *EGRIFTATM* is injected under the skin into the abdomen once a day.

For the purposes of FDA approval, *EGRIFTATM* was evaluated in two clinical trials involving 816 HIV-infected adult men and women with lipodystrophy and excess abdominal fat. In both studies, patients treated daily with *EGRIFTATM* experienced greater reductions in abdominal fat as measured by CT scan and greater improvements in belly appearance distress, compared with patients receiving another injectable solution (placebo). Once the treatment was terminated, the patients' condition reversed to its status prior to the beginning of the treatment. The most commonly reported adverse effects in the studies included reactions due to the release of endogenous hormone, such as joint pain (arthralgia), pain in the extremities, swelling in the lower limbs and muscle pain (myalgia), injection site reactions such as skin redness (erythema), itching (pruritis) and pain and clinically manageable changes in blood sugar control. Our clinical trials did not seek to measure any potential cardiovascular benefits of *EGRIFTATM* on cardiovascular events.

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

to develop a single vial presentation of the existing formulation of EGRIFTATM. We have developed a new presentation of EGRIFTATM which is quicker and easier to use than its current presentation. In the new presentation, EGRIFTATM will be available as a single unit dose (one vial containing 2 mg of tesamorelin) of sterile, lyophilized powder to be reconstituted with sterile water for injection. The FDA requires that this new presentation be available by November 2013 and we expect it to be commercially available before that date. The development of the new presentation is complete and the dossier is ready for regulatory submission.

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- to conduct a long-term observational safety study using EGRIFTATM. The purpose of the long-term observational study required by the FDA is to evaluate the safety of long-term administration of EGRIFTATM.
- to conduct a Phase 4 clinical trial using EGRIFTATM. The primary purpose of the Phase 4 clinical trial is to assess whether EGRIFTATM increases the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat.

The FDA requires that the proposed protocols for the long-term observational safety study and Phase 4 clinical trial be submitted by the second quarter of 2011. Under the terms of our collaboration and licensing agreement, EMD Serono is responsible for finalizing and obtaining approval of such protocols. We will continue to support EMD Serono in developing and finalizing such protocols.

#### Lipodystrophy

Lipodystrophy is characterized by abnormalities in the production and storage of fat. It has two components: lipohypertrophy, abnormal and excessive fat accumulation, and lipoatrophy, the noticeable, localized loss of fat tissue under the skin. In patients with lipohypertrophy, fat accumulation occurs mostly around the waist and may also occur in other regions, including breast tissue and in dorsocervical tissues in the neck, resulting in a "buffalo hump". Excess fat also appears as lipomas, or benign tumors composed of fat cells. In patients with lipoatrophy, the loss of fat tissue generally occurs in the limbs and facial area.

Excess abdominal fat in HIV-infected patients is associated with significant health risks beyond the mortality risk of the HIV infection itself. These health risks include metabolic disturbances such as hyperlipidemia, an increase in the amount of fat in the blood (such as triglycerides and cholesterol), and hyperglycemia, an increase in the amount of sugar in the blood, characterized by insulin resistance, both of which lead to increased risks for cardiovascular disease and diabetes.

In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy, or both. While there is evidence that suggests that lipoatrophy may be reduced with certain newer HIV therapies, we are not aware of any evidence showing that any currently-marketed HIV therapy reduces lipohypertrophy or the incidence of lipohypertrophy. Recent data suggest that different pathophysiological mechanisms are involved in the development of lipohypertrophy and lipoatrophy. The most common statistically significant independent risk factors identified for lipohypertrophy are duration of antiretroviral therapy, markers of disease severity and protease inhibitor use. Other factors include age, genetics, and gender.

#### Market Opportunity

Based on our analysis of 20 independent medical studies published from 2000 to 2004, we estimate that excess abdominal fat in HIV-infected patients affects approximately 29% of HIV-infected patients treated with antiretroviral therapies. According to a separate 2003 independent medical study, we estimate that an additional 12% of untreated HIV-infected patients are also affected by excess abdominal fat.

Based on the above-mentioned data, we have identified the following potential markets for EGRIFTATM.

 United States. The United States market represents the largest commercial opportunity for EGRIFTATM. We estimate the prevalence of HIV/AIDS in the United States will rise to 1.3 million people in 2012. Of this amount, approximately 650,000 people will be treated for

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HIV/AIDS and, of those patients treated, approximately 190,000 will suffer from excess abdominal fat. In addition, approximately 47,000 untreated patients will suffer from excess abdominal fat.

- Europe. We estimate the prevalence of HIV/AIDS in Europe will rise to 1.4 million people in 2012. Of this amount, approximately 590,000
  people will be treated for HIV/AIDS and, of those patients treated, approximately 170,000 will suffer from excess abdominal fat. In
  addition, approximately 42,000 untreated patients will suffer from excess abdominal fat.
- Latin America. We estimate the prevalence of HIV/AIDS in Latin America will rise to 2.2 million people in 2012. Of this amount, approximately 630,000 people will be treated for HIV/AIDS and, of those patients treated, approximately 180,000 will suffer from excess abdominal fat. This number is proportionately lower than the other territories due to a lower percentage of diagnosed and treated patients. With approximately 60,000 treated patients who will suffer from excess abdominal fat, Brazil offers the largest market in Latin America for EGRIFTATM. In addition, approximately 28,000 untreated patients will suffer from excess abdominal fat.

We estimate that the total number of patients diagnosed with and treated for HIV/AIDS who will suffer from excess abdominal fat in our primary target markets will be 540,000 in 2012. We estimate that an additional 117,000 untreated patients may develop lipohypertrophy in such markets.

The foregoing information is based on historical data from the CDC for the United States, and WHO/UNAIDS for Europe and Latin America. We used the historical growth rates derived from that data to estimate the prevalence of HIV/AIDS in 2012.

#### EGRIFTA<sup>™</sup> Commercialization Activities

We are working closely with EMD Serono to support the commercialization of *EGRIFTATM*. We are also working closely with Sanofi and Ferrer to obtain regulatory approval for and the subsequent commercialization of *EGRIFTATM*. Each of our commercial partners were chosen due to their commercial and regulatory capabilities in their respective territories.

#### EMD Serono Agreement — United States

On October 28, 2008, we entered into a collaboration and licensing agreement granting EMD Serono the exclusive commercialization rights to  $EGRIFTA^{TM}$  for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States.

Under the terms of the agreement, EMD Serono has the exclusive right to conduct *EGRIFTATM* commercialization activities in the United States. We are responsible for the manufacturing and supply of *EGRIFTATM* and for the development of a new formulation. The agreement also entitles us to conduct additional clinical programs to develop tesamorelin for potential additional indications. EMD Serono has the option to commercialize products resulting from such additional clinical programs in the United States. If EMD Serono exercises this option, it will pay half of the development and regulatory costs incurred and to be incurred by us in connection with such additional clinical programs. If EMD Serono decides not to exercise its option, we have the right to commercialize tesamorelin for such indications on our own or with third parties. We also have the option to co-promote any product resulting from such clinical programs under terms and conditions to be agreed with EMD Serono. This agreement extends until the expiration of the last valid claim based on a patent right (including patent applications) controlled by us in the United States covering *EGRIFTATM* or any other product based on an additional indication for tesamorelin that EMD Serono has elected to commercialize under the agreement.

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We may receive up to US\$215 million in upfront and milestone payments in addition to royalties and revenues from the sale of *EGRIFTATM* to EMD Serono. To date, we have received US\$65 million which includes an upfront payment and regulatory milestone payments of US\$57 million and an equity investment of US\$8 million. Future milestone payments will be made based on the achievement of certain sales milestones. We will also be entitled to receive royalties at an increasing rate based on achieving specified levels of annual net sales of *EGRIFTATM* in the United States.

We made our first delivery of *EGRIFTATM* to EMD Serono on December 13, 2010. In January 2011, EMD Serono launched *EGRIFTATM* in the United States. EMD Serono is executing a launch program that consists of increasing disease awareness through medical education to doctors, patient advocacy and advertising, marketing and promotion through their experienced sales force, and supporting market access through patient support, co-pay programs, reimbursement education and support for payors.

EMD Serono is responsible for establishing the sale price of *EGRIFTATM* in the United States. The wholesale acquisition cost has been set at US\$23,900 per patient per year. We expect to receive our first royalty payments in the second quarter of 2011.

#### Sanofi Agreement — Latin America, Africa and the Middle East

On December 6, 2010, we entered into a distribution and licensing agreement granting Sanofi, a subsidiary of Sanofi-aventis S.A., the exclusive commercialization rights to *EGRIFTATM* for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East.

Under the terms of the agreement, we will sell *EGRIFTATM* to Sanofi at a transfer price equal to the higher of a percentage of Sanofi's net selling price and a predetermined floor price. Sanofi will be responsible for conducting all regulatory and commercialization activities for *EGRIFTATM* for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTATM* to Sanofi. We have retained all development rights to *EGRIFTATM* for other indications and will be responsible for conducting development activities for any additional potential indications. We also granted Sanofi an option to commercialize tesamorelin for other indications on our own or with a third party. The initial term of this agreement extends until December 2020.

# Ferrer Agreement — Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries

On February 3, 2011, we entered into a distribution and licensing agreement granting Ferrer the exclusive commercialization rights to *EGRIFTATM* for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the agreement, we will sell *EGRIFTA*<sup>TM</sup> to Ferrer at a transfer price equal to the higher of a percentage of Ferrer's net selling price and a predetermined floor price. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with  $EGRIFTA^{TM}$  for the reduction of excess abdominal fat in HIV- infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of  $EGRIFTA^{TM}$  to Ferrer. We have retained all development rights to  $EGRIFTA^{TM}$  for other indications and will be responsible for conducting development activities for any additional potential indications. We have the option to co-promote  $EGRIFTA^{TM}$  for the reduction of excess abdominal fat in HIV-

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infected patients with lipodystrophy in the territories. Ferrer has the option to enter into a co-development and commercialization agreement using tesamorelin for potential additional indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development. This agreement extends until the later of the expiration of the last valid claim based on a patent right (including patent applications) controlled by us covering a product licensed under the agreement or ten years from the date of the first commercial sale of *EGRIFTA*TM for each country covered by the agreement.

#### Unpartnered Territories

We have retained full commercial rights for *EGRIFTATM* in certain territories, including Canada. In territories where we do not currently have commercial partners, we may commercialize *EGRIFTATM* directly or in collaboration with commercial partners.

### Tesamorelin — Our Lead Compound

Tesamorelin is a stabilized 44 amino acid human GRF analogue, which was synthesized in our laboratories in 1995 using our long-acting peptide method. Although natural peptides have significant therapeutic potential, they are subject to enzymatic degradation which severely limits their effectiveness in clinical use. Our long-acting peptide method is a peptide stabilization process which increases the target protein's resistance to enzymatic degradation, while maintaining its natural specificity. This usually results in a more stable and efficient compound, which can thus prolong its duration of action. Tesamorelin induces growth hormone secretion in a natural and pulsatile way. The clinical results obtained to date using tesamorelin suggest a therapeutic potential in both anabolic and lipolytic indications. *EGRIFTA*<sup>TM</sup> has demonstrated the ability to significantly reduce visceral adipose tissue, increase muscle mass and reduce waist circumference.

#### Mechanism of action

In vitro, tesamorelin binds and stimulates human GRF receptors with similar potency as the endogenous GRF. GRF is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone, which is both anabolic and lipolytic. Growth hormone exerts its effects by interacting with specific receptors on a variety of target cells, including chondrocytes, osteoblasts, myocytes, hepatocytes, and adipocytes, resulting in a host of pharmacodynamic effects. Some, but not all these effects, are primarily mediated by insulin-like growth factor one, IGF-1, produced in the liver and in peripheral tissues.

The effects of recombinant human growth hormone, or rhGH, and tesamorelin have been the subject of several clinical trials in the area of HIVassociated lipodystrophy. Based on these clinical trials, the safety profiles of rhGH and tesamorelin appear to be very different. The natural synthesis of growth hormone is regulated by a feedback mechanism preventing its overproduction. Tesamorelin induces optimal activity of the somatotrope function and retains the natural rhythm (pulsatility) of the physiological secretion of growth hormone without interfering with the feedback mechanism mentioned above. With the exogenous administration of rhGH, the feedback mechanisms are short-circuited, which gives rise to higher levels of growth hormone. The side effects associated with rhGH include nerve, muscle or joint pain, swelling due to fluid retention (edema), carpal tunnel syndrome, numbness and tingling of skin and increased risk of diabetes. These side effects are particularly frequent among older people. In addition, rhGH can cause hyperglycemia which makes it contraindicated for patients with diabetes or pre-diabetic conditions.

# Muscle Wasting in COPD — New Indication for Tesamorelin

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We have selected COPD as our second clinical program with tesamorelin. We chose to consider muscle wasting in COPD patients with decreased functioning in daily activities for a clinical program based on the anabolic properties of tesamorelin. The goal of the program is to show an improvement in functionality in daily activities in COPD patients with loss of muscle mass.

We completed a three-month Phase 2 clinical study involving 109 stable ambulatory COPD patients. Patients were randomized to receive either 1 mg or 2 mg doses of tesamorelin, or a placebo each day. Patients treated using 1 mg or 2 mg doses of tesamorelin experienced a statistically significant increase in lean body mass compared with patients receiving a placebo. In addition to the increase in lean body mass, such patients experienced improvements in three functional measures associated with tesamorelin, particularly for the 2 mg group. The three functional measures were:

- Respiratory symptoms, as assessed by St. George's Respiratory Questionnaire;
- Leg discomfort, as assessed by the Borg Scale following an exercise endurance test; and
- Breathing discomfort, as assessed by the Borg Scale following an exercise endurance test.

#### COPD

COPD is characterized by progressive airflow obstruction due to chronic bronchitis or emphysema, two commonly co-existing lung diseases. COPD results in a limitation of the flow of air to and from the lungs resulting in a shortness of breath. In contrast to asthma, the limitation of airflow is not easily reversible and usually gets progressively worse over time.

Many COPD patients are affected by a systemic manifestation which may lead to muscle wasting. Muscle wasting (cachexia or involuntary weight loss), a decrease or thinning of the muscle mass, is associated with several abnormalities, including impaired exercise capacity and functioning and decreased muscle strength. Muscle wasting is an independent predictor of a COPD patient's functional deterioration and mortality, and it is a common symptom in patients with moderate to severe COPD. The importance of improving not only muscle strength, but other functional parameters and quality of life is well recognized in order to improve the well being of patients with COPD and decreased functionality. We are not aware of any treatment for muscle wasting in COPD approved by any regulatory authorities.

#### Market opportunity

According to independent research, 26 million adults aged 40 or over were diagnosed with COPD in the United States, France, Germany, Italy, the United Kingdom, Spain and Japan in 2009. The prevalence of COPD increases with age and is much higher in adult males. The diagnosed population is expected to increase at a compound annual growth rate of 2.5%.

Treatment varies across countries and region, however 17.9 million patients were receiving treatment for COPD management in 2009 in the United States, France, Germany, Italy, the United Kingdom, Spain and Japan. COPD can be classified using four levels of severity, from mild to very severe (stages I to IV) using the GOLD classification. Our program will focus primarily on COPD patients in GOLD stage II and III. Based on available market data, we estimate that in 2009, the number of diagnosed COPD patients in GOLD stage II and III suffering from a muscle wasting condition, with a body mass index of under 25, was approximately 3.1 million in those markets.

Clinical development plan



Tesamorelin's anabolic properties have led us to pursue its development for muscle wasting in COPD patients as our second indication. This clinical development program will be conducted in stable ambulatory COPD patients, GOLD stage II and III, with muscle wasting experiencing decreased functionality in daily activities. It will include three studies:

- One Phase 2 study: This study will be a randomized, placebo controlled study in approximately 200 COPD patients with muscle wasting. Patients will be randomized to receive either one of two different dosages of tesamorelin or placebo each day for six months. We intend to randomize our first patient in this Phase 2 clinical study in the second half of 2011. The Phase 2 study will evaluate the safety and efficacy of using tesamorelin in COPD patients, GOLD stage II and III, with muscle wasting. The primary endpoint will be an increase in lean body mass. Other efficacy endpoints will be measured, such as a six minute walking distance test, exercise endurance time, and quality of life (daily activities). Safety assessments will include monitoring of adverse events and laboratory evaluations.
- Two Phase 3 studies: If the Phase 2 study is successful, we anticipate there will be two 12-month Phase 3 studies (one pivotal and one confirmatory) to be conducted in parallel. We expect a total of approximately 1,200 patients will be included in this program.

We currently believe that the clinical trials will last approximately four years and that the program will cost between approximately \$55 and \$65 million. A significant portion of the costs will be borne by our commercial partners if they elect to exercise their option to commercialize under their respective agreements.

#### **Other Product Candidates**

#### Novel Growth Hormone-Releasing Factor Analogues

We are working on several novel analogues of GRF that have improved chemical stability compared to tesamorelin. To date, we have synthesized over 80 different compounds. We believe that GRF compounds have the potential to improve patient outcome in many high-value indications. We also believe we can improve the route of administration of GRF peptides to make them quicker and easier to use for patients.

#### Compounds for Acute Kidney Injury

AKI is the acute deterioration of kidney function leading to increased urea waste products and electrolyte imbalance in blood. AKI is common among hospitalized patients and complicates the management of patients in intensive care units. According to a 2008 medical publication, AKI affected 3% to 7% of patients admitted to hospital and approximately 25% to 30% of patients in the intensive care unit within days of major surgery. The incidence of AKI was approximately 600,000 to 900,000 patients in the United States per year. Despite hospitalization and renal replacement, the mortality rate is 50% to 60% for dialyzed patients. We believe that hemodialysis is the only approved treatment for post-surgical AKI.

We have identified AKI as a potential clinical program for internal development. We have developed novel peptides specifically tailored for the prevention or treatment of AKI. One of these peptides, TH0673, is a peptide that is currently in preclinical development. We have tested TH0673 in animal models of AKI and have found that it increases creatinine clearance, improves excretion of nitrogenous waste compounds and limits kidney damage. We expect to have additional preclinical results in AKI in the first half of 2011.

Other Discovery Activities — Melanotransferrin Peptides (Anti-cancer compounds)

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In November 2010, we entered into a discovery and collaboration agreement with the UQAM, Gestion Valeo and Transfert Plus in connection with research led by Dr. Richard Béliveau seeking to discover short peptide mimics of melanotransferrin for the development of a new cancer treatment.

Melanotransferrin is related to the transferrin family of proteins and is expressed normally in melanocytes, but also in several cancer cells. Dr. Béliveau's research has demonstrated that soluble melanotransferrin reduces cell migration, invasion and angiogenesis, which are hallmarks of tumorigenesis and metastasis. We have identified small peptides from the melanotransferrin protein which could replicate the functions of the full length protein. Currently, we are optimizing the peptides for better pharmaceutical properties so that the optimized peptides can be tested in animal models of cancer and tumor angiogenesis.

# 2.6 INTELLECTUAL PROPERTY

# Our Current Patent Portfolio

Our current patent portfolio is comprised of patents and patent applications for the following compounds:

- Tesamorelin
- In the United States, we own a patent covering the composition of matter (tesamorelin), which is scheduled to expire in 2015. We have applied for a patent term extension requesting an extension of five years to this patent term. If our request for patent term extension for the entire five year term is granted, the patent protection for tesamorelin in the United States would be extended until 2020. In addition, we own an issued United States patent relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which is scheduled to expire in 2023. Because tesamorelin qualifies as a new chemical entity, we benefit from data protection for a five year period for *EGRIFTATM* ending November 2015. See "Regulatory Exclusivity".
- In Europe, tesamorelin is covered by granted patents scheduled to expire in 2016. In the event of receipt of marketing approval from the European Medicines Agency, or EMA, we intend to apply for supplementary protection certificates, or SPCs, in certain countries which, if granted, could extend the patents covering tesamorelin in the countries where SPCs are approved until 2021. We have also filed two patent applications relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy where, if such patents were granted, they would be scheduled to expire in 2023 and 2025, respectively. As discussed below, the first time a new product is approved in Europe, the regulation provides for a 10 year exclusivity period. Assuming approval in 2012, we would benefit from protection until 2022. See "Regulatory Exclusivity".
- We have obtained a patent covering the composition of matter (tesamorelin) in Brazil that expires in 2019.
- We have filed patent applications for the therapeutic indication of muscle wasting in COPD in several countries, including the United States, where, if such patents were granted, they would be scheduled to expire in 2024, with the exception of a recently granted patent in the United States, which benefits from a patent term adjustment extending its term to 2027.
- We have filed patent applications in several countries, including the United States, for the new formulation of tesamorelin where, if such patents were granted, they would be scheduled to expire in 2028.

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• We have filed United States and international Patent Cooperation Treaty applications, relating to combination therapies of tesamorelin with certain drugs indicated for the treatment of HIV which, if patents issued from these applications were granted, would be scheduled to expire in 2030.

Novel GRF Peptides

• We have recently filed a United States provisional patent application relating to new GRF analogues. Patents claiming priority from this application may be pursued and, if such patents were granted, they would be scheduled to expire in 2032.

AKI

We have filed patent applications in several countries, including the United States, relating to our peptide TH0673 and related peptides, and their use in the treatment of AKI, where, if such patents were granted, they would be scheduled to expire in 2028.

#### **Our Trademarks & Other Intellectual Property**

*EGRIFTATM* is the trademark used for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. Trademark registration in the United States necessitates a prior commercial use in the territory in order to be granted. We are in the process of filing the declaration of use to obtain trademark registration.

We have obtained registration for *EGRIFTATM* in Europe, Japan, Australia, Norway, Switzerland, Mexico and Lebanon and have filed trademark applications for this trademark in other countries. The use of the trademark in each jurisdiction generally requires the approval of the regulatory authorities in such jurisdictions.

Other trademarks related to tesamorelin have been filed as part of our business strategy. We have also reserved certain domain names in order to support future activities.

# **Our Policy on Intellectual Property**

Our intellectual property practice is to keep all information relating to proprietary compounds, inventions, improvements, trade secrets, know-how and continuing technological innovation confidential and, where practicable, file patent and trademark applications. In particular, as part of our intellectual property protection practice, we:

- perform surveillance of third party patents and patent applications in order to identify any third party patent or third party patent application which, if granted, could be infringed by our activities;
- where practicable, file patent applications for any new and patentable invention, development or improvement in the United States and in other countries;
- prosecute all pending patent applications in conformity with applicable patent laws and in a manner that efficiently covers our activities;
- file trademark applications in countries of interest for our trademarks;
- register domain names in countries of interest; and

maintain our intellectual property rights by paying such government fees as may be necessary to ensure such rights remain in force.

#### **Regulatory Exclusivity**

The regulatory regimes of the United States and Europe may provide market exclusivity for a pharmaceutical product. Data protection and patent term extension provide a patent holder with additional protection against third parties who may wish to commercialize a product similar to an approved product.

#### Data Protection

In the United States, the *Drug Price Competition and Patent Term Restoration Act of 1984*, also known as the *Hatch-Waxman Act*, awards, in certain circumstances, non-patent marketing exclusivities to pioneer drug manufacturers. The *Hatch-Waxman Act* provides five years of non-patent marketing exclusivity within the United States to an applicant who gains approval of a New Drug Application, or NDA, for a "new chemical entity," a drug for which the FDA has not previously approved any other new drug with the same active moiety, which is the molecule or ion responsible for the action of the drug. This marketing exclusivity prevents the FDA from approving, in certain circumstances, any abbreviated new drug application for a generic drug or any 505(b)(2) NDA. See "Government Regulation — United States — FDA Process" below.

In Europe, when a product based on a new compound is approved, the EMA grants a 10 year exclusivity period beginning on the date of such approval. When the same compound is approved for a second indication within the first eight years of this 10 year period, the exclusivity period is extended by one year, providing a total exclusivity period of 11 years for the compound.

#### Patent Term Extension

In the United States, the *Hatch-Waxman Act* permits patent term extension for one patent per approved drug of up to five years for patent term lost during product development and the FDA regulatory review process. However, patent term extension cannot extend the remaining patent term beyond a total of 14 years from the product's approval date. The patent term extension period is generally one-half the time between the effective date of an Investigational New Drug Application, or IND, and the submission date of an NDA plus the time between the submission date of an NDA and the NDA. We have applied for a patent term extension with respect to tesamorelin.

In the European Union, SPCs for medicinal products are governed by *Regulation 469/2009* with effect from May 2009. An SPC has the effect of extending the term of a patent relating to protection of a particular medicinal product by compensating the patentee for some lost patent protection caused by the length of time taken to obtain marketing authorisation for the product in question. An SPC is a national right, available in member states of the European Union by application to the national patent office of each state for which a certificate is desired. The SPC must be based on a patent but since an SPC is only granted in respect of a very specific active ingredient in a product, it is generally of rather more limited scope than the patent on which it is based. Typically, the term of the SPC is equal to the period which has elapsed between filing of the patent application and grant of the first European Union marketing authorisation less five years. The term of the SPC may not, generally, exceed five years. However, some European Union legislation regarding pediatric medicines provides for a six-month extension of the basic SPC term in certain circumstances. The SPC takes effect on expiry of the basic patent. In each country for which SPC protection is sought, a separate SPC application must be filed within six months of the grant of the first marketing authorisation in that country for the active ingredient(s) in question.

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# 2.7 MANUFACTURING

We do not own or operate commercial scale manufacturing facilities for the production of our product or any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, drug substance and finished product for clinical trials and commercial sale.

We are responsible for the manufacture and supply of tesamorelin to ensure the commercialization of *EGRIFTA*<sup>TM</sup> under our agreements with EMD Serono, Sanofi and Ferrer. As part of our agreement with EMD Serono, we are required to maintain certain levels of inventory. In order to fulfill these contractual obligations, we have negotiated and entered into various third-party supply agreements.

# Bachem

We have an agreement with Bachem Inc., an American subsidiary of Swiss-based Bachem AG, providing for the manufacturing and supply of the active pharmaceutical ingredient of tesamorelin for clinical programs and *EGRIFTATM* for commercial sale in the United States.

#### Draxis

We have an agreement with Draxis Pharma, a division of Draxis Specialty Pharmaceuticals, Inc., or Draxis, providing for the manufacture and supply of the finished form of tesamorelin for clinical programs and *EGRIFTATM* for commercial sale. Under our agreement, Draxis must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions.

We have identified and initiated discussions with possible secondary suppliers of these products. We believe that there are alternate sources of supply for these products that will be able to satisfy our needs and will be able to receive FDA qualification. We expect our new presentation as well as our new formulation of tesamorelin will significantly increase our production capacity for *EGRIFTATM* due to the smaller quantity of vials, shorter manufacturing process times and increased batch sizes.

We have also entered into the following manufacturing agreements as a result of our undertakings under the distribution and licensing agreement with EMD Serono wherein we agreed to supply the injection tool kits for *EGRIFTATM* namely:

#### **Becton Dickinson**

On November 6, 2009, we entered into a supply agreement with Becton Dickinson Canada Inc., or Becton Dickinson. Under this agreement, Becton Dickinson is responsible for supplying us with syringes and hypodermic needles which are provided with *EGRIFTA*<sup>TM</sup> in the United States.

#### Hospira

On March 26, 2009, we entered into a development and supply agreement with Hospira Worldwide, Inc., or Hospira. Under this agreement, Hospira is responsible for manufacturing and supplying us with sterile water for injection, filled and finished in plastic vials, in connection with the sale of *EGRIFTATM* in the United States.

#### ABAR

On January 5, 2010, we entered into a supply agreement with Gruppo Cartotecnico ABAR Litofarma S.R.L., or ABAR, an Italian company, in order to ensure the commercial supply of pharmaceutical mass market folding boxes for the sale of *EGRIFTATM* in the United States.

# 2.8 COMPETITION

The pharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and research institutions, many of whom have greater financial, technical and human resources than us. We believe the key competitive factors that will affect the development and commercial success of *EGRIFTA*TM and our product candidates are efficacy, safety and tolerability profile, reliability, product acceptance by physicians and other healthcare providers, convenience of dosing, price and reimbursement. Also, the development of new treatment methods for the indications we are targeting could render our drugs non-competitive or obsolete. We are not aware of other GRF products being commercialized or in development for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy although we may face indirect competition for *EGRIFTA*TM from other drugs that may be prescribed by physicians. The use of these other drugs for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy has not been approved by the FDA nor any other regulatory authority.

We believe that competition in the area of muscle wasting in COPD patients is limited. We are aware of one other compound which has completed a Phase 1 clinical study in COPD muscle wasting (GOLD stage I and II). We may face indirect competition from other drugs such as anabolic steroids, testosterone and growth hormone that may be prescribed by physicians. However, these drugs have not been approved by the FDA for muscle wasting in COPD.

### 2.9 GOVERNMENT REGULATION

#### Overview

The research, development, manufacture and marketing of pharmaceutical products are governed by various governmental authorities throughout the world to ensure efficacy and safety.

Governmental authorities in the United States at the federal, state and local level, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products, such as *EGRIFTA*<sup>TM</sup> and other product candidates that we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States or foreign requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. Sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

On November 10, 2010, the FDA approved *EGRIFTATM* as the first approved treatment for excess abdominal fat in HIV-infected patients with lipodystrophy. Our other product candidates must receive regulatory approval from the FDA or other relevant foreign regulatory authorities before they may legally be marketed in the United States or other countries.

In Canada, these activities are governed by the provisions of the *Food and Drugs Act* and its regulations, which is enforced by the Therapeutic Products Directorate of the Health Products and Food Branch of Health Canada. We have not yet applied to market *EGRIFTATM* in Canada.

United States — FDA Process

Before new pharmaceutical products may be sold in the United States, clinical trials of the product candidates must be conducted and the results submitted to the FDA for approval. The drug approval process requires, among other things, a demonstration of product safety and efficacy. Generally, a demonstration of safety and efficacy includes preclinical testing and clinical trials of product candidates. The testing, manufacture and marketing of pharmaceutical products in the United States requires the approval of the FDA. The FDA enforces laws and regulations which apply to preclinical testing, clinical trials, and manufacture of these products. The drug approval process in the United States is described in brief below.

Pre-Clinical Testing: Before testing of any compounds with potential therapeutic value in human subjects may begin in the United States, stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes laboratory evaluations of product pharmacology and toxicity in animal studies of the drug candidates. In parallel, the chemistry of the drug candidates must be elucidated and their manufacturing, including formulation and stability, clearly defined and controlled.

Investigational New Drug Application: Among other things, pre-clinical testing results obtained from animal studies and in vitro studies, are submitted to the FDA as part of an IND application and are reviewed by the FDA prior to the commencement of human clinical trials. An IND sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. Unless the FDA objects to an IND (referred to as a clinical hold), the IND becomes effective 30 days following its receipt by the FDA. Once trials have commenced, the FDA may stop the trials at any time by placing them on "clinical hold" because of safety concerns or noncompliance. If the FDA issues a clinical hold, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Accordingly, we cannot be sure that submission of a IND will result in the FDA allowing clinical trials to begin or that, once began, issues will not arise that suspend or terminate such trials.

Clinical Trials: Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator pursuant to an FDA-approved protocol. Each clinical trial must be conducted under the auspices of an Institutional Review Board, or IRB, that considers, among other things, ethical factors, the safety of human subjects and approves the patient informed consent, which must be agreed to by all participants prior to participation in the clinical trial. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the FDA for review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another.

All phases of clinical trials must be conducted in conformance with Good Clinical Practices, or GCP, which are ethical and scientific quality standards for conducting, recording, and reporting clinical trials to assure that the rights, safety, and well-being of trial participants are protected, and the FDA's regulations for the protection of human subjects.

Phase 1 Clinical Trials: Phase 1 clinical trials represent the initial administration of the investigational drug to a small group of healthy human subjects or, more rarely, to a group of select patients with the targeted disease or disorder. The goal of Phase 1 clinical trials is typically to test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.

Phase 2 Clinical Trials: Phase 2 clinical trials involve a small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine

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dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

Phase 3 Clinical Trials: Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase 3 clinical trials are initiated to establish further clinical safety and efficacy of the investigational drug in a broader sample of the patient population with the target disease or disorder at geographically dispersed study sites in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for regulatory approval and product labeling.

New Drug Application: All data obtained from a comprehensive development program including research and product development, manufacturing, pre-clinical and clinical trials and related information are submitted in an NDA to the FDA. In addition to reports of the trials conducted under the IND, the NDA includes information pertaining to the preparation of the new drug, chemistry manufacturing and controls, or CMC, analytical methods, details of the manufacture of finished products and proposed product packaging and labeling. The submission of an application is no guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. The re-submitted application is also subject to review before the FDA accepts it for filing. Once an application is accepted for filing, an FDA review team — medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts — evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use and whether the applicant's manufacturing complies with Good Manufacturing Practices, or GMP, to assure and preserve the product's identity, strength, quality and purity. As part of the approval process, the FDA will inspect the facility or facilities where the product is manufactured. The FDA review process may be extended by FDA requests for additional information or clarification. In some cases, the FDA may decide to expedite the review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs.

As part of its review, the FDA may refer the application to an advisory committee for evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Under legislation enacted in 2007, the FDA may determine that a risk evaluation and mitigation strategy, or REMS, is necessary to ensure that the benefits of a new product outweigh its risks. If required, a REMS may include various elements, such as publication of a medication guide, patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

In reviewing an NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. The FDA may require larger or additional clinical trials, leading to unanticipated delay or expense. Even if such additional information and data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials may be subject to different interpretation, and the FDA may interpret data differently than the applicant. The receipt of regulatory approval often takes a number of years, involving the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, or restrictions on direct-to-consumer advertising or commitments to conduct additional research post-approval. The FDA will

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issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The deficiencies may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. In addition, changes in FDA approval policies or requirements may occur, or new regulations may be promulgated, which may result in delay or failure to receive FDA approval.

Changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components requires review and approval of the FDA.

Under the *Hatch-Waxman Act*, the U.S. Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. The *Hatch-Waxman Act* requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the Orange Book. The *Hatch-Waxman Act* allows for, under certain circumstances, an abbreviated NDA, or ANDA, where an applicant seeks to determine that its proposed product is biologically equivalent to the reference drug. ANDA applicants do not have to conduct extensive clinical trials to prove the safety or efficacy of the drug product; rather, they are required to conduct less rigorous bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, are listed as such by the FDA, and can often be substituted by pharmacists under prescriptions written for the original listed drug. In addition, in certain cases, an application for marketing approval may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant and for which the applicant has not obtained a specific right to reference those studies. Such applications, known as a 505(b)(2) NDA, are permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approval cuive ingredient in a novel formulation or for a new indication. Section 505(b)(2) also permits the FDA to rely for such approvals on literature or on a finding by the FDA of safety and efficacy of the previously approved drug product. In addition, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA's finding of safety and efficacy of the previously approved drug product. In addition, a 505(b)(2) NDA for changes to a previously approved drug product may rely on the FDA or

The *Pediatric Research Equity Act*, or PREA, requires NDAs (or NDA supplements) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to contain data assessing the safety and efficacy for the claimed indication in all relevant pediatric subpopulations. Data to support dosing and administration also must be provided for each pediatric subpopulation for which the drug is safe and effective. FDA may grant deferrals for the submission of data, or full or partial waivers from the PREA requirements. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation, as described below, has been granted.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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Post-Approval Studies and Registries: Post-approval studies, also referred to as Phase 4 clinical trials are studies that are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies be conducted post-approval, and in these cases these Phase 4 studies are called post-marketing commitments.

Adverse Event Reporting: Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal or suspension of the product from the market. Furthermore, in September 2007 the *Food and Drug Administration Amendments Act of 2007* was enacted, which provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA's authority with respect to post-marketing safety surveillance including, among other things, the authority to require additional post-approval studies or clinical trials and mandate label changes as a result of safety findings, including the development and implementation of a REMS.

#### Orphan Drug Designation

Under the *Orphan Drug Act*, the FDA may grant orphan designation to a drug intended to treat a "rare disease or condition," which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales in the United States of the drug. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in, or shorten the duration of the regulatory review and approval process.

If a drug that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Competitors, however, may receive approval of different drugs for the indication for which the orphan product has exclusivity or may obtain approval for the same drug but for a different indication for which the orphan product has exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug designated as an orphan drug receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in the European Union.

#### **Expedited Development and Review Programs**

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the

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FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for market, including a fast track program, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

#### Non-U.S. Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations governing clinical studies and commercial sales and distribution of our products in other jurisdictions around the world. Whether or not we obtain FDA approval for a product, we must obtain approvals from the comparable regulatory authorities of foreign countries before we can commence clinical studies or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary greatly from country to country. In some international markets, additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

In the European Union, medicinal products must be authorized either through the decentralized procedure by the competent authorities of the European Union Member States, or through the centralized procedure by the European Commission following an opinion by the EMA. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The centralized procedure is compulsory for medicines produced by certain biotechnological processes, products with a new active substance indicated for the treatment of certain diseases such as neurodegenerative disorder or diabetes and products designated as orphan medicinal products, and optional for those products which are highly innovative or for which a centralized process is in the interest of patients. The decentralized approval procedure provides for approval by one or more "concerned" member states based on an assessment of an application performed by one member state, known as the reference member state. Under the decentralized approval procedure, an applicant submits an application, or dossier, and related materials (draft summary of product characteristics, draft labeling and package leaflet) to the reference member state and concerned member states. The reference member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report, each concerned member state must decide whether to approve the assessment report and related materials. If a member state objects to approval of the

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assessment report and related materials on the grounds of potential serious risk to public health, the disputed points may eventually be referred to the European Commission, whose decision is binding on all member states. In many European Union countries, pricing and reimbursement negotiations must also take place before the product is sold in their national market between the company marketing the product and the competent national authorities.

In order to obtain approval for commercializing new drugs in Canada, we must satisfy many regulatory conditions. We must complete preclinical studies in order to file a Clinical Trial Application, or CTA, in Canada. We then receive different clearance authorizations to proceed with Phase 1 clinical trials, which can then lead to Phase 2 and Phase 3 clinical trials. Once all three phases of trials are completed, we file a registration file named a New Drug Submission, or NDS, in Canada. If the NDS demonstrates that the product was developed in accordance with the regulatory authorities' rules, regulations and guidelines and demonstrates favourable safety, efficacy and receives a risk/benefit analysis, then the regulatory authorities issue a notice of compliance, which allows us to market the product.

### **Good Manufacturing Practices**

The FDA, the EMA, the competent authorities of the European Union Member States and other foreign regulatory agencies regulate and inspect equipment, facilities, and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. Among the conditions for NDA or equivalent foreign approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures adhere to the FDA's or other competent authorities' current GMP. Before approval of an NDA or equivalent foreign approval, the FDA or other competent authority may perform a pre-approval inspection of a manufacturing facility to determine its compliance with GMP and other rules and regulations. In complying with GMP, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Similarly, NDA or equivalent foreign approval, and the correction of these shortcomings may be beyond our control. Facilities are also subjected to the requirements of other government bodies, such as the U.S. Occupational Safety & Health Administration and the U.S. Environmental Protection Agency.

If, after receiving clearance from regulatory agencies or competent authorities, a company makes certain changes in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Our third-party suppliers must adhere to GMP and product-specific regulations enforced by the FDA or other competent authorities following product approval. The FDA, the European Union and other national competent authorities and regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our suppliers' equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against them, including the suspension of manufacturing operations.

# **Good Clinical Practices**

The FDA, the EMA and other competent authorities promulgate regulations and standards, commonly referred to as GCP, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the European Union and other foreign national competent authorities and regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. We rely on third-party service providers to conduct our clinical trials. If our study sites fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed

unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications.

# **Good Laboratory Practices**

The FDA and other regulatory authorities promulgate regulations and standards, commonly referred to as Good Laboratory Practices, or GLP, for the conduct of non-clinical, commonly referred to as "preclinical," non-human studies to provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. Compliance with GLP is intended to assure regulatory authorities of the quality and integrity of the results obtained during the preclinical studies. Before we may test our product candidates on humans in clinical trials, we must first conduct preclinical testing, including animal studies, in accordance with GLP. The FDA or other regulatory authorities may inspect the testing facilities where our pre-clinical studies are conducted. The results of preclinical studies in the United States, Europe or other countries, not conducted in accordance with GLP, might be inadmissible in support of an NDA in the United States, or comparable applications in other countries.

# United States Sales and Marketing

Our commercial partner, EMD Serono, will be subject to various United States regulations relating to the sales and marketing of *EGRIFTA*<sup>TM</sup> in the United States. The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA actively enforces the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The FDA does not regulate the practice of medicine by physicians in their choice of treatment, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

Marketing of *EGRIFTA*TM within the United States is also subject to various federal and state laws pertaining to health care "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our commercial partners' practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent.

In addition, several states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. The recently enacted health care reform legislation will require record-keeping and disclosure to the federal government of payments to physicians commencing in 2012. Any activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege or convict our commercial partner of violating these laws, our business could be harmed. In addition, there is ability for private individuals to bring similar actions.

Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

# 2.10 PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and in other countries, sales of *EGRIFTATM* and our other product candidates will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities (such as the Centers for Medicare & Medicaid Services in the United States), managed care providers, private health insurers and other organizations. We believe *EGRIFTATM* will achieve a high degree of physician and payor acceptance, driven by our product's safety and efficacy, the lack of approved alternative therapies for these patients and the prominent medical and social need to treat HIV/AIDS patients.

However, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare product candidates. We, or our commercial partners, may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of *EGRIFTATM* or our other product candidates may not be considered cost-effective. It is time consuming and expensive for us, and our commercial partners, to seek reimbursement from third-party payors. Reimbursement may not be available or sufficient to allow us to sell *EGRIFTATM* or our other product candidates on a competitive and profitable basis.

#### **United States**

Pursuant to our agreement with EMD Serono, they are responsible for identifying and obtaining possible reimbursements under such government programs in the United States. The U.S. Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably. For example, in March 2010, President Obama signed into law the *Patient Protection and Affordable Care Act*, and the associated reconciliation bill, which we refer to collectively as the *Health Care Reform Law*, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the *Health Care Reform Law* revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposes a significant annual fee on companies that manufacture or import certain branded prescription drug products and biologic agents. Substantial new provisions affecting compliance also have been enacted, which may require us, or EMD Serono, to modify our business practices with healthcare practitioners. We will not know the full effects of the *Health Care Reform Law* until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the *Health Care Reform Law*, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and aslo may increase our regulatory burdens and operating costs.

The *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, or MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries, and included a major expansion of the prescription drug benefit under a new Medicare Part D. Medicare Part D went into effect on January 1, 2006. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient

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prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee.

It is not clear what effect the MMA will have on the prices paid for *EGRIFTATM* and our other product candidates. Some studies indicate that Part D lowered the average price and increased the utilization of prescription drugs by Medicare beneficiaries. Government payment for some of the costs of prescription drugs may increase demand for products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

There are also laws that govern a company's eligibility to participate in Medicare and Medicaid reimbursements. For example, a company may be debarred from participation if it is found to have violated federal anti-kickback laws, which could have a significant effect on a company's ability to operate its business.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations, and additional legislative proposals. Indeed, we expect that there will continue to be a number of U.S. federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. At the present time, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress is considering passing legislation that would lift the ban on federal negotiations. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could harm our business, financial condition and results of operations.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

#### Europe and other countries covered by our agreements

Outside of the United States, sales of *EGRIFTA*<sup>TM</sup> and our other product candidates will depend in part on the availability and level of reimbursement from third-party payers. Third-party payers can be public or private or a combination of both. In order to obtain public reimbursement, prescription drugs are often evaluated by specialized bodies in a country. This process is in many cases independent of marketing approval and the time to carry out the evaluation differs in each country, often extending beyond the initial regulatory approval date of the drug.

The requirements and aspects considered during the assessment of a new prescription drug are not necessarily the same in each country and are given different weight depending on the countries' attitudes towards providing public healthcare and the government's willingness to pay for these new



drugs. We or our commercial partners could be required to conduct specific health economic and other studies or analyses in order to satisfy such requirements. The decision to comply with such requirements will depend on the prospects of obtaining a positive opinion and the costs involved in the process and the profitability of the market.

In many jurisdictions, pricing plays an important role in the evaluation of prescription drugs for reimbursement and in most cases, there are price controls that can include, but are not limited to, reference pricing to drugs sold within the country and in other countries, the evaluation of what a fair price would be based on the condition that is being treated and innovative quality of the new drug.

Many countries, particularly in Europe, have initiated cost-cutting measures which have been reflected in reduced budgets for drugs, higher discounts imposed on manufacturers and price negotiations between authorities and manufacturers among other actions. We expect the current reimbursement evaluation process and pricing policies to keep evolving in ways that we may not foresee.

In Latin America, Brazil has a formal price procedure through Agência Nacional de Vigilância Sanitoria (ANVISA) which determines the price of a pharmaceutical based on five reference countries, including the United States. However, there is uncertainty in pricing of pharmaceutical drugs in Latin America in general.

Pursuant to our agreements with Sanofi and Ferrer, each is responsible for identifying and obtaining possible reimbursements under such government programs in their respective territories.

#### 2.11 EMPLOYEES

As at November 30, 2010, we had 99 employees, all of whom were employed in Canada. All of our employees are engaged in administration, finance, research and development, regulatory and business development functions. None of our employees are unionized. We believe the relations with our employees are good.

### 2.12 FACILITIES

We carry out our activities at 2310 Alfred-Nobel Boulevard in the Technoparc Montréal in Ville Saint-Laurent, Québec, Canada. We lease a 36,400 square-foot building, which houses both offices and laboratories which enable us to conduct small-scale peptide manufacturing, discovery and manage preclinical and clinical research.

The facilities contain laboratories which enable us to conduct small-scale peptide manufacturing, discovery and preclinical research. Peptide compounds are synthesized by our pharmaceutical development department using manual and semiautomatic methods with reactors of different sizes (from 50 to 8000 ml) and also a 12-channel automated peptide synthesizer. The peptides are purified using preparative high performance liquid chromatography, or HPLC, comprising either the Dynamic Axial Compression column, or a number of pre-packed columns. The final peptides are dried to a solid form using lyophilization equipment. The analyses on the quality of the peptides are done using a variety of equipment including HPLC instruments Agilent 1100 and 1200, UV spectrophotometers and a water content analyzer.

We also have discovery and preclinical research laboratories which include two cell culture rooms and several chemical hoods. A Mesoscale chemiluminometer (Sector PR100) is used for sensitive immunological and cell-based assays. Several HPLC instruments for preformulation and purity determinations, scintillation spectrophotometers for radioactivity measurements, and fluorospectrophotometers and colorimetric plate readers for cell-based screens and immunoassays

enable in-house discovery and preclinical research. A designated laboratory section is equipped to conduct studies according to GLP.

# 2.13 ENVIRONMENT

To our knowledge, at our current development stage, environmental protection requirements do not have a significant financial or operational impact on our capital expenditures, income or competitive position within the normal course of our operating activities.

# **ITEM 3 RISK FACTORS**

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

# 3.1 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCT AND PRODUCT CANDIDATES

# Our commercial success depends largely on the commercialization of EGRIFTA™; the failure of EGRIFTA™ to obtain commercial acceptance would have a material adverse effect on us.

Our ability to generate revenues in the future is primarily based on the commercialization of *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. In the short-term, these revenues should be primarily derived from the U.S. market alone. Although we have entered into a collaboration and licensing agreement with EMD Serono for the commercialization of *EGRIFTA*<sup>TM</sup> in the United States, there can be no assurance that *EGRIFTA*<sup>TM</sup> will be successfully commercialized in the United States, or in any other country. Although we are developing other peptides, all of them are at earlier stages of development and none of them may reach the clinical trial phase, obtain regulatory approval or, even if approved, be successfully commercialized.

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

- receipt of regulatory approvals for EGRIFTATM from regulatory agencies in the territories other than the United States in which we wish to
  expand the commercialization of tesamorelin;
- market acceptance of *EGRIFTATM* by the medical community, patients and third-party payors (such as governmental health administration authorities and private health coverage insurers);
- the amount of resources devoted by our commercial partners to commercialize EGRIFTATM in their respective territories;
- maintaining manufacturing and supply agreements to ensure the availability of commercial quantities of EGRIFTATM through validated processes;
- the number of competitors in our market; and
- · protecting and enforcing our intellectual property and avoiding patent infringement claims.

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

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

Although our collaboration and licensing agreements with EMD Serono, Sanofi and Ferrer contain provisions governing their respective responsibilities as partners for the commercialization of *EGRIFTATM* in their respective territories, our dependence on these partners to commercialize *EGRIFTATM* is subject to a number of risks, including:

- our limited control of the amount and timing of resources that our commercial partners will be devoting to the commercialization, marketing and distribution of tesamorelin, including obtaining patient reimbursement for EGRIFTATM, which could adversely affect our ability to obtain or maximize our royalty payments;
- disputes or litigation that may arise between us and our commercial partners, which could adversely affect the commercialization of tesamorelin, all of which would divert our management's attention and our resources;
- our commercial partners not properly defending our intellectual property rights or using them in such a way as to expose us to potential litigation, which could, in both cases, adversely affect the value of our intellectual property rights; and
- corporate reorganizations or changes in business strategies of our commercial partners, which could adversely affect a commercial partner's willingness or ability to fulfill its obligations under its respective agreement.

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

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

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

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

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

Our reliance on third-party manufacturers exposes us to a number of risks. We may be subject to delays in or suspension of the manufacturing of *EGRIFTATM* and tesamorelin if a third-party manufacturer:

- becomes unavailable to us for any reason, including as a result of the failure to comply with GMP regulations;
- experiences manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with GMP or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis.

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

Any delay in or suspension of the supply of tesamorelin could delay or interrupt the conduct of clinical trials of our new clinical programs relating to muscle wasting in COPD.

# Even though we have received regulatory approval for EGRIFTATM in the United States, we still may not be able to successfully commercialize it if we do not gain market acceptance and the revenue that we generate from its sales, if any, may be limited.

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

acceptance of the product by physicians and patients as safe and effective treatments and addressing a significant unmet medical need;

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

If *EGRIFTATM* does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from this product, and we may not be able to achieve profitability. Our efforts, and the efforts of our commercial partners, to educate the medical community and third-party payors on the benefits of tesamorelin may require significant resources and may never be successful.

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

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

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

#### We are substantially dependent on revenues from EGRIFTATM.

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

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

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

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

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

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

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

- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market, with low or lower prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in foreign economies and markets;
- compliance with tax, employment, immigration and labour laws for employees traveling abroad;

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- foreign taxes;
- foreign exchange contracts and foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labour unrest is more common than in the United States and Canada;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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

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

In several countries, including countries which are in Europe, Latin America, Africa, and the Middle East, the pricing of prescription drugs may be subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the marketing of a product. To obtain reimbursement or pricing approval in some countries, a clinical trial that compares the cost-effectiveness of a product candidate to other available therapies may be required. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our commercial partners may not be willing to devote resources to market and commercialize *EGRIFTATM* or may decide to cease marketing such product. In such case, our business, prospects and results of operations could be materially adversely affected.

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

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

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

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

We import and export products and raw materials from and to several jurisdictions around the world. This process requires us and our commercial partners to operate in a number of jurisdictions with different customs and import/export regulations. The regulations of these countries are subject to change from time to time and we cannot predict the nature, scope or impact of these changes upon our operations. We and our commercial partners are subject to periodic reviews and audits by U.S. and foreign authorities responsible for administering these regulations. To the extent that we or our commercial partners are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties and increased duties, which may, individually or in the aggregate, negatively impact our business, operating results and financial condition.

### 3.2 RISKS RELATED TO THE REGULATORY REVIEW PROCESS

# Even after regulatory approval has been obtained regulatory agencies may impose limitations on the indicated uses for which our products may be marketed, subsequently withdraw approval or take other actions against us that would be adverse to our business.

Even though we have obtained marketing approval of *EGRIFTA*<sup>TM</sup> in the United States, the FDA and regulatory agencies in other countries have the ability to limit the indicated use of a product. Also, the manufacture, marketing and sale of our products will be subject to ongoing and extensive governmental regulation in the country in which we intend to market our products. For example, although we obtained marketing approval of *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States, the marketing of *EGRIFTA*<sup>TM</sup> will be subject to extensive regulatory requirements administered by the FDA, such as adverse event reporting and compliance with marketing and promotional requirements. The FDA has also requested that we comply with certain post-approval requirements in connection with the approval of *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, namely, the development of a single vial formulation of *EGRIFTA*<sup>TM</sup> (the development of a new presentation of the same formulation), a long-term observational safety study using *EGRIFTA*<sup>TM</sup>; and a Phase 4 clinical trial. Although we have received marketing approval from the FDA of tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, there can be no guarantee that regulatory agencies in other countries will approve tesamorelin for this treatment in their respective countries.

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

- restrictions on the use of the product, manufacturers or manufacturing processes;
- warning letters;
- civil or criminal penalties;
- fines;
- injunctions;
- product seizures or detentions;



- import or export bans or restrictions;
- product recalls and related publicity requirements;
- suspension or withdrawal of regulatory approvals;
- total or partial suspension of production; and
- refusal to approve pending applications for marketing approval of new product candidates or supplements to approved applications.

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

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

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

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

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

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

Obtaining regulatory approval is subject to the discretion of regulatory agencies in each relevant jurisdiction. Therefore, even if we obtain regulatory approval from one agency, or succeed in filing the equivalent of an NDA, in other countries, or have obtained positive results relating to the safety and efficacy of a product candidate, a regulatory agency may not accept the filing or the results contained therein as being conclusive evidence of the safety and efficacy of a product candidate in order to allow us to sell the product candidate in its country. A regulatory agency may require that additional

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tests on the safety and efficacy of a product candidate be conducted prior to granting approval of such product candidate. These additional tests may delay the approval of such product candidate, can have a material adverse effect on our financial condition and results of operations based on the type of additional tests to be conducted and may not necessarily lead to the approval of the product candidate.

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

Obtaining FDA approval for the commercialization of drug products requires a demonstration through preclinical studies and clinical trials that the drug is safe and effective. All of our product candidates are at the discovery stage, except our peptide for the treatment of AKI, which is in preclinical development. In addition, in order to market tesamorelin for other indications, we will need to demonstrate its effectiveness and safety through additional studies and clinical trials. Favourable results in our trials of tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy may not be predictive of the efficacy and safety results in our Phase 2 clinical trials of tesamorelin for the treatment of muscle wasting in COPD.

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

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

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

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

In the United States, the MMA changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional

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pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and sales price that we receive for *EGRIFTATM* or any other approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

### 3.3 RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

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

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

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

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

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

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

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

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

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

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

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violate third-party patents and other third-party intellectual property rights in the United States or other jurisdictions.

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

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

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

We have not been served with any notice alleging that we infringe a third-party patent, but there may be issued patents that we are unaware of that our products may infringe, or patents that we believe we do not infringe but ultimately could be found to infringe. We are aware of third-party patents for the reduction of accumulation of fat tissue in HIV patients and, if a patent infringement suit was brought against us, we believe that we should not be found to infringe any valid claims of these patents. If we were to challenge the validity of a competitor's issued United States patent in a United States court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. We cannot guarantee that a court would find in our favour on questions of infringement and validity. Any finding that we infringe or violate a third-party patent or other intellectual property right could materially adversely affect our business, financial condition and operating results.

#### 3.4 OTHER RISKS RELATED TO OUR BUSINESS

#### We have a history of net losses and we may never achieve high profitability.

We have been reporting losses since our inception (except for the financial years ended November 30, 2010, 2001 and 2000) and, as at November 30, 2010, we had an accumulated deficit of \$235,116,000. We do not expect to generate significant recurrent revenues sufficient to cover our overall activities in the immediate future. As a result of the foregoing, we will need to generate significant revenues to achieve profitability.

Our profitability will depend on, among other things, our commercial partners' ability and willingness to successfully commercialize *EGRIFTA*<sup>TM</sup> and to obtain regulatory approval for the use of tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Latin America, Africa and the Middle East. However, there is no guarantee that our commercial partners will succeed in commercializing *EGRIFTA*<sup>TM</sup> or that our product candidates will ever receive approval for commercialization in any jurisdiction and, accordingly, we may never sustain profitability.

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

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

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

Any selection of new third-party service providers to carry out work related to preclinical studies and clinical trials would be time-consuming and would result in additional delays in receiving data, analysis and reports from such third-party service providers which, in turn, would delay the filing of any new drug application with regulatory agencies for the purposes of obtaining regulatory approval to commercialize our product candidates. Furthermore, such delays could increase our expenditures to develop a product candidate and materially adversely affect our financial condition and operating results.

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

The conduct of clinical trials requires the enrolment of patients. We may have difficulties enrolling patients for the conduct of our future clinical trials as a result of design protocol, the size of the patient population, the eligibility criteria to participate in the clinical trials, the availability of competing therapies, the patient referral practices of physicians and the availability of clinical trial sites. Difficulty

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in enrolling patients for our clinical trials could result in the cancellation of clinical trials or delays in completing them. Once patients are enrolled in a clinical trial, the occurrence of any adverse drug effects or side effects observed during the trial could result in the clinical trial being cancelled. Any of these events would have material adverse consequences on the timely development of our product candidates, the filing of an NDA, or its equivalent, with regulatory agencies and the commercialization of such product candidates.

# We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements, including to continue and complete the research and development of our product candidates and their commercialization.

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

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

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

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

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

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

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

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

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

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

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

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

our liquidity and capital resources, or shares may be issued which could cause significant dilution to our existing shareholders.

#### We may not achieve our publicly announced milestones on time.

From time to time, we publicly announce the timing of certain events to occur. 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 may differ from what has been publicly disclosed. Events such as completion of a clinical program, discovery of a new product candidate, filing of an application to obtain regulatory approval, beginning of commercialization of our products or announcement of additional clinical programs for a product candidate may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including the nature of the results obtained during a clinical trial or during a research phase, problems with a supplier or a commercial partner or any other event having the effect of delaying the publicly announced timeline. 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 could have an adverse material effect on our business plan, financial condition or operating results.

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

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

#### 3.5 RISKS RELATED TO OUR COMMON SHARES

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

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

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

#### Our quarterly operating results may fluctuate significantly.

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

- variations in the level of revenues and royalties received related to EGRIFTATM;
- variations in the level of expenses related to our development programs;

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- addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- the achievement and timing of milestone payments under our existing strategic partnership agreements.

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

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

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

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

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

- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize the product candidates;
- the outcome of any litigation; changes in foreign currency fluctuations;
- the timing of achievement and the receipt of milestone payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties; and

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• failure to introduce the product candidates to the market in a manner that generates anticipated revenues.

#### We may be adversely affected by currency fluctuations.

A substantial portion of our revenue is earned in U.S. dollars, but a substantial portion of our operating expenses are incurred in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and other currencies, such as the Canadian dollar, may have a material adverse effect on our business, financial condition and operating results. We do not currently engage in transactional hedging schemes but we do attempt to hedge or mitigate the risk of currency fluctuations by actively monitoring and managing our foreign currency holdings relative to our foreign currency expenses.

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

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

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.

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# **ITEM 4 DIRECTORS AND EXECUTIVE OFFICERS**

# 4.1 DIRECTORS

The following table lists the names of our directors, their province or state and country of residence, their principal occupation, their position or office held (if any), the year in which each of them first became a director and the number of common shares and deferred share units each of them beneficially owned, directly or indirectly, or over which they exercised control or direction as of February 21, 2011. Each elected director remains in office until the next annual meeting of shareholders, unless he resigns or his position becomes vacant following his death, destitution or for any other reason before the next annual meeting of shareholders.

# DIRECTORS

Name and Place of Residence	Principal Occupation	Director Since	Number of Common Shares	Number of Deferred Share Units
Paul Pommier(1) (2) (3) (4) (5) Québec, Canada	Chairman of the Board	1997	190,100	20,998
John-Michel T. Huss <sup>(4)</sup> Québec, Canada	President and Chief Executive Officer of the Company	2010	_	44,248
Gilles Cloutier(3) (5) North Carolina, United States	Corporate Director	2003	71,000	3,000
A. Jean de Grandpré(2) (3) (4) (5) Québec, Canada	Corporate Director	1993	200,000	5,250
Robert G. Goyer(3) Québec, Canada	Emeritus Professor Faculty of Pharmacy Université de Montreal	2005	10,000	5,250
Gérald A. Lacoste(1) (3) (5) Québec, Canada	Corporate Director	2006	11,000	5,250
Bernard Reculeau <sup>(2)</sup> Paris, France	Corporate Director	2005	18,100	3,000
Jean-Denis Talon(1) (2) (4) Québec, Canada	Chairman of the Board AXA Canada (Insurance Company)	2001	60,000	3,000
Luc Tanguay <sup>(4)</sup> Québec, Canada	Senior Executive Vice President and Chief Financial Officer of the Company	1993	83,000	27,572
<ol> <li>Member of the Audit Committien</li> <li>Member of the Compensation</li> <li>Member of the Nominating and</li> </ol>				

(4) Member of the Finance Committee

(5) Member of the Strategic Review Committee

# **Biographical Notes of the Directors**

**Paul Pommier, MBA.** *Chairman of the Board.* Mr. Paul Pommier worked for more than 25 years at National Bank Financial Inc., his last position being Senior Executive Vice President, Corporate and Government Finance. Throughout his career, he oversaw public and private financings, mergers and acquisitions, as well as the marketing of investment offerings. Under his leadership, National Bank Financial Inc. developed notable expertise in tax-shelter financings.

John-Michel T. Huss, MBA. *President & Chief Executive Officer.* John-Michel T. Huss brings more than 20 years of global experience in the pharmaceutical industry to Theratechnologies. He began his career at Merck & Co., occupying various sales and marketing positions in the United States and in Europe. In 1996, he accepted an International Product Manager position at the headquarters of F. Hoffman-La Roche, in Basel, Switzerland. Mr. Huss joined Sanofi-Synthelabo GmbH in 1999, where he held positions in Germany and in Canada. He was appointed General Manager of the Swiss subsidiary at Sanofi in 2007 (Sanofi-Synthelabo merged with Aventis in 2004), and in 2009 was promoted to the position of Chief of Staff, Office of the CEO, in Paris.

**Gilles Cloutier, Ph.D.** *Corporate Director.* Dr. Gilles Cloutier has over 30 years of experience in the pharmaceutical industry including five years with contract research organizations, providing strategic support to biotechnology and pharmaceutical companies. Dr. Cloutier has also held key positions with large North-American pharmaceutical companies, where he developed expertise in the field of clinical research. His experience includes the development and approval of several drugs in Canada, the United States and Europe. Dr. Cloutier sits on our board of directors and is also Chairman of the Fondation André Delambre for amyotrophic lateral sclerosis (ALS).

**A. Jean de Grandpré, C.C., Q.C.** *Corporate Director.* A. Jean de Grandpré contributed to Bell Canada's significant growth as Chairman of the Board and Chief Executive Officer, and went on to become the founding Chairman of the Board and Chief Executive Officer of BCE. In recognition of these achievements, he was inducted into the Canadian Business Hall of Fame. Mr. de Grandpré also served on the boards of directors of other important Canadian and US corporations, namely Northern Telecom Limited, Chrysler Corporation, Sun Life Financial Inc. and Toronto Dominion Bank, and as a member of the international advisory boards of Chemical Bank and Goldman Sachs. He has been a member of our board of directors since our founding in October 1993 and was appointed Chairman in 1996. He resigned his position as Chairman in March 2007.

**Robert G. Goyer, Ph.D.** *Emeritus professor, Faculty of Pharmacy of the Université de Montréal.* Dr. Goyer has more than 40 years of experience in the pharmaceutical field. Dr. Goyer is the former President of Jouveinal Canada and is also a former dean of the Faculty of Pharmacy of Université de Montréal. Recognized for his broad expertise in drug development, he has served on the boards of several companies and governmental organizations. He was notably Chairman of the Advisory Committee on drug approval procedures of Health Canada's Therapeutic Products Directorate and a member of the board of directors of the Régie de l'assurance maladie du Québec. He was Chairman of the Conseil du médicament du Québec from 2003 to 2005.

**Gérald A. Lacoste, Q.C.** *Corporate Director.* Gérald A. Lacoste is a lawyer with extensive experience in the fields of securities regulation, financing and corporate governance. He was previously Chairman of the Québec Securities Commission (now known as the *Autorité des marchés financiers*) and was also President and CEO of the Montreal Stock Exchange. During his career, Mr. Lacoste acted as legal counsel to the Canadian Standing Senate Committee on Banking, Trade and Commerce, he chaired the Québec Advisory Committee on Financial Institutions, and was a member of the task force on the capitalization of life insurance companies in Québec. Mr. Lacoste is currently a corporate director, actively involved in the biotechnology industry, and is a member of the North American Free Trade Agreement (NAFTA) arbitration panel.

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**Bernard Reculeau.** *Corporate Director.* Mr. Bernard Reculeau brings over 25 years of pharmaceutical industry experience to Theratechnologies. From September 2006 to December 2009, he was the President of CIS Bio International, a French company specializing in nuclear medicine and biomedical technologies. Prior to joining CIS Bio International, Mr. Reculeau was Senior Vice President Pharmaceutical Operations of Sanofi for the InterContinental Region. In his previous functions, he was responsible for product development and commercialization in numerous countries around the world. Mr. Reculeau has close to 25 years in pharmaceutical operations, notably in France where he ran the pharmaceutical operations for Rhône-Poulenc and Rhône-Poulenc Rorer as well as in other countries in the European Union. Mr. Reculeau retired in early 2010.

Jean-Denis Talon. Chairman of the Board, AXA Canada. Mr. Jean-Denis Talon had a successful career with AXA Insurance over a period of more than 20 years, ultimately becoming President and Chief Executive Officer. He is currently Chairman of the Board of AXA Canada. Mr. Talon is also former President of the Financial Affairs Committee at the Insurance Bureau of Canada.

Luc Tanguay, M.Sc., CFA. Senior Executive Vice President and Chief Financial Officer of the Company. Mr. Luc Tanguay has been active in the biotechnology industry for over 15 years. As a member of our senior management since 1996, he has contributed to our growth by facilitating access to public and private capital funding. A member of the board of directors since 1993, he has held various management positions since joining the Company. Prior to joining us, Mr. Tanguay had a career in investment banking at National Bank Financial Inc.

#### 4.2 AUDIT COMMITTEE

Our board of directors has established an Audit Committee to review our annual financial statements prior to their approval by the board of directors and also to perform other duties, as is described in the Audit Committee's charter adopted by the board of directors and attached hereto as Appendix A.

As of November 30, 2010, the Audit Committee was composed of three members: Paul Pommier, its Chair, Jean-Denis Talon and Gérald A. Lacoste. All three are independent and financially literate. The details mentioned hereunder describe the education and experience of the Audit Committee members that is relevant to the performance of their responsibilities, in particular any experience in preparing, auditing, analyzing and evaluating financial statements.

**Paul Pommier.** Mr. Pommier holds an MBA degree and has more than 25 years of experience in the financial field, notably in public and private company financings, as well as in merger and acquisition activities. While acting as a director of Royal Aviation Inc., he was also a member of its audit committee.

Jean-Denis Talon. Mr. Talon has more than 20 years of experience in the insurance field as a senior officer. Mr. Talon acted as a member of the audit committee of AXA Canada from March 1995 to April 2008. He has been a member of the audit committee of InnovAssur since March 1999 and since November 1999, he has been acting as Chairman of its audit committee.

**Gérald A. Lacoste.** Mr. Lacoste has more than 30 years of experience in the fields of securities regulation, corporate finance and corporate governance. Mr. Lacoste was president of the audit committee of Amisco Ltd. from 2002 to 2009 and was also a member of the audit committee of Andromed Inc. from 2004 to 2007. Mr. Lacoste has been a member of the audit committee of Génome Québec from 2006 to 2009.

Each member of the Audit Committee has acquired in-depth financial expertise giving each the ability to read and understand a set of financial statements which presents the breadth and level of

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complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised in the issuer's financial statements.

# External Auditors Service Fees

	Financial Year Ended November 30, 2010	Financial Year Ended November 30, 2009
Audit Fees	\$122,000	\$80,000
Audit-Related Fees (1)	\$158,025	\$17,500
Tax Fees (2)	\$ 56,600	\$39,626
All Other Fees	_	—

(1) Audit-related fees relate principally to services rendered in connection with our annual financial statements and, for the financial year ended November 30, 2010, audit fees paid to KPMG also included fees related to services rendered in connection with the audit of IFRS adjustments and the translation of the financial statements to IFRS standards.

(2) Tax fees relate to services rendered in connection with the preparation of corporate tax returns and general tax advice.

#### 4.3 EXECUTIVE OFFICERS

The following table lists the names of all executive officers, their province or state and country of residence, their office and the number of common shares and deferred share units beneficially owned, directly or indirectly, by each of them or over which they exercised control or direction as at February 21, 2011.

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Name and Place of Residence	Office	Number of Common Shares of the Company over which Control or Direction is Exercised	Number of Deferred Share Units
Paul Pommier Québec, Canada	Chairman of the Board	190,100	20,998
John-Michel T. Huss Québec, Canada	President and Chief Executive Officer	_	44,248
Luc Tanguay Québec, Canada	Senior Executive Vice President and Chief Financial Officer	83,000	27,572
Marie-Noël Colussi Québec, Canada	Vice President, Finance	10,075	3,182
Chantal Desrochers Québec, Canada	Vice President, Business Development and Commercialization	16,300	_
Andrea Gilpin Québec, Canada	Vice President, Investor Relations and Communications	6,000	2,005
Jocelyn Lafond Québec, Canada	Vice President, Legal Affairs, and Corporate Secretary	_	5,000
Christian Marsolais Québec, Canada	Vice President, Clinical Research and Medical Affairs	8,597	6,312
Martine Ortega Québec, Canada	Vice President, Compliance and Regulatory Affairs	3,000	7,532
Pierre Perazzelli Québec, Canada	Vice President, Pharmaceutical Development	1,800	4,061
Krishna Peri Québec, Canada	Vice President, Research	35,000	—

# **EXECUTIVE OFFICERS**

#### **Biographical Notes of the Executive Officers**

For the biographical notes of Paul Pommier, John-Michel T. Huss and Luc Tanguay, please refer to Item 4 of this AIF.

**Marie-Noël Colussi, CA.** *Vice President, Finance.* Ms. Marie-Noël Colussi is a graduate of *Université du Québec à Montréal* in business administration. Prior to joining us, Ms. Colussi worked for eight years with KPMG, a major accounting firm. Ms. Colussi has experience in accounting, auditing, control and taxation, particularly in research and development. She joined us in March 1997, and prior to her appointment as Vice President, Finance in February 2002, she held the positions of Director, Accounting and Internal Control and Controller.

**Chantal Desrochers, B.Ph., MBA.** *Vice President, Business Development and Commercialization.* Ms. Chantal Desrochers obtained her degrees in pharmacy and business from the *Université de Montréal*. She began her career at Schering-Plough in sales and ultimately became a Product Director. After obtaining her M.B.A., Ms. Desrochers joined Bristol-Myers Squibb Company in Canada as Marketing Director, Pharmaceuticals and became Vice President, Institutional Business in 1995. In 1997, Ms. Desrochers was promoted to European Franchise Marketing Director, Cardiovascular, in

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France where she contributed to the commercial development of cardiovascular products. This led to her appointment as International Marketing Director, Cardiovascular, at Bristol-Myers Squibb in Princeton, New Jersey. Prior to joining us in 2005, Ms. Desrochers offered consulting services in business development and product development strategies.

Andrea Gilpin, Ph.D., MBA. Vice President, Investor Relations and Communications. Prior to joining us in 2007, Dr. Gilpin was Director, Investor Relations at MethylGene Inc. and held various positions at biotechnology companies. Dr Gilpin has a Ph.D. (Genetics/Biochemistry) from the University of Toronto and an MBA from the Asper School of Business.

Jocelyn Lafond, LL.B., LL.M. Vice President, Legal Affairs, and Corporate Secretary. Mr. Lafond has over 15 years of experience in the fields of corporate and securities law. Mr. Lafond holds a law degree from *Université Laval* and a Masters Degree in Law from the University of Toronto. He has been a member of the Barreau du Québec since 1992. Prior to joining us in 2007, Mr. Lafond was a partner with the international law firm of Fasken Martineau DuMoulin LLP.

**Christian Marsolais, Ph.D.** *Vice President, Clinical Research and Medical Affairs.* Dr. Christian Marsolais has over 15 years of experience in clinical research for large pharmaceutical companies, such as Sandoz Canada Inc. and BioChem Therapeutics Inc. Before joining us in 2007, Dr. Marsolais held various positions at Pfizer Global Pharmaceuticals, where he was appointed Director of Medical Affairs, Therapeutic Areas, in 2004. In this position, Dr. Marsolais was responsible for the clinical program and scientific initiatives development, as well as the integration of the Scientific Affairs and Clinical Research for the oncology and HIV Franchise. Dr. Marsolais holds a Ph.D. in Biochemistry from the *Université de Montréal.* 

Martine Ortega, Pharm. D. Vice President, Compliance and Regulatory Affairs. Ms. Martine Ortega joined us in 2006. A graduate in pharmacy from the Université d'Aix-Marseille II, she holds a postdoctoral degree in dermatology. Ms. Ortega has close to 20 years of experience in the pharmaceutical industry, where she has gained knowledge of the drug development process. During her career, she has acquired broad expertise in GLP, GCP and GMP practices and procedures as well as in computerized systems validation. She is also experienced in relations with US, European and Canadian regulatory agencies. Prior to joining us, she held senior management positions at Ventana Clinical Research Corporation, MDS Pharma Services and Sandoz Canada Inc.

**Pierre Perazzelli, B. Sc.** *Vice President, Pharmaceutical Development.* A graduate of *Université Laval*, Mr. Perazzelli has been working in the pharmaceutical manufacturing industry for over 20 years. Throughout his career, he has held various positions in large pharmaceutical companies, including Bristol Myers Squibb and Abbott Laboratories, Ltd. He was Director of the LAB Laboratory, a research centre specializing in pharmaceutical formulation. He is also experienced in the production of generic drugs. Mr. Perazzelli joined us in May 2000.

Krishna Peri, Ph.D. Vice President, Research. Co-inventor of the ExoPep<sup>™</sup> technology and a founder of Pharma-G, Dr. Krishna Peri holds a Ph.D. in biochemistry from the University of Saskatchewan, Canada. He pursued post-doctoral research in cancer as an NCI fellow at McGill University and at Ste. Justine Hospital Research Center. After our acquisition of Pharma-G in 2000, he served as director of discovery research, and was subsequently appointed Vice-President, Research, in June 2004.

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# 4.4 DECLARATION OF THE DIRECTORS' AND OFFICERS' ANTECEDENTS

Except as described below, to our knowledge, no director or executive officer (a) is, as at the date of this Annual Information Form, or has been within the ten years before the date of this Annual Information Form, a director or executive officer of any company (including us) that, while that person was acting in that capacity, (i) was the subject of a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty consecutive days; (ii) was subject to an event that resulted, after the director or executive officer ceased to be a director or executive officer, in the company being the subject of a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty consecutive days; (ii) was subject to a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty consecutive days; (ii) was subject to a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty consecutive days; or (iii) within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankrupt or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or (b) has, within the ten years before the date of this Annual Information Form, become bankrupt, made a proposal under any legislation relating to bankrupt or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his assets.

Paul Pommier was a member of the board of directors of Royal Aviation Inc. from September 1996 until it was acquired by Canada 3000 Inc. in March 2001. Subsequently, at the end of 2001, Canada 3000 Inc. and its subsidiaries, including Royal Aviation Inc., made assignments in bankruptcy under Item 49 of the *Bankruptcy and Insolvency Act* (R.S. 1985, c. B-3), or *Bankruptcy Act*.

Jean-Denis Talon was a member of the board of directors of Toptent Inc., or Toptent, from August 1, 2007 to November 26, 2009. On December 3, 2009, Toptent filed a notice of intention to make a proposal under the *Bankruptcy Act*. Subsequently, on May 7, 2010, Toptent filed a proposal under the *Bankruptcy Act*. The proposal was accepted by Toptent's creditors on May 20, 2010.

Luc Tanguay was a member of the board of directors of Ambrilia Biopharma Inc., or Ambrilia, from August 22, 2006 to March 30, 2010. On July 31, 2009, Ambrilia obtained court protection from its creditors under the *Companies' Creditors Arrangement Act* (Canada). The purpose of the order issued by the court granting Ambrilia protection from its creditors was to provide Ambrilia and its subsidiaries the opportunity to restructure its affairs. On July 31, 2009, the TSX halted the trading of Ambrilia's shares pending its review of Ambrilia's meeting the requirements for continuous listing. On January 31, 2011, TSX determined to delist the common shares of Ambrilia at the close of market on March 4, 2011 for failure to meet the continued listing requirements of TSX. The common shares will remain suspended from trading.

### 4.5 SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS

As at February 21, 2011, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 723,972, which represented 1.20% of our outstanding common shares.

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# **ITEM 5 INTERESTS OF EXPERTS**

KPMG LLP, our auditors, is the only person or company who is named as having prepared or certified a statement, report or evaluation, included or mentioned in a filing under securities regulations during our most recently completed financial year.

KPMG LLP and its partners are independent in accordance with the auditor's rules of professional conduct in the jurisdiction of Québec.

### **ITEM 6 SECURITIES OF THE COMPANY**

### 6.1 AUTHORIZED SHARE CAPITAL

We are authorized to issue an unlimited number of common shares and an unlimited number of preferred shares issuable in series.

Subject to the priority rights of holders of preferred shares, holders of common shares are entitled to any dividend declared by the board of directors, to one vote per share at meetings of our shareholders and, in the event of our liquidation or dissolution, to participate in the distribution of the assets.

Preferred shares carry no voting rights. Preferred shares may be issued at any time in one or more series. Our articles of incorporation give our board of directors the power to fix the number of preferred shares and the consideration per share, as well as to determine the provisions attached to the preferred shares of each series (including dividends, redemption and conversion rights, if any). The shares of every series of preferred shares, will have priority over all our other shares, including common shares, with respect to the payment of dividends and return of capital in the event of our liquidation or dissolution.

The common shares issued represent the total voting rights pertaining to our securities.

#### 6.2 DIVIDEND POLICY

We have never declared or paid cash dividends on our common shares and do not anticipate paying any cash dividends on our common shares in the foreseeable future. We presently intend to retain future earnings, if any, to finance the expansion and growth of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors the board of directors deems relevant. In addition, the terms of any future debt or credit facility may preclude us from paying dividends.

### 6.3 TRANSFER AGENT AND REGISTRAR

Our transfer agent and registrar is Computershare Trust Company of Canada which holds, at its Montreal office, the registers related to our common shares, shareholders and transfers.

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# **ITEM 7 MARKET FOR SECURITIES**

# 7.1 TRADING PRICE AND VOLUME

The following table sets forth the high and low closing sale prices for our common shares for the periods indicated, as reported on the TSX. However, you should not view this presentation as an indication that the market price of our common shares will continue at such levels.

	P	rice	
Period	\$ High	\$ Low	Volume
February 1 to February 18, 2011	\$5.88	\$5.01	4,371,300
January 2011	\$5.90	\$5.43	3,319,500
December 2010	\$5.69	\$5.27	4,038,000
November 2010	\$5.80	\$4.91	8,127,400
October 2010	\$5.15	\$4.44	2,944,000
September 2010	\$4.98	\$4.78	1,230,300
August 2010	\$5.08	\$4.75	1,934,900
July 2010	\$5.48	\$4.82	3,795,500
June 2010	\$5.59	\$4.61	6,188,600
May 2010	\$5.02	\$2.09	11,593,700
April 2010	\$5.20	\$4.82	1,960,000
March 2010	\$5.50	\$4.80	2,612,100
February 2010	\$5.03	\$4.67	2,205,500
January 2010	\$5.42	\$4.28	4,505,000
December 2009	\$4.45	\$3.55	5,517,800

## 7.2 PRIOR SALES

The following table summarizes the distribution of securities other than our common shares that we issued during the most recently completed financial year, identifying the type of security, the price per security, the number of securities issued, and the date on which the securities were issued.

Type of Security	Price per Security	Number of Securities
Options	\$3.84	265,000
Options	\$4.75	70,000
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	Options	Options \$3.84 Options \$4.75

### **ITEM 8 LEGAL PROCEEDINGS**

On July 26, 2010, we received a motion for authorization to institute a class action lawsuit against us, our chairman and our former chief executive officer. This motion was filed in the Superior Court of Québec, district of Montreal. The applicant is seeking to initiate a class action suit and to certify and represent a class of persons who were shareholders at May 21, 2010 and who sold their common shares on May 25 or 26, 2010. This applicant alleges that we did not comply with our continuous disclosure obligations as a reporting issuer by failing to disclose certain alleged adverse effects relating to the administration of *EGRIFTATM*. We are of the view that the allegations contained in the motion are entirely without merit and intend to take all appropriate actions to vigorously defend our position. The Motion has not yet been heard by the Superior Court of Québec and no date has been set for the hearing. We have subscribed for insurance covering our potential liability and the potential liability of our directors and officers in the performance of all their duties for us subject to a \$200,000 deductible and standard terms, conditions and exclusions.

We are not otherwise currently subject to any material legal proceedings.

## **ITEM 9 MATERIAL CONTRACTS**

**Licensing Agreements**. We have executed commercialization agreements with third parties for the exclusive distribution rights to *EGRIFTATM* for the reduction of excess abdominal fact in HIV-infected patients with lipodystrophy for (i) the United States; (ii) Latin America, Africa and the Middle East; and (iii) Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. For a description of these agreements, see Item 2.5.

Supply Agreements. We have executed five supply agreements with Bachem, Draxis, Becton Dickinson, Hospira and ABAR. For a description of these agreements, see Item 2.7.

**Shareholder Rights Plan Agreement.** On February 10, 2010, we entered into a shareholder rights plan agreement, or Rights Plan. The Rights Plan entitles a holder of rights (other than the Acquiring Person, as defined below, or any affiliate or associate of an Acquiring Person or any person acting jointly or in concert with an Acquiring Person or any affiliate or associate of an Acquiring Person) to purchase to our common shares at a discount of 50% to the market price upon a person becoming an "Acquiring Person", subject to certain exceptions and the terms and conditions set out in the Rights Plan. An "Acquiring Person" is defined in the Rights Plan as a beneficial owner of 20% or more of our common shares. The Rights Plan will expire at the close of our annual meeting of shareholders in 2013.

In order to implement the Rights Plan, we issued one right in respect of each common share outstanding as of 6:00 p.m. (Montreal time) on February 9, 2010, the "Effective Date". One right will also be issued and attached to each subsequently issued common share. The rights will separate and trade separately from the common shares to which they are attached and will become exercisable after the "Separation Time", as defined below:

The "Separation time" is the close of business on the tenth business day following the earliest of:

- (a) the date of the first public announcement made by us or an Acquiring Person that a person has become an Acquiring Person;
- (b) the date of the commencement of, or first public announcement of the intent of any Person to commence, a take-over bid (other than a Permitted Bid (as defined in the Rights Plan) or a Competing Permitted Bid (as defined in the Rights Plan)) by any person for our common shares;
- (c) the date upon which a Permitted Bid or Competing Permitted Bid ceases to be such; or
- (d) such later date as may be determined by the board of directors.

After the time at which a person becomes an Acquiring Person, and subject to the terms and conditions set out in the shareholder rights plan agreement, each right would, upon exercise, entitle a rights holder, other than the Acquiring Person and related persons, to purchase common shares at a 50% discount to the market price at the time.

Under the Rights Plan, a "Permitted Bid" is a bid made to all holders of the common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties, have been tendered, the offeror may take up and pay for the common shares but must extend the bid for a further 10 days to allow other shareholders to tender.



**Lease Agreement.** In October 2009, we entered into a new lease agreement with *Société de portefeuille immobilier GE Q-Tech inc.* for the renewal of our lease for our offices and laboratories located in Montréal, Québec. The new lease became effective on May 1, 2010 and will expire on April 30, 2021. Under the terms of this new lease agreement, we have two five year renewal options. If exercised, the first renewal option will start on May 1, 2021 and expire on April 30, 2026 and the second renewal option, if exercised, will start on May 1, 2026 and expire on April 30, 2031.

# **ITEM 10 ADDITIONAL INFORMATION**

Additional information with respect to our company, including directors' and officers' compensation, principal holders of our securities and securities authorized for issuance under equity compensation plans, where applicable, is contained in our Management Proxy Circular for our most recent annual and special meeting of shareholders. Our financial information is provided in our comparative financial statements and Management Discussion & Analysis for our financial year ended November 30, 2010.

Additional information regarding our company is available on SEDAR at www.sedar.com or upon request addressed to Jocelyn Lafond, Corporate Secretary, at 2310 Alfred Nobel Boulevard, Montreal, Québec, Canada H4S 2B4. Except when our securities are in the process of distribution pursuant to a prospectus, we may charge reasonable fees if the request is from a person who does not hold any of our securities.

# APPENDIX A — AUDIT COMMITTEE CHARTER

### I. <u>Mandate</u>

The Audit Committee (the "Committee") is responsible for assisting the Company's Board of Directors (the "Board") in overseeing the following:

- A. the integrity of the Company's financial statements and related information;
- B. the internal control systems of the Company;
- C. the appointment and performance of the external auditor; and
- D. the supervision of the Company's Risk Management.

### II. Obligations and Duties

The Committee carries out the duties usually entrusted to an audit committee and any other duty assigned from time to time by the Board. Management has the responsibility to ensure the integrity of the financial information and the effectiveness of the Company's internal controls. The external auditor has the responsibility to verify and certify the accurate presentation of the Company's financial statements; at the same time evaluating the internal control process to determine the nature, extent and chronology of the auditing procedures used. The Committee has the responsibility to supervise the participants involved in the preparation process of the financial information and to report on this to the Board.

Specifically, the Committee is charged with the following obligations and duties:

- A. Integrity of the Company's Financial Statements and Related Information
  - 1. Review annual and quarterly consolidated financial statements and all financial information legally required to be disclosed by the Company, i.e. financial information contained in the "Management Discussion and Analysis" report, the annual information form and the press releases, as the case may be, discuss such with management and the external auditor, and suggest recommendations to the Board, as the case may be.
  - 2. Approve the interim Financial Statements, the interim "Management Discussion and Analysis" reports and all supplements to these "Management Discussion and Analysis" reports which have to be filed with regulatory authorities.
  - 3. On a periodic basis, review and discuss with management and the external auditor the following:
    - a. major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles, and major issues as to the adequacy of the Company's internal controls and any special audit steps adopted in light of material control deficiencies;
    - b. the effect of regulatory and accounting initiatives, as well as off-balance sheet structures, on the financial statements of the Company; and
    - c. the type and presentation of information to be included in press releases dealing with financial results (paying particular attention to any use of pro-forma information or information adjusted by means of non-generally accepted accounting principles).



- 4. Review and discuss reports from the external auditor on:
  - a. all critical accounting policies and practices used by the Company; and
  - b. all material alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, including the ramifications of the use of such alternate treatments and disclosures and the treatment preferred by the external auditor.
- B. Supervision of the Company's Internal Control Systems
  - 1. Review and discuss with management and with the external auditor present reports and, when appropriate, provide recommendations to the Board on the following:
    - a. actual financial data compared with budgeted data;
    - b. the Company's internal control system;
    - c. the relationship of the Committee with the management and audit committees of the Company's consolidated subsidiaries. With respect to the subsidiaries, the Committee must:
      - obtain precisions as to the mandate of the audit committees;
      - enquire about internal controls and study related risks;
      - obtain the external auditors' report to the audit committees on the planning of external auditing;
      - obtain the external auditors' report to the audit committees on the auditing results;
      - obtain copy of the minutes of the audit committees' meetings; and
      - ensure that the critical accounting policies and practices are identical to the Company's.
  - Study the feasibility of implementing an internal auditing system and when implemented, establish its responsibilities and supervise its work.
  - 3. Establish procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and procedures for the confidential, anonymous submission by employees of concerns regarding questionable accounting or auditing matters.
- C. Appointment and Performance Supervision of the External Auditor
  - 1. Provide recommendations to the Board on the selection of the external auditor to be appointed by the shareholders.
  - 2. Approve in advance and recommend to the Board the external auditor's remuneration and more specifically fees and terms of all audit, review or certification services to be provided by the external auditor to the Company and any consolidated subsidiary.
  - 3. Supervise the performance of the external auditor in charge of preparing or issuing an audit report or performing other audit services or certification services for the Company or any consolidated subsidiary of the Company,

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where required, and review all related questions as to the terms of its mission and the revision of its mission.

- 4. Pre-approve all engagements for permitted non-audit services provided by the external auditor to the Company and any consolidated subsidiary, and to this effect and at its convenience, establish policies and procedures for the engagement of the external auditor to provide to the Company and any consolidated subsidiary permitted non-audit services, which shall include approval in advance by the Committee of all audit/review services and permitted non-audit services to be provided to the Company and any consolidated subsidiary by the external auditor.
- 5. At least annually, consider, assess and report to the Board on:
  - a. the independence of the external auditor, including whether the external auditor's performance of permitted non-audit services is compatible with the external auditor's independence;
  - b. the obtaining from the external auditor of a written statement i) describing all relationships between the external auditor and the Company; ii) assuring that lead audit partner rotation is carried out, as required by law; and iii) describing any other relationship that may adversely affect the independence of the external auditor; and
  - c. the evaluation of the lead audit partner, taking into account the opinions of management and the internal auditor.
- 6. At least annually, obtain and review a report by the external auditor describing:
  - a. the external auditor's internal quality-control procedures; and
  - b. any material issues raised by the most recent internal quality-control review (or peer review) of the external auditor's firm, or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, with respect to one or more independent audits carried out by the external auditor's firm, and any steps taken to deal with any such issues.
- 7. Resolve any disagreement between management and the external auditor regarding financial reporting.
- 8. Review the audit process with the external auditor.
- 9. Review and discuss with the Chief Executive Officer and Chief Financial Officer of the Company the process for the certifications to be provided in the Company's public disclosure documents.
- 10. Meet periodically with the external auditor in the absence of management.
- 11. Establish procedures with respect to hiring the external auditor's employees and former employees.
- D. Supervision of the Company's Risk Management

Review, report and, where appropriate, provide recommendations to the Board on the following:

- 1. the Company's processes for identifying, assessing and managing risk;
- 2. the Company's major financial risk exposures and the steps the Company has taken to monitor and control such exposures;

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- 3. the Company's insurance portfolio and the adequacy of the coverage; and
- 4. the Company's investment policy.

### III. External Advisors

In discharging its duties and responsibilities, the Committee is empowered to retain external legal counsel or other external advisors, as appropriate. The Company shall provide the necessary funds to secure the services of such advisors.

#### IV. Composition of the Committee

The Committee is composed of any number of Directors, but no less than three, as may be determined by the Board from time to time by resolution. Each member of the Committee shall be independent from the Company and is financially literate, as determined by the Board and in conformity with applicable laws, rules and regulations.

#### V. Term of the Mandate

Committee members are appointed by Board resolution to carry out their mandate extending from the date of the appointment to the next annual general meeting of the shareholders or until their successors are so appointed.

### VI. <u>Vacancy</u>

The Board may fill vacancies at any time by resolution. Subject to the constitution of the quorum, the Committee's members can continue to act even if there is one or many vacancies on the Committee.

#### VII. <u>Chairman</u>

The Board appoints the Committee Chairman who will call and chair the meetings. The Chairman reports to the Board the deliberations of the Committee and its recommendations.

#### VIII. <u>Secretary</u>

Unless otherwise determined by resolution of the Board, the Secretary of the Company shall act as Committee Secretary. The Secretary must attend Committee meetings and prepare the minutes. He/she must provide notification of meetings as directed by the Committee Chairman. The Secretary is the guardian of the Committee's records, books and archives.

### IX. Meeting Proceedings

The Committee establishes its own procedures as to how meetings are called and conducted. Unless it is otherwise decided, the Committee shall meet privately and independently from Management at each regularly scheduled meeting. In the absence of the regularly appointed Chairman, the meeting shall be chaired by another Committee member selected among attending participants and appointed accordingly. In the absence of the regularly appointed Secretary, Committee members shall designate someone to carry out this duty.

The Committee shall meet at least four times a year with management and the external auditor, and at least once a year, separately in executive session in the absence of management and the external auditor. At least once a year, the Committee invites the Chief

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Financial Officer of each subsidiary to present the financial information and internal control systems related to such subsidiary.

# X. Quorum and Voting

Unless the Board otherwise specifies by resolution, two Committee members shall constitute an appropriate quorum for deliberation of items on the agenda. During meetings, decisions are reached by a majority of votes from Committee members, unless the quorum is of two members, in which case decisions are made by consensus of opinion.

# XI. Records

The Committee keeps records that are deemed necessary of its deliberations and reports regularly to the Board on its activities and recommendations.

### XII. Effective Date

This charter was adopted by the Directors at its May 3, 2004 Board meeting. It was amended by the Directors during the April 13, 2005 and February 8, 2006 Board meetings.



# THERATECHNOLOGIES INC.

Years ended November 30, 2010 and 2009 and as at December 1, 2008



KPMG LLP Chartered Accountants 600 de Maisonneuve Blvd. West Suite 1500 Tour KPMG Montréal (Québec) H3A 03A

AUDITORS' REPORT TO THE SHAREHOLDERS

We have audited the consolidated statements of financial position of Theratechnologies Inc. as at November 30, 2010 and 2009 and December 1, 2008, and the consolidated statements of comprehensive income, statements of changes in equity and statements of cash flows for the years ended November 30, 2010 and 2009. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at November 30, 2010 and 2009 and December 1, 2008, and its financial performance and its cash flows for the years ended November 30, 2010 and 2009 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

KPMG LLP

**Chartered Accountants** 

Montréal, Canada February 8, 2011

\*CA Auditor permit no 14553

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Consolidated Financial Statements

Years ended November 30, 2010 and 2009 and as at December 1, 2008

### **Financial Statements**

Consolidated Statement of Financial Position Consolidated Statement of Comprehensive Income Consolidated Statement of Changes in Equity Consolidated Statement of Cash Flows Notes to the Consolidated Financial Statements

Consolidated Statement of Financial Position

As at November 30, 2010 and 2009 and December 1, 2008 (in thousands of Canadian dollars)

	Note	November 30, 2010	November 30, 2009	December 1 2008
	Note	\$	\$	200
Assets				
Current assets:				
Cash		26,649	1,519	133
Bonds	8	1,860	10,036	10,955
Trade and other receivables	9	161	375	610
Tax credits and grants receivable	10	332	1,333	1,452
Inventories	11	4,317	2,225	_
Prepaid expenses		1,231	630	739
Total current assets		34,550	16,118	13,888
Non-current assets:				
Bonds	8	36,041	51,807	35,249
Property and equipment	12	1,060	1,229	1,299
Other assets		_		2,776
Total non-current assets		37,101	53,036	39,324
Total assets		71,651	69,154	53,212
Liabilities Current liabilities:				
Accounts payable and accrued liabilities	13	4,977	5,568	6,865
Current portion of deferred revenue	4	6,847	6,847	· _
Total current liabilities		11,824	12,415	6,865
Non-current liabilities:				
Other liabilities	14	325	_	_
Deferred revenue	4	6,846	13,691	_
Total non-current liabilities		7,171	13,691	
Total liabilities		18,995	26,106	6,865
Equity				
Share capital	15	279,398	279,169	269,219
Contributed surplus		7,808	6,757	5,760
Deficit		(235,116)	(244,160)	(229,004
Accumulated other comprehensive income		566	1,282	372
Fotal equity		52,656	43,048	46,347
Contingent liability	18			
Commitments	23			
Subsequent events	26			
Total liabilities and equity		71,651	69,154	53,212
See accompanying notes to the consolidated financial statement	ts.			
On behalf of the Board,				

(signed) Paul Pommier Director (signed) Jean-Denis Talon Director

Consolidated Statement of Comprehensive Income

Years ended November 30, 2010 and 2009 (in thousands of Canadian dollars, except per share amounts)

	Note	November 30, 2010 \$	November 30, 2009 \$
Revenue:			
Research services:			
Milestone payments	4	25,000	10,884
Upfront payments and initial technology access fees	4	6,846	6,560
Royalties and license fees		22	24
Total revenue		31,868	17,468
		100	
Cost of sales		469	—
Research and development expenses, net of tax credits of \$934 (2009 - \$1,795)	10	14,064	20,810
Selling and market development expenses	6	2,670	6,862
General and administrative expenses		8,002	6,543
Total operating expenses		25,205	34,215
Results from operating activities		6,663	(16,747)
Finance income	7	1.888	2,252
Finance income	7	493	(661)
Total net financial income		2.381	1,591
		2,501	1,001
Net profit (loss) before income taxes		9,044	(15,156)
Income tax expense	16	114	—
Net profit (loss)		8,930	(15,156)
Other comprehensive income (loss), net of tax:			
Net change in fair value available-for-sale financial assets, net of tax		(390)	1,039
Net change in fair value available-for-sale financial assets transferred to net profit		. ,	
(loss), net of tax		(326)	(129)
		(716)	910
Total comprehensive income (loss) for the year		8,214	(14,246)
Basic and diluted earnings (loss) per share	15	0.15	(0.25)

See accompanying notes to the consolidated financial statements.

Consolidated Statement of Changes in Equity

Years ended November 30, 2010 and 2009 (in thousands of Canadian dollars)

		Share ca	nital	Contributed	Unrealized gains or losses on available-for-sale financial		
	Note	Number	Dollars	surplus	assets (i)	Deficit	Total
Balance as at December 1, 2008		58,215,090	\$ 269,219	\$ 5,760	\$ 372	\$ (229,004)	\$ 46,347
Total comprehensive income (loss) for the year:							
Net loss			_		_	(15,156)	(15,156)
Other comprehensive income (loss):						(,)	(,)
Net change in fair value of available-for- sale financial assets, net of tax		_	_	_	1,039	_	1,039
Net change in fair value of available-for- sale financial assets transferred to net profit (loss),							
net of tax		_	_	_	(129)	—	(129)
Total comprehensive income (loss) for the year		_	_	_	910	(15,156)	(14,246)
·						(,)	(= :,= :•)
Transactions with owners, recorded directly in equity:							
Issue of common shares	15(i)	2,214,303	9,950	—	-	—	9,950
Share-based compensation for stock							
option plan	15 (iv)			997	—	—	997
Total contributions by owners		2,214,303	9,950	997			10,947
Balance as at November 30, 2009		60,429,393	279,169	6,757	1,282	(244,160)	43,048
Total comprehensive income (loss) for the year:							
Net profit						8,930	8,930
Other comprehensive income (loss):						-,	-,
Net change in fair value of available-for-							
sale financial assets, net of tax			_	—	(390)	—	(390)
Net change in fair value of available-for-							
sale financial assets transferred to net							
profit (loss), net of tax					(326)	_	(326)
Total comprehensive income (loss) for the							
year					(716)	8,930	8,214
Transactions with owners, recorded directly in equity:							
Issue of common shares	15(i)	2,880	15		—	—	15
Income tax related to share issue costs						114	114
Share-based compensation plan:							
Share-based compensation for stock							
option plan	15 (iv)	_	_	1,133	_	_	1,133
Exercise of stock options:							
Monetary consideration	15 (iv)	80,491	132	_	_	_	132
Attributed value	15 (iv)		82	(82)			
Total contributions by owners		83,371	229	1,051		114	1,394
Balance as at November 30, 2010		60,512,764	279,398	7,808	566	(235,116)	52,656

(i) Accumulated other comprehensive income.

See accompanying notes to the consolidated financial statements.

Consolidated Statement of Cash Flows

Years ended November 30, 2010 and 2009 (in thousands of Canadian dollars)

	Note	November 30, 2010	November 30, 2009
		\$	\$
Operating activities:			
Net profit (loss)		8,930	(15,156)
Adjustments for:		-,	(,)
Depreciation of property and equipment	12	466	612
Share-based compensation		1.133	997
Income tax expense		114	
Write-down of inventories	11	192	
Lease inducements and amortization	17	325	
Operating activities before changes in operating assets and liabilities		11,160	(13,547)
Change in accrued interest income on bonds		728	(923)
Change in trade and other receivables		214	235
Change in tax credits and grants receivable		1,001	118
Change in inventories		(2,284)	(2,225)
Change in prepaid expenses		(2,204)	109
Change in other assets		(001)	2,776
Change in accounts payable and accrued liabilities		(473)	(1,424)
Change in deferred revenue		(6,845)	20,538
		(8,260)	19,204
Cash flows from operating activities		2,900	5,657
Financing activities:			
Proceeds from issue of share capital		15	9,950
Proceeds from exercise of stock options	15	132	
Share issue costs			(8)
Cash flows from financing activities		147	9,942
Investing activities:			
Acquisition of property and equipment	12	(415)	(407)
Proceeds from sale of bonds		22,498	15,305
Acquisition of bonds			(29,111)
Cash flows from (used in) investing activities		22,083	(14,213)
Net change in cash		25,130	1,386
Cash as at December 1		1,519	133
Cash as at November 30		26,649	1,519

See note 19 for supplemental cash flow information.

See accompanying notes to the consolidated financial statements.

Notes to the Consolidated Financial Statements

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 1. Reporting entity:

Theratechnologies Inc. is a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on growth hormone releasing factor peptides. Theratechnologies Inc. is leveraging its expertise in the field of metabolism to discover and develop products in specialty markets. Its commercialization strategy is to retain all or a significant portion of the commercial rights to its products. Its first product, EGRIFTATM (tesamorelin for injection), was approved by the United States Food and Drug Administration ("FDA") in November 2010. To date, EGRIFTATM is the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

The consolidated financial statements include the accounts of Theratechnologies Inc. and its wholly-owned subsidiaries (together referred to as the "Company" and individually as "the subsidiaries of the Company").

Theratechnologies Inc. is incorporated under Part 1A of the Québec *Companies Act* and is domiciled in Quebec, Canada. The Company is located at 2310 boul. Alfred-Nobel, Montreal, Quebec, H4S 2B4.

#### 2. Basis of preparation:

(a) Statement of compliance:

The consolidated financial statements of the Company have been prepared in accordance with IFRSs as issued by the International Accounting Standards Board ("IASB"). These are the Company's first consolidated financial statements prepared in accordance with International Financial Reporting Standards ("IFRSs"). The Company has applied IFRS 1, *First-time Adoption of International Financial Reporting Standards*, using December 1, 2008 as the date of transition to IFRSs.

An explanation of how the transition to IFRSs has affected the reported financial position, financial performance and cash flows of the Company is provided in note 27.

The consolidated financial statements were authorized for issue by the Board of Directors on February 8, 2011.

#### (b) Basis of measurement:

The Company's consolidated financial statements have been prepared on a going concern and historical cost basis, except for available-for-sale financial assets which are measured at fair value.

The methods used to measure fair value are discussed further in note 22.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 2. Basis of preparation (continued):

(c) Functional and presentation currency:

These consolidated financial statements are presented in Canadian dollars, which is the Company's functional currency. All financial information presented in Canadian dollars has been rounded to the nearest thousand.

(d) Use of estimates and judgements:

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

Information about critical judgements in applying accounting policies and assumption and estimation uncertainties that have the most significant effect on the amounts recognized in the consolidated financial statements is included in the following notes:

- Note 4 Revenue and deferred revenue;
- Note 15 (iv) Stock option plan;
- Note 16 Income taxes;
- Note 18 Contingent liability.

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

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

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

### 3. Significant accounting policies:

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements and in preparing the opening IFRS statement of financial position at December 1, 2008, the date of transition to IFRSs.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

The accounting policies have been applied consistently by the subsidiaries of the Company.

(a) Basis of consolidation:

The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases. Subsidiaries are entities controlled by the Company. Control is present where the Company has the power to govern the financial and operating policies of the entity so as to obtain benefits from its activities. In assessing control, potential voting rights that are exercisable currently are taken into consideration. The accounting policies of subsidiaries are changed when necessary to align them with the policies adopted by the Company.

Reciprocal balances and transactions, revenues and expenses resulting from transactions between subsidiaries and with the Company are eliminated in preparing the consolidated financial statements.

(b) Foreign currency:

Transactions in foreign currencies are translated to the respective functional currencies of the subsidiaries of the Company at exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies at the reporting date are retranslated to the functional currency at the exchange rate at that date. The foreign currency gain or loss on monetary items is the difference between amortized cost in the functional currency at the beginning of the period, adjusted for effective interest and payments during the period, and the amortized cost in foreign currency translated at the exchange rate at the end of the reporting period.

Foreign currency differences arising on translation are recognized in net profit (loss), except for differences arising on the translation of available-for-sale equity instruments, which are recognized in other comprehensive income. Non-monetary assets and liabilities denominated in foreign currencies that are measured at fair value are translated to the functional currency at the exchange rate at the date on which the fair value was determined. Non-monetary items that are measured at historical cost in a foreign currency are translated using the exchange rate at the date of the transaction.

(c) Revenue recognition:

Collaboration agreements that include multiple deliverables are considered to be multi-element arrangements. Under this type of arrangement, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(c) Revenue recognition (continued):

Payments received under the collaboration agreement may include upfront payments, milestone payments, research services, royalties and license fees. Revenues for each unit of accounting are recorded as described below:

(i) Sale of goods:

Revenues from the sale of goods are recognized when the Company has transferred to the buyer the significant risks and rewards of ownership of the goods, there is no continuing management involvement with the goods, and the amount of revenue can be measured reliably.

(ii) Royalties and license fees:

Royalties and license fees are recognized when conditions and events under the license agreement have occurred and collectibility is reasonably assured.

(iii) Research services:

Revenues from research contracts are recognized when services to be provided are rendered and all conditions under the terms of the underlying agreement are met.

(a) Upfront payments and initial technology access fees:

Upfront payments and initial technology access fees are deferred and recognized as revenue on a systematic basis over the period during which the related products or services are delivered and all obligations are performed.

(b) Milestone payments:

Revenues subject to the achievement of milestones are recognized only when the specified events have occurred and collectibility is reasonably assured.

(d) Cost of sales:

Cost of sales represents the cost of goods sold and includes the cost of raw materials, supplies, direct overhead charges, unallocated indirect costs related to production as well as write-down of inventories. Other direct costs, such as manufacturing start-up costs between validation and the achievement of normal production, are expensed as incurred.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(e) Employee benefits:

Salaries and short-term employee benefits:

Salaries and short-term employee benefit obligations are measured on an undiscounted basis and are expensed as the related service is provided. A liability is recognized for the amount expected to be paid under short-term profit-sharing or cash bonus plans if the Company has a legal or constructive obligation to pay an amount as a result of past services rendered by an employee and the obligation can be estimated reliably.

#### Post-employment benefits:

Post-employment benefits include a defined contribution plan under which an entity pays fixed contributions into a separate entity and will have no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution plans are recognized as an employee benefit expense when due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in future payments is available. The Company's defined contribution plan comprises the registered retirement savings plan, the Quebec Pension Plan and unemployment insurance.

#### Termination benefits:

Termination benefits are recognized as an expense when the Company is committed demonstrably, without realistic possibility of withdrawal, to a formal detailed plan to either terminate employment before the normal retirement date, or to provide termination benefits as a result of an offer made to encourage voluntary redundancy.

#### (f) Finance income and finance costs:

Finance income comprises interest income on available-for-sale financial assets and gains (losses) on the disposal of available-forsale financial assets. Interest income is recognized as it accrues in profit (loss), using the effective interest method.

Finance costs are comprised of bank charges, impairment losses on financial assets recognized in profit (loss) and of foreign currency gains and losses which are reported on a net basis.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(g) Inventories:

Inventories are presented at the lower of cost, determined using the first-in first-out method, or net realizable value. Inventory costs include the purchase price and other costs directly related to the acquisition of materials, and other costs incurred in bringing the inventories to their present location and condition. Inventory costs also include the costs directly related to the conversion of materials to finished goods, such as direct labour, and a systematic allocation of fixed and variable production overhead, including manufacturing depreciation expense. The allocation of fixed production overheads to the cost of inventories is based on the normal capacity of the production facilities. Normal capacity is the average production expected to be achieved over a number of periods under normal circumstances.

Net realizable value is the estimated selling price in the Company's ordinary course of business, less the estimated costs of completion and selling expenses.

#### (h) Property and equipment:

#### Recognition and measurement:

Items of property and equipment are recognized at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset and the costs of dismantling and removing the item and restoring the site on which it is located, if any.

When parts of an item of property and equipment have different useful lives, they are accounted for as separate items (major components) of property and equipment.

Gains and losses on disposal of an item of property and equipment are determined by comparing the proceeds from disposal with the carrying amount of property and equipment, and are recognized in net profit (loss).

#### Subsequent costs:

The cost of replacing a part of an item of property and equipment is recognized in the carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to the Company, and its cost can be measured reliably. The carrying amount of the replaced part is derecognized. The costs of the day-to-day servicing of property and equipment are recognized in profit (loss) as incurred.



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(h) Property and equipment (continued):

Depreciation:

The estimated useful lives and the methods of depreciation for the current and comparative periods are as follows:

Asset	Method	Rate/Period
Computer equipment	Declining balance	50%
Laboratory equipment	Declining balance	20%
	and straight-line	5 years
Office furniture and equipment	Declining balance	20%
Leasehold improvements	Straight-line	Lower of term of lease or economic life

This most closely reflects the expected pattern of consumption of the future economic benefits embodied in the asset.

Estimates for depreciation methods, useful lives and residual values are reviewed at each reporting period-end and adjusted if appropriate.

(i) Intangible assets:

#### Research and development:

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is expensed as incurred.

Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditure is capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete development and to use or sell the asset. These criteria are usually met when a regulatory filing has been made in a major market and approval is considered highly probable. The expenditure capitalized includes the cost of materials, direct labour, and overhead costs that are directly attributable to preparing the asset for its intended use. Other development expenditures are expensed as incurred. Capitalized development expenditures are measured at cost less accumulated amortization and accumulated impairment losses.

During the years ended November 30, 2010 and 2009 and as at December 1, 2008, no development expenditures were capitalized.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(j) Financial instruments:

The Company's financial instruments are classified into one of three categories: loans and receivables, available-for-sale financial assets and other financial liabilities. Loans and receivables and other financial liabilities are measured at amortized cost.

The Company has classified its bonds as available-for-sale financial assets. The Company has classified cash and trade and other receivables as loans and receivables, and accounts payable and accrued liabilities as other financial liabilities.

Available-for-sale financial assets are non-derivative financial assets that are designated as available-for-sale and that are not classified in any of the other categories. Subsequent to initial recognition, they are measured at fair value and changes therein, other than impairment losses and foreign currency differences on available-for-sale debt instruments, are recognized in other comprehensive income and presented within equity. When an investment is derecognized, the cumulative gain or loss in other comprehensive income is transferred to profit (loss).

(k) Other assets:

Other assets consist of prepaid expenses for research supplies that are not expected to be used within one year from the date of the consolidated statement of financial position.

Research supplies are purchased in advance, in accordance with specific regulatory requirements, to be used in connection with the Company's clinical trials.

(I) Leases:

Operating lease payments are recognized in net profit (loss) on a straight-line basis over the term of the lease.

Lease inducements arising from leasehold improvement allowances and rent-free periods form an integral part of the total lease cost and are deferred and recognized in net profit (loss) over the term of the lease on a straight-line basis.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(m) Impairment:

Financial assets:

A financial asset not carried at fair value through profit or loss is assessed at each consolidated financial statement reporting date to determine whether there is objective evidence that it is impaired. The Company considers that a financial asset is impaired if objective evidence indicates that one or more loss events had a negative effect on the estimated future cash flows of that asset that can be estimated reliably.

An impairment test is performed, on an individual basis, for each material financial asset. Other individually non-material financial assets are tested as groups of financial assets with similar risk characteristics. Impairment losses are recognized in net profit (loss).

An impairment loss in respect of a financial asset measured at amortized cost is calculated as the difference between its carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses are recognized in net profit (loss) and reflected in an allowance account against the respective financial asset. Interest on the impaired asset continues to be recognized through the unwinding of the discount. When a subsequent event causes the amount of impairment loss to decrease, the decrease in impairment loss is reversed through net profit (loss).

Impairment losses on available-for-sale investment securities are recognized by transferring the cumulative loss that has been recognized in other comprehensive income, and presented in unrealized gains/losses on available-for-sale financial assets in equity, to net profit (loss). The cumulative loss that is removed from other comprehensive income and recognized in net profit (loss) is the difference between the acquisition cost, net of any principal repayment and amortization, and the current fair value, less any impairment loss previously recognized in net profit (loss). Changes in impairment provisions attributable to time value are reflected as a separate component of interest income.

If, in a subsequent period, the fair value of an impaired available-for-sale debt security increases and the increase can be related objectively to an event occurring after the impairment loss was recognized in net profit (loss), then the impairment loss is reversed, with the amount of the reversal recognized in net profit (loss). However, any subsequent recovery in the fair value of an impaired available-for-sale equity security is recognized in other comprehensive income.

#### Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(m) Impairment (continued):

#### Non-financial assets:

The carrying amounts of the Company's non-financial assets, other than inventories and deferred tax assets, are reviewed at each reporting date to determine whether there is any indication of impairment. If such an indication exists, the recoverable amount is estimated.

The recoverable amount of an asset or a cash-generating unit is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of cash inflows from other assets or groups of assets ("cash-generating unit"). Impairment losses recognized in prior periods are determined at each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. An asset's carrying amount, increased through reversal of an impairment loss, must not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized.

#### (n) Provisions:

A provision is recognized if, as a result of a past event, the Company has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation. Provisions are assessed by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount on provisions is recognized in finance costs.

#### Onerous contracts:

A provision for onerous contracts is recognized when the expected benefits to be derived by the Company from a contract are lower than the unavoidable cost of meeting its obligations under the contract. The provision is measured at the present value of the lower of the expected cost of terminating the contract and the expected net cost of continuing with the contract. Before a provision is established, the Company recognizes any impairment loss on the assets associated with that contract. There were no onerous contracts as at November 30, 2010 and 2009 and December 1, 2008.



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

#### (n) Provisions (continued):

Site restoration:

Where there is a legal or constructive obligation to restore leased premises to good condition, except for normal aging on expiry or early termination of the lease, the resulting costs are provisioned up to the discounted value of estimated future costs and increase the carrying amount of the corresponding item of property and equipment. The Company amortizes the cost of restoring leased premises and recognizes an unwinding of discount expense on the liability related to the term of the lease.

#### Contingent liability:

A contingent liability is a possible obligation that arises from past events and of which the existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the Company; or a present obligation that arises from past events (and therefore exists), but is not recognized because it is not probable that a transfer or use of assets, provision of services or any other transfer of economic benefits will be required to settle the obligation, or the amount of the obligation cannot be estimated reliably.

#### (o) Income taxes:

Income tax expense comprises current and deferred tax. Current tax and deferred tax are recognized in net profit (loss) except to the extent that they relate to items recognized directly in other comprehensive income or in equity.

#### Current tax:

Current tax is the expected tax payable or receivable on the taxable income or loss for the year, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous years. The Company establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

#### Deferred tax:

Deferred tax is recognized in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted or substantively enacted by the reporting date.

A deferred tax liability is generally recognized for all taxable temporary differences.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(o) Income taxes (continued):

Deferred tax (continued):

A deferred tax asset is recognized for unused tax losses and deductible temporary differences, to the extent that it is probable that future taxable profits will be available against which they can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

(p) Share-based compensation:

The Company records share-based compensation related to employee stock options granted using the fair value based method estimated using the Black-Scholes model. Under this method, compensation cost is measured at fair value at the date of grant and expensed, as employee benefits, over the period in which employees unconditionally become entitled to the award. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service conditions are expected to be met, such that the amount ultimately recognized as an expense is based on the number of awards that do meet the related service and non-market performance conditions at the vesting date.

Share-based payment arrangements in which the Company receives goods or services as consideration for its own equity instruments are accounted for as equity-settled share-based payment transactions, regardless of how the equity instruments are obtained by the Company.

As permitted by IFRS 1, the Company elected not to restate options that were granted before November 7, 2002 and those granted after November 7, 2002 that were fully vested prior to the date of transition to IFRS.

(q) Government grants:

Government grants consisting of grants and investment tax credits, are recorded as a reduction of the related expense or cost of the asset acquired. Government grants are recognized when there is reasonable assurance that the Company has met the requirements of the approved grant program and there is reasonable assurance that the grant will be received.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(r) Share capital:

#### Common shares:

Common shares are classified as equity. Incremental costs directly attributable to the issue of common shares and share options are recognized as a deduction from equity, net of any tax effects.

(s) Earnings per share:

The Company presents basic and diluted earnings per share ("EPS") data for its common shares. Basic EPS is calculated by dividing the net profit or loss attributable to common shareholders of the Company by the weighted average number of common shares outstanding during the period, adjusted for own shares held, if applicable. Diluted EPS is determined by adjusting the profit or loss attributable to common shareholders and the weighted average number of common shares outstanding, adjusted for own shares held if applicable, for the effects of all dilutive potential common shares, which consist of the stock options granted to employees.

(t) New standards and interpretations not yet applied:

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning on or after January 1, 2010 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on the Company's results and financial position:

### Annual improvements to IFRS:

The IASB's improvements to IFRS published in April 2009 contain fifteen amendments to twelve standards that result in accounting changes for presentation, recognition or measurement purposes largely for annual periods beginning on or after January 1, 2010, with early adoption permitted. These amendments were considered by the Company and deemed to be not applicable to the Company other than for the amendment to IAS 17 — Leases relating to leases which include both land and buildings elements. In this case, the Company early adopted this amendment.

The IASB's improvements to IFRS contain seven amendments that result in accounting changes for presentation, recognition or measurement purposes. The most significant features of the IASB's annual improvements project published in May 2010 are included under the specific revisions to standards discussed below.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(t) New standards and interpretations not yet applied (continued):

Annual improvements to IFRS (continued):

(i) IFRS 3:

Revision to IFRS 3, Business Combinations:

Effective for annual periods beginning on or after July 1, 2010 with earlier adoption permitted.

Clarification on the following areas:

- the choice of measuring non-controlling interests at fair value or at the proportionate share of the acquiree's net assets applies only to instruments that represent present ownership interests and entitle their holders to a proportionate share of the net assets in the event of liquidation. All other components of non-controlling interest are measured at fair value unless another measurement basis is required by IFRS.
- application guidance relating to the accounting for share-based payments in IFRS 3 applies to all share-based payment
  transactions that are part of a business combination, including unreplaced awards (i.e., unexpired awards over the acquiree
  shares that remain outstanding rather than being replaced by the acquirer) and voluntarily replaced share-based payment
  awards.
- (ii) IFRS 7:

Amendment to IFRS 7, Financial Instruments: Disclosures:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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

(iii) IAS 1:

Amendment to IAS 1, Presentation of Financial Statements:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

(t) New standards and interpretations not yet applied (continued):

Annual improvements to IFRS (continued):

(iv) IAS 27:

Amendment to IAS 27, Consolidated and Separate Financial Statements:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

The 2008 revisions to this standard resulted in consequential amendments to IAS 21, *The Effects of Changes in Foreign Exchange Rates, IAS 28, Investments in Associates,* and IAS 31, *Interests in Joint Ventures.* IAS 27 now provides that these amendments are to be applied prospectively.

(v) IAS 34:

Amendment to IAS 34, Interim Financial Reporting:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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

New or revised standards and interpretations:

In addition, the following new or revised standards and interpretations have been issued but are not yet applicable to the Company:

(i) IAS 24:

Amendments to IAS 24, Related Party Disclosures:

Effective for annual periods beginning on or after January 1, 2011, with earlier adoption permitted.

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

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 3. Significant accounting policies (continued):

- (t) New standards and interpretations not yet applied (continued):
  - New or revised standards and interpretations (continued):
  - (ii) IFRS 8:

IFRS 8, Operating Segments:

Effective for annual periods beginning on or after January 1, 2010. Requires purchase information about segment assets.

### (iii) IFRS 9:

New standard IFRS 9, Financial Instruments:

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

As part of the project to replace IAS 39, Financial Instruments: Recognition and Measurement, this standard retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets. More specifically, the standard:

- deals with classification and measurement of financial assets
- establishes two primary measurement categories for financial assets: amortized cost and fair value
- classification depends on entity's business model and the contractual cash flow characteristics of the financial asset
- eliminates the existing categories: held to maturity, available for sale, and loans and receivables.

Certain changes were also made regarding the fair value option for financial liabilities and accounting for certain derivatives linked to unquoted equity instruments.

### 4. Revenue and deferred revenue:

On October 28, 2008, the Company entered into a collaboration and licensing agreement with EMD Serono Inc. ("EMD Serono"), an affiliate of the Group Merck KGaA, of Darmstadt, Germany, regarding the exclusive commercialization rights of tesamorelin in the United States for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy (the "Initial Product"). The Company retains all tesamorelin commercialization rights outside of the United States.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 4. Revenue and deferred revenue (continued):

Under the terms of the agreement, the Company is responsible for the development of the Initial Product up to obtaining marketing approval in the United States, which was obtained on November 10, 2010. The Company is also responsible for product production and for developing a new formulation of the Initial Product. EMD Serono is responsible for conducting product commercialization activities.

At the closing of the agreement on December 15, 2008, the Company received US\$30,000 (C\$36,951), which includes an initial payment of US\$22,000 (C\$27,097) and US\$8,000 (C\$9,854) as a subscription for common shares in the Company by Merck KGaA at a price of US\$3.67 (C\$4.52) per share. The Company may receive up to US\$215,000, which amount includes the initial payment of US\$22,000, the equity investment of US\$8,000, as well as payments based on the achievement of certain development, regulatory and sales milestones. The Company will also be entitled to receive increasing royalties on annual net sales of tesamorelin in the United States, if applicable.

The initial payment of \$27,097 has been deferred and is being amortized on a straight-line basis over the estimated period for developing a new formulation of the Initial Product. This period may be modified in the future based on additional information that may be received by the Company. At November 30, 2010, an amount of \$6,846 (2009 — \$6,560) was recognized as revenue. As at November 30, 2010, the deferred revenue related to this transaction amounted to \$13,692 (2009 — \$20,537).

On August 12, 2009, the FDA accepted the New Drug Application ("NDA") made by the Company for tesamorelin. Under the terms of the Company's collaboration and licensing agreement with EMD Serono, the acceptance of the tesamorelin NDA resulted in a milestone payment of US\$10,000 (C\$10,884).

On November 10, 2010, the FDA approved EGRIFTA<sup>TM</sup> as the first approved treatment in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. By virtue of the collaboration and licensing agreement entered into in 2008 with EMD Serono, the Company received a milestone payment of US\$25,000 (C\$25,000) associated with the FDA-approval of EGRIFTA<sup>TM</sup>. This payment was received by the Company on November 30, 2010.

The Company may conduct research and development activities for additional indications. Under the collaboration and licensing agreement, EMD Serono will also have the option to commercialize additional indications for tesamorelin in the United States. If it exercises this option, EMD Serono will pay half of the development costs related to such additional indications. In such cases, the Company will also have the right, subject to an agreement with EMD Serono, to participate in promoting these additional indications.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 5. Personnel expenses:

	Note	November 30, 2010	November 30, 2009
		\$	\$
Salaries and short-term employee benefits		11,577	10,779
Post-employment benefits		579	542
Termination benefits		20	275
Share-based compensation	15 (iv)	1,133	997
Total personnel expenses		13,309	12,593

### 6. Selling and market development expenses:

In 2008, the Company completed a formal review of the strategic alternatives regarding its operations which culminated in the signing of the collaborative licensing agreement with EMD Serono (note 4). As a result of this process, \$4,269 was recorded in 2009 for professional fees related to the closing of the agreement with EMD Serono.

#### 7. Finance income and finance costs:

Recognized in net profit (loss):

	November 30, 2010	November 30, 2009
	\$	\$
Interest income	1,562	2,123
Net gain on disposal of available-for-sale financial assets transferred from equity	326	129
Finance income	1,888	2,252
Bank charges	(18)	(26)
Net foreign currency gain (loss)	511	(635)
Finance costs	493	(661)
Net finance income recognized in net profit (loss)	2,381	1,591

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 7. Finance income and finance costs (continued):

Recognized in other comprehensive income:

	November 30, 2010	November 30, 2009
	\$	\$
Net change in fair value of available-for-sale financial assets	(390)	1,039
Net change in fair value of available-for-sale financial assets transferred to net profit (loss)	(326)	(129)
Finance (costs) income recognized in other comprehensive income, net of tax	(716)	910

#### 8. Bonds:

Bonds are interest-bearing available-for-sale financial assets, with a carrying amount of \$37,901 as at November 30, 2010 (\$61,843 in 2009, and \$46,204 as at December 1, 2008), have stated interest rates of 2.37% to 6.75% (2.37% to 6.75% in 2009 and 3.00% to 6.85% as at December 1, 2008) and mature in 1.9 year (2.16 in 2009 and 1.8 in 2008).

The Company's exposure to credit and interest rate risks related to bonds is presented in note 20.

### 9. Trade and other receivables:

	Note	November 30, 2010	November 30, 2009	December 1, 2008
		\$	\$	\$
Trade receivables		6	3	12
Sales tax receivable		100	190	419
Loans granted to employees under the share purchase plan	15 (iii)	25	74	91
Loans granted to related parties under the share purchase plan	15 (iii)	22	75	59
Other receivables	.,	8	33	29
		161	375	610

The Company's exposure to credit and currency risks related to trade and other receivables is presented in note 20.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

#### 10. Tax credits and grants receivable:

	November 30, 2010	November 30, 2009
	\$	\$
Balance at beginning of the year	1,333	1,451
Investment tax credits and grants received	(1,935)	(1,913)
Investment tax credits and grants recognized in net profit (loss)	934	1,795
	332	1,333

Tax credits and grants receivable comprise research and development investment tax credits receivable from the provincial government which relate to qualifiable research and development expenditures under the applicable tax laws. The amounts recorded as receivable are subject to a government tax audit and the final amounts received may differ from those recorded. There are no unfulfilled conditions or contingencies associated with the government assistance received.

\$

15,835

Unused federal tax credits may be used to reduce future income tax and expire as follows:

2023	452
2024 2025	1,597
2025	1,863
2026	2,178
2027	3,000 3,328
2028	3,328
2028 2029	2,250 1,167
2030	1,167

#### 11. Inventories:

	November 30, 2010	November 30, 2009	December 1, 2008
	\$	\$	\$
Raw materials	3,395	2,225	_
Work in progress	922	—	—
	4,317	2,225	—

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 11. Inventories (continued):

In 2010, \$123 of raw materials, and \$69 of work in progress were written down to their net realizable value (November 30, 2009 — nil and nil; December 1, 2008 — nil and nil). Consequently, a write-down of \$192 was recorded to cost of sales in 2010 (2009 — nil).

The write-down was due to unfavourable pricing related to raw materials that were not originally purchased under the conditions of the Company's current long-term procurement agreements.

### 12. Property and equipment:

	Computer	Laboratory	Office furniture and	Leasehold	
	equipment \$	equipment \$	equipment \$	improvements \$	Total \$
Cost:	Φ	Φ	Φ	Φ	φ
Balance at December 1, 2008	682	1,824	1,015	1,846	5,367
Additions	222	125	188	8	543
Disposals	(30)	(4)	(79)	_	(113)
Balance at November 30, 2009	874	1,945	1,124	1,854	5,797
Additions	130	116	7	46	299
Disposals	(63)	(43)	(2)	_	(108)
Balance at November 30, 2010	941	2,018	1,129	1,900	5,988
Accumulated depreciation:					
Balance at December 1, 2008	500	1,427	700	1,441	4,068
Depreciation for the year	147	96	79	290	612
Disposals	(30)	(4)	(78)	_	(112)
Balance at November 30, 2009	617	1,519	701	1,731	4,568
Depreciation for the year	170	88	85	123	466
Disposals	(63)	(41)	(2)	_	(106)
Balance at November 30, 2010	724	1,566	784	1,854	4,928
Net carrying amounts:					
December 1, 2008	182	397	315	405	1,299
November 30, 2009	257	426	423	123	1,229
November 30, 2010	217	452	345	46	1,060



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### **12.** Property and equipment (continued):

Depreciation expense for the year has been recorded in the following accounts in the consolidated statement of comprehensive income:

	November 30, 2010	November 30, 2009
	\$	\$
Cost of sales	8	—
Research and development expenses	231	306
Selling and market development expenses	10	14
General and administrative expenses	217	292
	466	612

#### 13. Accounts payable and accrued liabilities:

	Note	November 30, 2010	November 30, 2009	December 1, 2008
		\$	\$	\$
Trade payables		1,001	1,984	284
Accrued liabilities and other payables		1,440	1,768	4,692
Salaries and benefits due to related parties	25	565	450	504
Employee salaries and benefits payable		1,971	1,366	1,385
		4,977	5,568	6.865

The Company's exposure to currency and liquidity risks related to accounts payable and accrued liabilities is presented in note 20.

### 14. Other liabilities:

Other liabilities consist of deferred lease inducements relating to rent free periods amounting to \$325 as at November 30, 2010 (November 30, 2009 and December 1, 2008 — nil) (note 17).

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

#### 15. Share capital:

Authorized in unlimited number and without par value:

Common shares

Preferred shares issuable in one or more series

All issued shares are fully paid, except for 33,524 (2009 — 90,298) issued under the share purchase plan and for which the loan has not been repaid in full (see note 15 (iii)).

Common shareholders are entitled to receive dividends as declared by the Company at its discretion and are entitled to one vote per share at the Company's annual general meeting.

No preferred shares are outstanding.

(i) 2010:

In 2010, the Company received subscriptions in the amount of \$15 for the issuance of 2,880 common shares in connection with its share purchase plan.

2009:

Under the terms of the collaboration and licensing agreement with EMD Serono, the Company issued 2,179,837 common shares for a cash consideration of \$9,854 (see note 4).

In 2009, the Company also received subscriptions in the amount of \$96 for the issuance of 34,466 common shares in connection with its share purchase plan.

All shares issued were for cash consideration.

(ii) Shareholder rights plan:

On February 10, 2010, the Company's Board of Directors adopted a shareholder rights plan (the "Plan"), effective as of that date. The Plan is designed to provide adequate time for the Board of Directors and the shareholders, to assess an unsolicited takeover bid for the Company. In addition, the Plan provides the Board of Directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, as well as provide shareholders with an equal opportunity to participate in a takeover bid to receive full and fair value for their common shares. The Plan will expire at the close of the Company's annual meeting of shareholders in 2013.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

#### 15. Share capital (continued):

(ii) Shareholder rights plan (continued):

The rights issued under the Plan will initially attach to and trade with the common shares and no separate certificates will be issued unless a triggering event occurs. The rights will become exercisable only when a person, including any party related to it, acquires or attempts to acquire 20% or more of the outstanding shares without complying with the "Permitted Bid" provisions of the Plan or without approval of the Board of Directors. Should such an acquisition occur or be announced, each right would, upon exercise, entitle a rights holder, other than the acquiring person and related persons, to purchase common shares at a 50% discount to the market price at the time.

Under the Plan, a Permitted Bid is a bid made to all holders of the common shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties, have been tendered, the offeror may take up and pay for the common shares, but must extend the bid for a further 10 days to allow other shareholders to tender.

(iii) Share purchase plan:

The Share Purchase Plan entitles full-time and part-time employees of the Company who, on the participation date, are residents of Canada, are not under a probationary period and do not hold, directly or indirectly, five percent (5%) or more of the Company's outstanding common shares, to directly subscribe for common shares of the Company. Under the Share Purchase Plan, a maximum of 550,000 common shares may be issued to employees.

On May 1 and November 1 of each year (the "Participation Dates"), an employee may subscribe for a number of common shares under the Share Purchase Plan for an amount that does not exceed 10% of that employee's gross annual salary for that year. Under the Share Purchase Plan, the Board of Directors has the authority to suspend or defer a subscription of common shares, or to decide that no subscription of common shares will be allowed on a Participation Date if it is in the Company's best interest.

The Share Purchase Plan provides that the number of common shares that may be issued to insiders, at any time, under all sharebased compensation arrangements of the Company, cannot exceed 10% of the Company's outstanding common shares, and the number of common shares issued to insiders, within any one-year period, under all security-based compensation arrangements, cannot exceed 10% of the outstanding common shares.

The subscription price for each new common share subscribed for under the Share Purchase Plan is equal to the weighted average closing price of the common shares on the Toronto Stock Exchange during a period of five days prior to the Participation Date. Employees may not assign the rights granted under the Share Purchase Plan.



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 15. Share capital (continued):

(iii) Share purchase plan (continued):

An employee may elect to pay the subscription price for common shares in cash or through an interest-free loan from the Company. Loans granted by the Company under the Share Purchase Plan are repayable through salary withholdings over a period not exceeding two years. All loans may be repaid prior to the scheduled repayment at any time. The loans granted to any employee may at no time exceed 10% of that employee's current annual gross salary. All common shares purchased through an interest-free loan are hypothecated to secure full and final repayment of the loan and are held by a trustee until repayment in full. Loans are immediately due and payable on the occurrence of any of the following events: (i) termination of employment; (ii) sale or seizure of the hypothecated common shares; (iii) bankruptcy or insolvency of the employee; or (iv) suspension of the payment of an employee's salary or revocation of the employee's right to salary withholdings.

At November 30, 2010, \$47 (November 30, 2009 - \$149; December 1, 2008 - \$150) was receivable under these loans (see note 9).

(iv) Stock option plan:

The Company has established a stock option plan under which it can grant to its directors, officers, employees, researchers and consultants non-transferable options for the purchase of common shares. The exercise date of an option may not be later than 10 years after the grant date. A maximum number of 5,000,000 options can be granted under the plan. Generally, the options vest at the date of the grant or over a period up to 5 years. As at November 30, 2010, 981,005 options could still be granted by the Company (2009 - 1,244,834).

All options are to be settled by physical delivery of shares.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 15. Share capital (continued):

(iv) Stock option plan (continued):

Changes in the number of options outstanding during the past two years were as follows:

		Weighted average exercise price
	Options	per option
		\$
Options at December 1, 2008	2,161,800	6.52
Granted	680,500	1.83
Expired	(58,500)	5.16
Forfeited	(118,000)	9.92
Options at November 30, 2009	2,665,800	5.20
Granted	335,000	4.03
Expired	(32,500)	11.15
Forfeited	(38,671)	3.61
Exercised (weighted average share price: \$5.14)	(80,491)	1.66
Options at November 30, 2010	2,849,138	5.12
Exercisable at November 30, 2010	2,196,403	5.77

The following table provides stock option information as at November 30, 2010:

	Number of	Weighted average remaining	ns outstanding Weighted average
	options	life	exercise
Price range (\$)	outstanding	(years)	price \$
			Ŧ
1.20 — 2.00	1,183,015	6.54	1.71
2.01 — 2.75	141,459	3.85	2.59
2.76 — 3.75	70,000	5.51	3.37
3.76 — 4.60	265,000	9.03	3.84
4.61 — 6.00	95,000	7.69	4.93
6.01 — 9.00	570,664	4.82	8.17
9.01 — 13.50	480,000	2.86	10.72
13.51 — 15.30	44,000	0.36	15.12
	2,849,138	5.59	5.12

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 15. Share capital (continued):

(iv) Stock option plan (continued):

The fair value of options granted was estimated at the grant date using the Black-Scholes model and the following weighted average assumptions:

	Nove	mber 30, 2010	Nove	mber 30, 2009
Risk-free interest rate		2.49%		1.83%
Expected volatility		81.13%		79.50%
Average option life in years		7.5		7.5
Expected dividends		nil		nil
Grant-date share price	\$	4.03	\$	1.83
Option exercise price	\$	4.03	\$	1.83

The risk-free interest rate is based on the implied yield on a Canadian Government zero-coupon issue with a remaining term equal to the expected term of the option. The volatility is based solely on historical volatility equal to the expected life of the option. The life of the options is estimated considering the vesting period at the grant date, the life of the option and the average length of time similar grants have remained outstanding in the past. The dividend yield was excluded from the calculation since it is the present policy of the Company to retain all earnings to finance operations and future growth.

The following table summarizes the measurement date weighted average fair value of stock options granted during the years ended November 2010 and 2009:

	Number of options	Weighted average grant-date fair value
		\$
2010 2009	335,000 680,500	3.05 1.36

The Black-Scholes model used by the Company to calculate option values was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differs from the Company's stock option awards. This model also requires four highly subjective assumptions, including future stock price volatility and average option life, which greatly affect the calculated values.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 15. Share capital (continued):

#### (v) Earnings per share:

The calculation of basic earnings per share at November 30, 2010 was based on the net profit (loss) attributable to common shareholders of the Company of \$8,930 (2009 - (\$15,156)), and a weighted average number of common shares outstanding of 60,480,032 (2009 — 60,314,309), calculated as follows:

	November 30, 2010	November 30, 2009
Issued common shares at December 1	60,429,393	58,215,090
Effect of share options exercised	49,030	_
Effect of shares issued during the year	1,609	2,099,219
5		
Weighted average number of common shares at November 30	60.480.032	60.314.309

The calculation of diluted earnings per share was based on a weighted average number of common shares calculated as follows:

November 30, 2010	November 30, 2009
60 480 032	60,314,309
842,959	
61 222 001	60.314.309
	<u>2010</u> 60,480,032

At November 30, 2010, 1,119,664 options (2009 — 1,371,167) were excluded from the diluted weighted average number of common shares calculation as their effect would have been anti-dilutive.

The average market value of the Company's shares for purposes of calculating the dilutive effect of share options was based on quoted market prices for the period during which the options were outstanding.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 16. Income taxes:

Current tax expense:

	November 30, 2010	November 30, 2009
	\$	\$
Current tax expense:		
Current tax expense for the year	3,285	_
Recognition of previously unrecognized tax losses	(3,171)	—
Current Income tax expense	114	
Deferred tax expense:		
Recognition and reversal of temporary differences		(4,031)
Change in unrecognized deductible temporary differences	—	4,031
Deferred income tax expense		
Total income tax expense	114	

Reconciliation between effective and applicable tax amounts:

	November 30, 2010	November 30, 2009
	\$	\$
Income taxes at domestic tax statutory rate	2,713	(4,683)
Change in unrecognized deductible temporary differences	(3,171)	4,031
Non-deductible expenses and other	572	652
	114	—

Deferred tax assets:

Deferred tax asset of \$114 (2009 - nil) related to share issue costs was recognized directly in equity.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

### 16. Income taxes (continued):

Deferred tax assets (continued):

Unrecognized deferred tax assets:

At November 30, 2010, temporary differences for which no deferred tax asset was recognized were as follows:

	November 30, 2010	November 30, 2009
	\$	\$
Long-term:		
Research and development expenses	30,143	29,380
Deferred non-capital losses	21,013	21,490
Property and equipment	609	674
Intellectual property and patent fees	9,230	12,307
Available deductions and other	4,648	4,963
	65,643	68,814

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

Given the Company's past losses, management does not believe that it is more probable than not that the Company can realize its deferred tax assets and therefore it has not recognized any amount in the statement of financial position.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 16. Income taxes (continued):

Deferred tax assets (continued):

Unrecognized deferred tax assets (continued):

At November 30, 2010, the amounts and expiry dates of tax attributes to be deferred for which no deferred tax asset was recognized were as follows:

		November 30, 2010		November 30, 2009
	Federal	Provincial	Federal	Provincial
	\$	\$	\$	\$
Research and development expenses, without time limitation	103,324	123,062	103,346	115,686
Losses carried forward:				
2014	1,216	_	9,603	_
2015	275	_	275	_
2027	7,638	7,628	7,638	7,628
2028	46,316	32,174	46,316	46,271
2029	19,484	16,467	21,785	18,802
2030	11,440	11,436	—	—
Other temporary differences, without time limitation:				
Excess of tax value of property and equipment over carrying value	2,773	1,666	3,121	1,785
Tax value of intellectual property and patent fees	34,301	34,289	45,735	45,718
Available deductions and other	57,343	1,412	58,415	2,732

### 17. Operating leases:

The Company rents its headquarters and main office pursuant to an operating lease (the "Lease") expiring in April 2021. Under the terms of the Lease, the Company has also been granted two renewal options for periods of five years each. Lease payments will increase by 11% beginning on November 1, 2015.

During the year ended November 30, 2010, an amount of \$628 was recognized as an expense in respect of operating leases (2009 — \$805). Of the amount \$133 (2009 — \$176) is included in General and administrative expenses and \$495 (2009 — \$629) is included in Research and development expenses.



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

## 17. Operating leases (continued):

The Company's lease includes a lease of land and building. Since the land title does not pass, and the Company does not participate in the residual value of the building, it was determined that substantially all the risks and rewards of the building are with the lessor. As such, the Company determined that the lease is an operating lease.

The Company has committed to pay the lessor for its share of some operating expenses of the leased premises. This amount has been set at \$240 per year beginning May 1, 2010 and will be increased by 2.5% annually for the duration of the Lease. Refer to note 23 for the contractual commitments related to this lease.

The lessor granted the Company a monetary allowance in the amount of \$728 to make leasehold improvements. This amount had not been received as at November 30, 2010. Furthermore, the Company benefits from a 25-month rent free period which is deferred and recognized over the lease term. As at November 30, 2010, \$325 was included in Other liability (nil — November 30, 2009) in regards to the deferred free rent inducement (note 14 — Other liabilities).

The Company had issued an irrevocable letter of credit in favour of the lessor in the amount of \$323 under the terms of the Lease renewal, along with a first ranking movable hypothec in the amount of \$1,150 covering all the Company's tangible assets located in the rented premises. The letter of credit and the hypothec were cancelled on April 30, 2010.

### 18. Contingent liability:

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

The Motion had not yet been heard by the Superior Court of Quebec and a date has not been set for the hearing.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 18. Contingent liability (continued):

The Company has subscribed to insurance covering its potential liability and the potential liability of its directors and officers in the performance of their duties for the Company subject to a \$200 deductible. At November 30, 2010, an amount of \$96 in legal fees has been accrued and included in general and administrative expenses, of which \$61 was paid during the year and \$35 remained in accounts payable and accrued liabilities.

# 19. Statement of cash flows:

The Company entered into the following transactions which had no impact on the cash flows:

	November 30,	November 30,	December 1,
	2010	2009	2008
	\$	\$	\$
Additions to property and equipment included in accounts payable and accrued liabilities	65	183	48
Share issue costs included in accounts payable and accrued liabilities		—	8
In addition, interest received totalled \$2,290 (2009 — \$1,200).			

### 20. Financial instruments:

Overview:

This note provides disclosures relating to the nature and extent of the Company's exposure to risks arising from financial instruments, including credit risk, liquidity risk, currency risk and interest rate risk, and how the Company manages those risks.

(a) Credit risk:

Credit risk is the risk of an unexpected 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.



Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 20. Financial instruments (continued):

Overview (continued):

(a) Credit risk (continued):

The Company's exposure to credit risk currently relates to accounts receivable with only one customer (see note 4). Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragovernmental and municipal bodies (\$37,542 as at November 30, 2010) as well as from companies with high credit ratings (\$359 as at November 30, 2010). As at November 30, 2010, the Company was not exposed to any credit risk over the carrying amount of the bonds.

(b) 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 the capital management section below, 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 to ensure the Company's liquidity needs are met. The instruments are selected with regard to the expected timing of expenditures and prevailing interest rates.

The following are amounts due on the contractual maturities of financial liabilities as at November 30, 2010 and 2009:

					November 30, 2010
	Total	Carrying amount	Less than 1 year	1 to 5 years	More than 5 years
	\$	\$	\$	\$	\$
Accounts payable and accrued liabilities	4,977	4,977	4,977	_	_
	38				

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

## 20. Financial instruments (continued):

Overview (continued):

(b) Liquidity risk (continued):

					November 30, 2009
	Total	Carrying amount	Less than 1 year	1 to 5 years	More than 5 years
	\$	\$	\$	\$	\$
Accounts payable and accrued liabilities	5,568	5,568	5,568		—

(c) 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 the Canadian dollar, primarily revenues from milestone payments and expenses for research and development incurred in US dollars, euros and pounds sterling ("GBP"). The Company does not use derivative financial instruments to reduce its foreign exchange exposure.

The Company manages currency risk by maintaining cash in US dollars on hand to support US forecasted cash budgets for a maximum 12-month period. The Company does not currently view its exposure to the euro and GBP as a significant foreign exchange risk due to the limited volume of transactions conducted by the Company in these currencies.

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

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 20. Financial instruments (continued):

Overview (continued):

(c) Currency risk (continued):

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

			November 30, 2010
	\$US	EURO	GBP
Cash	26,424	—	1
Trade and other receivables		—	—
Accounts payable and accrued liabilities	(465)	(26)	(81)
Items exposed to currency risk	25,959	(26)	(80)
			November 30, 2009
	\$US	EURO	GBP
Cash	1,471		_
Trade and other receivables		4	_
Accounts payable and accrued liabilities	(1,095)	_	(25)
Items exposed to currency risk	376	4	(25)
			December 1, 2008
	\$US	EURO	GBP
Cash	1	_	_
Trade and other receivables	_		
Accounts payable and accrued liabilities	(2,589)	(159)	(348)
Items exposed to currency risk	(2,588)	(159)	(348)

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 20. Financial instruments (continued):

Overview (continued):

# (c) Currency risk (continued):

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

		November 30, 2010		November 30, 2009		December 1, 2008
	Average rate	Reporting date rate	Average rate	Reporting date rate	Average rate	Reporting date rate
\$US — C\$	1.0345	1.0266	1.0594	1.0556	1.0479	1.2370
EURO — C\$	1.3848	1.3326	1.5808	1.5852	1.5440	1.5711
GBP — C\$	1.6051	1.5969	1.7597	1.7366	1.9767	1.9060

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

	November 30, 2010			November 30, 2009		
	\$US	EURO	GBP	\$US	Euro	GBP
Increase in net profit (loss)	1,298	(1)	(4)	19	_	(1)

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

#### (d) 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 to maturity. The unrealized gains or losses on bonds are recorded in accumulated other comprehensive income.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

## 20. Financial instruments (continued):

Overview (continued):

(d) Interest rate risk (continued):

Based on the value of the Company's short and long-term bonds at November 30, 2010, 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 \$336; an assumed increase in interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

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

Based on the average value of variable interest-bearing cash during the year ended November 30, 2010 (\$3,219), an assumed 0.5% increase in interest rates during such period would have increased future cash flow and net profit by approximately \$16; an assumed decrease of 0.5% would have had an equal but opposite effect.

### 21. Capital management:

The Company's objective in managing capital is to ensure a sufficient liquidity position to finance its research and development activities, general and administrative expenses, working capital and capital spending.

To fund its activities, the Company relied primarily on public offerings of common shares in Canada and private placements of its common shares as well as up-front payments and milestone payments primarily associated with EMD Serono. When possible, the Company optimizes its liquidity position using non-dilutive sources, including investment tax credits, grants and interest income.

The Company has a \$1,800 revolving credit facility for its short-term financing needs which was unused at November 30, 2010 (see note 23 (c)).

The capital management objectives remain the same as for the previous year.

At November 30, 2010, cash and bonds amounted to \$64,550 and tax credits and grants receivable amounted to \$332, for a total of \$64,882. The Company believes that its cash position will be sufficient to finance its operations and capital needs for the next year.

Currently, the Company's general policy on dividends is to retain cash to keep funds available to finance the Company's growth.

The Company is not subject to any externally imposed capital requirements.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

## 22. Determination of fair values:

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.

#### Financial assets and liabilities:

In establishing fair value, the Company uses a fair value hierarchy based on levels as defined below:

- Level 1: defined as observable inputs such as quoted prices in active markets.
- Level 2: defined as inputs other than quoted prices in active markets that are either directly or indirectly observable.
- Level 3: defined as inputs that are based on little or no observable market data, therefore requiring entities to develop its own assumptions.

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

Bonds are stated at estimated fair value, determined by inputs that are primarily based on broker quotes at the reporting date (Level 2).

#### Share-based payment transactions:

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

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 23. Commitments:

(a) Leases:

At November 30, 2010 and 2009 and December 1, 2008, the minimum payments required under the terms of the non-cancellable lease are as follows:

	November 30, 2010	November 30, 2009	December 1, 2008
	\$	\$	\$
Less than one year	55	340	816
Between one and five years	2,239	2,020	340
More than five years	3,943	4,216	—
	6,237	6,576	1,156

### (b) Long-term procurement agreements:

During and after the years ended November 30, 2010 and 2009, the Company entered into long-term procurement agreements with third-party suppliers in anticipation of the commercialization of EGRIFTATM.

## (c) Credit facility:

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

As at November 30, 2010 and 2009, the Company did not have any borrowings outstanding under this credit facility.

## 24. Operating segments:

The Company has a single operating segment. As described in note 4, all of the Company's revenues are generated from one customer, EMD Serono, which is domiciled in the United States.

All of the Company's non-current assets are located in Canada, the Company's headquarters.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

#### 25. Related parties:

The Company has a related party relationship with its wholly-owned subsidiaries. There are no transactions between the Company and its subsidiaries.

The key management personnel of the Company are the Directors.

Key management personnel compensation comprised:

	Note	November 30, 2010	November 30, 2009
		\$	\$
Short-term employee benefits		1,891	1,647
Post-employment benefits		61	59
Share-based compensation	15 (iv)	331	175
		2,283	1,881

Directors of the Company control 1.2 percent of the voting shares of the Company.

On November 30, 2010, loans granted to key management personnel under share purchase plan (note 15 (iii)) amount to \$22 as at November 30, 2010 (\$75 as at November 30, 2009 and \$59 as at December 1, 2008).

#### 26. Subsequent events:

Distribution and licensing agreement:

On December 6, 2010, the Company announced the signing of a distribution and licensing agreement with Sanofi-aventis ("Sanofi"), covering the commercial rights for EGRIFTA<sup>™</sup> in Latin America, Africa, and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

Under the terms of the agreement, the Company will sell EGRIFTA<sup>™</sup> to Sanofi at a transfer price equal to the higher of a percentage of Sanofi's net selling price and a predetermined floor price. The Company has retained all future development rights to EGRIFTA<sup>™</sup> and will be responsible for conducting research and development for any additional potential indications. Sanofi will be responsible for conducting all regulatory activities for EGRIFTA<sup>™</sup> in the aforementioned territories, including applications for approval in the different countries for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. The Company also granted Sanofi an option to commercialize tesamorelin for other indications in the territories mentioned above. If such option is not exercised, or is declined, by Sanofi, the Company may commercialize tesamorelin for such indications on its own or with a third party.

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Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

#### 26. Subsequent events (continued):

#### Distribution and licensing agreement (continued):

On February 3, 2011, the Company entered into a distribution and licensing agreement with Ferrer covering the commercial rights for EGRIFTATM for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the Agreement, the Company will sell EGRIFTA<sup>TM</sup> to Ferrer at a transfer price equal to the higher of a significant percentage of the Ferrer's net selling price and a predetermined floor price. The Company has retained all development rights to EGRIFTA<sup>TM</sup> for other indications and will be responsible for conducting research and development for any additional programs. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with EGRIFTA<sup>TM</sup> for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. The Company will be responsible for the manufacture and supply of EGRIFTA<sup>TM</sup> to Ferrer. The Company has the option to co-promote EGRIFTA<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Ferrer has the option to enter into a co-development and commercialization agreement using tesamorelin relating to any such new indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development.

#### Deferred share unit plan:

In December 2010, the Company adopted a deferred share unit plan ("Plan") to provide long-term incentive compensation for its directors and executive officers. Under the Plan, directors must receive their annual remuneration as a board member in fully vested deferred share units ("DSUs") until they reach a percentage of their annual remuneration and, once such percentage is attained, they have the option to elect to receive part or all of this annual remuneration in DSUs. Under the plan, executive officers have the option of receiving all or a portion of their annual bonus in the form of fully-vested DSUs. The units are only redeemable for cash when a participant ceases to be an employee or member of the Board of Directors. The Company manages the risk associated with the issuance of the DSU by entering into a yearly forward contract with a third party. As at February 7, 2011, all of the 99,912 DSU outstanding were covered by a prepaid forward contract.

#### Stock option plan:

Between December 1, 2010 and February 7, 2011, the Company granted 250,000 options at an exercise price of \$5.65 per share. Also 27,832 options were forfeited and expired at a weighted exercise average price of \$12.06 per share. Furthermore, 3,000 options were exercised at a weighted exercise average price of \$1.80 per share for a cash consideration of \$5.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 27. Transition to IFRS:

As stated in note 2 (a), these are the Company's first consolidated financial statements prepared in accordance with IFRSs. The Company has applied IFRS 1 and the accounting policies set out in note 3 in preparing the financial statements for the year ended November 30, 2010, the comparative information presented in these financial statements for the year ended November 30, 2009 and in the opening IFRS statement of financial position at December 1, 2008 (the Company's date of transition).

In preparing these consolidated financial statements in accordance with IFRS 1, the Company has applied the mandatory exceptions and certain of the optional exemptions from full retrospective application of IFRSs.

The Company elected to apply the following optional exemptions from full retrospective application:

(i) Share-based payment transaction exemption:

The Company has elected to apply the share-based payment exemption. It applied IFRS 2 from December 1, 2008 to those stock options that were issued after November 7, 2002 but that had not vested by December 1, 2008. The application of the exemption is detailed below.

(ii) Designation of financial assets and financial liabilities exemption:

The Company elected to re-designate cash from the held-for-trading category to loans and receivables.

As required by IFRS 1, estimates made under IFRS at the date of transition must be consistent with estimates made for the same date under previous GAAP, unless there is evidence that those estimates were in error.

In preparing its opening IFRS consolidated statement of financial position, the Company has adjusted amounts reported previously in financial statements prepared in accordance with Canadian GAAP.

An explanation of how the transition from previous Canadian GAAP to IFRS has affected the Company's financial position, financial performance and cash flows is set out in the following tables and accompanying notes.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 27. Transition to IFRS (continued):

Reconciliation of equity as at December 1, 2008 and November 30, 2009:

					ember 1, 2008				mber 30, 2009
	Note	Canadian GAAP	IFRS adjust- ments	IFRS reclassi- fications	IFRS	Canadian GAAP	IFRS adjust- ments	IFRS reclassi- fications	IFRS
	Hote	\$	\$	\$	\$	\$	\$	\$	\$
Assets									
Current assets:									
Cash		133	—	_	133	1,519			1,519
Bonds		10,955	—	—	10,955	10,036	—	—	10,036
Trade and other									
receivables		610	—	—	610	375	—	—	375
Tax credits and grants	(-)	1 70 4		(000)	4 454	1.000		(000)	1 000
receivable	(a)	1,784	—	(333)	1,451	1,666	—	(333)	1,333
Inventories	(a)	201		(201)	—	2,225 287		(207)	2,225
Research supplies Prepaid expenses	(a)	301 397	—	(301) 342	739	302	-	(287) 328	630
	(a)	14,180	_	(292)			_		
Total current assets		14,180		(292)	13,888	16,410	_	(292)	16,118
Non-current assets:									
Bonds		35,249	_	_	35,249	51,807	_	_	51,807
Property and		00,210			00,210	01,001			01,001
equipment		1,299	_	_	1,299	1,229	_	_	1,229
Other assets	(a)	2,817	_	(41)	2,776	41	_	(41)	
Total non-current	X-7	,-		. ,	, -				
assets		39,365	_	(41)	39,324	53,077	_	(41)	53,036
Total assets		53,545		(333)	53,212	69,487	_	(333)	69,154
Liabilities Current liabilities:									
Accounts payable and accrued liabilities	(a)	7,198	_	(333)	6,865	5,901	_	(333)	5,568
Current portion of	()	.,		()	-,	-1		()	-,
deferred revenue		_	_	_	_	6,847	_	_	6,847
Total current liabilities		7,198		(333)	6,865	12,748		(333)	12,415
Non-current liabilities:									
Deferred revenue			_			13,691	_	_	13,691
Total non-current liabilities		_	_	_	_	13,691	_	_	13,691
Total liabilities		7,198		(333)	6,865	26,439	_	(333)	26,106
Equity									
Share capital		269,219		—	269,219	279,169	—		279,169
Contributed surplus	(b)	5,585	175	_	5,760	6,484	273		6,757
Deficit	(b)	(228,829)	(175)	—	(229,004)	(243,887)	(273)	—	(244,160)
Accumulated other comprehensive									
income		372			372	1,282			1,282
Total equity		46,347	_	—	46,347	43,048	_	_	43,048
Total liabilities and					50.040	<b>00</b> 10 <b>-</b>			
equity		53,545		(333)	53,212	69,487	_	(333)	69,154
				48					

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

# 27. Transition to IFRS (continued):

Reconciliation of comprehensive income for the year ended November 30, 2009:

		Canadian	IFRS adjust-	IFRS reclassi-	
	Note	GAAP	ments	fication	IFRS
		\$	\$	\$	\$
Revenue:					
Research services:					
Milestone payments	(C)	_	_	10,884	10,884
Upfront payments and initial technology access fees	(c)	_	_	6,560	6,560
Royalties and license fees	(C)	17,468	_	(17,444)	24
Interest	(c)	2,252	_	(2,252)	_
Total revenue		19,720		(2,252)	17,468
Research and development expenses, net of tax					
credits	(b),(c)	20,431	33	346	20,810
Selling and market development expenses	(b),(c)	2,583	10	4,269	6,862
General and administrative expenses	(b),(c)	7,149	55	(661)	6,543
Patents	(C)	346		(346)	—
Fees associated with the collaboration and licensing					
agreement	(C)	4,269	_	(4,269)	
Total operating expenses		34,778	98	(661)	34,215
Results from operating activities		(15,058)	(98)	(1,591)	(16,747)
Finance income	(C)	—	—	2,252	2,252
Finance costs	(C)	—	—	(661)	(661)
Total net finance income		—	—	1,591	1,591
Netland			(00)		
Net loss		(15,058)	(98)		(15,156)
Other comprehensive income:					
Net change in fair value of available-for-sale financial					
assets		1,039		_	1,039
Net change in fair value of available-for-sale financial		1,000			1,000
assets transferred to net profit (loss)		(129)	_	_	(129)
Other comprehensive income for the year		910	_	_	910
Total comprehensive income for the year		(14,148)	(98)		(14,246)
Total comprehensive income for the year		(14,140)	(96)		(14,240)

Material adjustments to the consolidated statement of cash flows for 2009:

There are no material differences between the consolidated statement of cash flows presented under IFRS and the consolidated statement of cash flows presented under previous Canadian GAAP.

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

## 27. Transition to IFRS (continued):

Notes to the reconciliations:

(a) Reclassification in the consolidated statement of financial position:

Certain corresponding figures as at December 1, 2008 and November 30, 2009 have been reclassified to conform to the new presentation under IFRS.

(b) Share-based compensation:

In certain situations, stock options granted vest in instalments over a specified vesting period. When the only vesting condition is service from the grant date to the vesting date of each tranche awarded, then each instalment should be accounted for as a separate share-based payment arrangement under IFRS, otherwise known as graded vesting. Canadian GAAP permits an entity the accounting policy choice with respect to graded vesting awards. Each instalment can be considered as a separate award, each with a different vesting period, consistent with IFRS, or the arrangement can be treated as a single award with a vesting period based on the average vesting period of the instalments depending on the policy elected.

The Company's policy under Canadian GAAP was to treat graded vesting awards under the latter method and, as a result, an adjustment of \$175 was required on the application of IFRS 2 at the transition date, and an adjustment of \$98 was required for the restated 2009 comparative balances as shown below:

	December 1, 2008	November 30, 2009
	\$	\$
Consolidated statement of comprehensive income:		
Increase in research and development expenses	_	33
Increase in selling and market development expenses	_	10
Increase in general and administrative expenses		55
Adjustment to net loss and total comprehensive loss	_	98
Deficit	(175)	(273)
Increase in contributed surplus	175	273

Notes to the Consolidated Financial Statements, Continued

Years ended November 30, 2010 and 2009 and as at December 1, 2008 (in thousands of Canadian dollars, except per share amounts)

## 27. Transition to IFRS (continued):

Notes to the reconciliations (continued):

(c) Reclassification in the consolidated statement of comprehensive income:

Under IFRS, the Company elected to present expenses using a classification based on their function and presents net finance income separately. The effect of these changes is summarized below:

	November 30, 2009
	\$
Decrease in interest	(2,252)
Increase in finance income	2,252
Increase in research and development expenses	346
Decrease in patent fees	(346)
Decrease in general and administrative expenses	(661)
Increase in finance costs	661
Increase in selling and market development expenses	4,269
Decrease in fees associated with the collaboration and licensing agreement	(4,269)
	_

Changes in presentation were also made to the revenue caption in order to conform with the new presentation under IFRS as noted below:

	November 30,
	2009
	\$
Decrease in royalties and license fees	(17,444)
Increase in upfront payments and initial technology access fees	6,560
Increase in milestone payments	10,884



#### **Forward-Looking Information**

This Management's discussion and analysis ("MD&A") contains certain statements that are considered "forward-looking information" within the meaning of applicable securities legislation. This forward-looking information includes, but is not limited to, information regarding the preparation and filing of applications seeking regulatory approval of *EGRIFTATM* in the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in various territories outside of the United States, the revenue to be generated as a result of sales of *EGRIFTATM* to EMD Serono, Inc., ("EMD Serono"), the receipt of royalties from EMD Serono in connection with the sale of *EGRIFTATM* in the United States, and the development of tesamorelin in a new clinical program for a new indication. Furthermore, the words "will", "may", "could", "should", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms or variations of them and the use of future or conditional tenses as well as similar expressions denote forward-looking information.

Forward-looking information is based upon a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond the Company's control, that could cause actual results to differ materially from those that are disclosed in or implied by such forward-looking information. These risks and uncertainties are described under the section "Risks and Uncertainties" on page 21 and include, but are not limited to, the risk that *EGRIFTATM* is not approved in all or some of the territories referred to in this MD&A, the revenue and royalties we expect to generate from sales of *EGRIFTATM* is lower than anticipated, the supply of *EGRIFTATM* to our commercial partners is delayed or suspended as a result of problems with our suppliers, *EGRIFTATM* is withdrawn from the market as a result of defects or recalls, our intellectual property is not adequately protected and our liquidity level decreases based on unexpected activities that must be carried out in order to achieve our business plan.

Although the forward-looking information contained in this MD&A is based upon what we believe are reasonable assumptions, investors are cautioned against placing undue reliance on this information since actual results may vary materially from the forward-looking information contained in this MD&A. Certain assumptions made in preparing the forward-looking information include the assumption that tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will receive approval in the territories referred to in this MD&A, no additional clinical studies will be required to obtain said regulatory approval of tesamorelin, *EGRIFTATM* will be accepted by the marketplace in the United States and will be on the list of reimbursed drugs by third-party payers, our relations with third-party suppliers of *EGRIFTATM* will be conflict-free and that such third-party suppliers will have enough capacity to manufacture and supply *EGRIFTATM* to meet its demand and on a timely-basis and that our business plan will not be substantially modified.

Consequently, all of the forward-looking information contained in this MD&A is qualified by the foregoing cautionary statements, and there can be no guarantee that the results or developments that we anticipate will be realized or, even if substantially realized, that they will have the expected consequences or effects on our business, financial condition or results of operation.

## Management's Discussion and Analysis

The following discussion and analysis provides management's point of view on the financial position and the results of operations of Theratechnologies Inc., on a consolidated basis for the twelve-month periods ended November 30, 2010 ("fiscal 2010") and November 30, 2009 ("fiscal 2009"). Unless otherwise indicated or unless the context requires otherwise, all references in this MD&A to "Theratechnologies", "the Company", "we", "us", "our" or similar terms refer to Theratechnologies Inc. and its consolidated subsidiaries. This information is dated February 8, 2011, and should be read in conjunction with the Audited Consolidated Financial Statements and the accompanying notes. Unless specified otherwise, all amounts are in Canadian dollars. In this MD&A, the use of "*EGRIFTATM*" refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy regardless of the trade name used for such product in any particular territory. *EGRIFTATM* is the trade name used in the United States for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Except as otherwise indicated, the financial information contained in this MD&A and in our Audited Consolidated Financial Statements has been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Our financial statements were previously prepared in accordance with Canadian Generally Accepted Accounting Principles ("GAAP"). For more information regarding the conversion to IFRS, please refer to the heading "Conversion to IFRS" in this MD&A and to note 27 of the Audited Consolidated Financial Statements, which are our first consolidated financial statements prepared in accordance with IFRS.

The Audited Consolidated Financial Statements and MD&A have been reviewed by our Audit Committee and approved by our Board of Directors.

#### Overview

We are a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products with an emphasis on growthhormone releasing factor peptides. We are leveraging our expertise in the field of metabolism to discover and develop products in specialty markets. Our commercialization strategy is to retain all or a significant portion of the commercial rights to our products. Our first product,  $EGRIFTA^{TM}$  (tesamorelin for injection), was approved by the United States Food and Drug Administration ("FDA") in November 2010. To date,  $EGRIFTA^{TM}$  is the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Lipodystrophy in HIV-infected patients presents a serious medical condition, affecting approximately 29% of all diagnosed and treated HIV-infected patients. This condition is associated with a range of physiological and psychological complications beyond the significant health and mortality risks of the HIV infection itself. *EGRIFTA*<sup>™</sup> is currently marketed in the United States by EMD Serono, Inc. ("EMD Serono"), an affiliate of Merck KGaA, pursuant to a collaboration and licensing agreement entered into by us and EMD Serono in October 2008. In addition, we have signed distribution and licensing agreements with Sanofi Winthrop Industries, an affiliate of Sanofi-aventis (collectively, "Sanofi"), for the commercialization rights for *EGRIFTA*<sup>™</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East and with Ferrer Internacional S.A. ("Ferrer") for the commercialization rights for *EGRIFTA*<sup>™</sup> for the reduction of excess abdominal fat in HIV-

infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries. *EGRIFTA*<sup>TM</sup> is the trade name used in the United States for tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

The first six months of fiscal 2010 were devoted to preparing for a public meeting with the Endocrinologic and Metabolic Drugs Advisory Committee, which the FDA of the United States had asked us to attend in the context of its review of our New Drug Application ("NDA") for  $EGRIFTA^{TM}$ . As an integral part of the FDA review process for a NDA, the principal role of an advisory committee is to provide an independent point of view to enhance the quality of the agency's regulatory decision-making process. At the public meeting held on May 27, 2010, the committee of experts unanimously recommended to the FDA, the approval of  $EGRIFTA^{TM}$ .

In the second half of fiscal 2010, we focused primarily on responding to the FDA's questions and began building our inventory in anticipation of the launch of  $EGRIFTA^{\text{TM}}$  in the United States. We were also focused on securing strategic alliances for the commercialization of  $EGRIFTA^{\text{TM}}$  in territories outside of the United States.

On November 10, 2010, the FDA approved *EGRIFTA*<sup>™</sup> as the first approved treatment in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. By virtue of the collaboration and licensing agreement entered into in 2008 with EMD Serono, we received a milestone payment of US\$25,000,000 associated with the FDA-approval of *EGRIFTA*<sup>™</sup>. This payment was received by us on November 30, 2010. Under the collaboration and licensing agreement, EMD Serono has the exclusive right to commercialize *EGRIFTA*<sup>™</sup> in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Concurrent with these regulatory activities in fiscal 2010, our third-party suppliers began manufacturing inventory of *EGRIFTA*<sup>™</sup> in preparation for the launch of *EGRIFTA*<sup>™</sup> in the United States by our commercial partner, EMD Serono. The first product shipment of *EGRIFTA*<sup>™</sup> took place in December 2010.

Fiscal 2010 was also marked by a change in our management. On December 1, 2010, John-Michel T. Huss, previously Chief of Staff, Office of the CEO, of Sanofi in Paris, became our President and Chief Executive Officer. Mr. Huss replaced Yves Rosconi who, in June 2010, announced his desire to retire after six years as the head of the Company.

On December 6, 2010, we entered into a distribution and licensing agreement with Sanofi granting them the exclusive commercialization rights of  $EGRIFTA^{TM}$  for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East.

On February 3, 2011, we entered into a distribution and license agreement with Ferrer granting them the exclusive commercialization rights of tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

### **Financial Position**

We completed fiscal 2010 with a liquidity position of \$64,882,000, consisting of \$64,550,000 of cash and highly liquid bonds, and \$332,000 of tax credits and grants receivable.

# **Economic Environment**

In 2008 and 2009, capital markets were characterized by significant stock market volatility and a notable decline in access to capital, particularly for the biotechnology industry. An economic slowdown occurred in almost all sectors and the general decline of the capital markets had a negative effect on the cost of capital for companies.

In early 2010, the situation remained challenging and it was only in the second half of the year that we began to see an improvement in economic conditions, which resulted in better access to capital and lower credit risk. Interest rates, however, remained extremely low throughout the year.

Despite the improvement in general market conditions, our investment policy continues to be conservative. We have invested our funds in highly liquid, low-risk instruments as described under the heading "Liquidity and capital resources".

#### Perspectives for 2011

In 2011, our focus is to maximize the global opportunities for *EGRIFTATM* and tesamorelin. In order to do so we intend to:

- Support our commercial partner, EMD Serono, in commercializing EGRIFTATM in the United States;
- Support our commercial partner, Sanofi, in seeking regulatory approval of *EGRIFTATM* in Latin America, Africa and the Middle-East for potential commercialization;
- Support our commercial partner, Ferrer, in seeking regulatory approval of EGRIFTATM in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries for potential commercialization;
- Assess expansion opportunities into other territories where EGRIFTATM could be used for the reduction of excess abdominal fat in HIVinfected patients with lipodystrophy;
- Initiate a new clinical program evaluating tesamorelin in a new indication;
- Continue working on EGRIFTATM. We have developed a new presentation of EGRIFTATM which is easier to use than its current presentation. This new presentation complies with one of the FDA's post-approval requirements. See "Post-Approval Commitments"; and
- Develop a new formulation for EGRIFTA™ pursuant to our agreement with EMD Serono.

## **Selected Annual Information**

Consolidated statement of comprehensive income YEARS ENDED NOVEMBER 30 (in thousands of			
Canadian dollars, except per share amounts)	2010	2009	2008(1)
Revenue <sup>(2)</sup>	\$31,868	\$ 17,468	\$ 2,641
Research and development expenses, net of tax credits	\$14,064	\$ 20,810	\$ 33,215
Results from operating activities	\$ 6,663	\$(16,747)	\$(48,611)
Net financial income	\$ 2,381	\$ 1,591	_
Net profit (loss)	\$ 8,930	\$(15,156)	\$(48,611)
Basic and diluted earnings (loss) per share	\$ 0.15	\$ (0.25)	\$ (0.85)
Consolidated statement of financial position AT NOVEMBER 30 (in thousands of Canadian dollars)	2010	2009	2008(1)
Liquidities (cash and bonds)	\$ 64,550	\$ 63,362	\$ 46,337
Tax credits and grants receivable	\$ 332	\$ 1,333	\$ 1,784
Total assets	\$ 71,651	\$ 69,154	\$ 53,545
Total share capital	\$279,398	\$279,169	\$269,219
Total equity	\$ 52,656	\$ 43,048	\$ 46,347

(1) We adopted IFRS in fiscal 2010 with a transition date of December 1, 2008. Consequently, the selected financial information for the year ended November 30, 2008, as presented in our 2009 Audited Consolidated Financial Statements, which were presented in conformity with Canadian GAAP, was not restated in terms of IFRS and accordingly, is not comparable with the information for fiscal 2010 and 2009. See "Conversion to IFRS" for the policy differences between Canadian GAAP and IFRS.

(2) Revenue in 2008 includes interest income of \$2,427,000. Revenue in 2009 includes a milestone payment of \$10,884,000 received from EMD Serono following the FDA's acceptance to file our NDA for EGRIFTATM. Revenue in 2010 includes a milestone payment of \$25,000,000 received from EMD Serono following marketing approval of EGRIFTATM by the FDA.

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# **Operating Results**

#### Revenue

Our consolidated revenue for the year ended November 30, 2010 was \$31,868,000, compared to \$17,468,000 in 2009. The increased revenue in fiscal 2010 was related to the milestone payment of US\$25,000,000 (C\$25,000,000) received by us from EMD Serono on November 30, 2010 associated with the satisfaction of the condition of approval of *EGRIFTA*<sup>TM</sup> by the FDA. In fiscal 2009, a payment of US\$10,000,000 (C\$10,884,000) was received by us from EMD Serono following the acceptance by the FDA of the Company's NDA for *EGRIFTA*<sup>TM</sup> in conformity with the collaboration and licensing agreement with EMD Serono.

The initial payment of US\$22,000,000 (C\$27,097,000) received on December 15, 2008, upon the closing of the transaction with EMD Serono, has been deferred and is being amortized over its estimated service period of four years on a straight-line basis. For the year ended November 30, 2010, an amount of \$6,846,000 related to this transaction was recognized as revenue. At November 30, 2010, the deferred revenue related to this transaction recorded on the consolidated statement of financial position amounted to \$13,692,000.

We expect to generate revenue from sales of *EGRIFTA*<sup>TM</sup> to EMD Serono throughout fiscal 2011. We also expect to receive royalties on sales of *EGRIFTA*<sup>TM</sup> in the United States by EMD Serono beginning in the second quarter of fiscal 2011 upon receipt and confirmation of the sales report relating to the previous quarter. The royalty rate we receive from EMD Serono is based on the level of annual net sales achieved, with the rate increasing as higher levels of net sales are attained.

#### **R&D** Activities

For the year ended November 30, 2010, consolidated research and development ("R&D") expenses, net of tax credits, amounted to \$14,064,000, compared to \$20,810,000 in 2009, a decrease of 32.4%. The majority of R&D expenses incurred in fiscal 2010 are related to follow-up on work derived from the regulatory filing with the FDA, notably responding to the FDA's questions, and preparation for the FDA Advisory Committee meeting. In parallel with the United States FDA review, we continued to advance our regulatory filing in Europe and to work on a new presentation of the existing formulation of *EGRIFTATM*. Furthermore, we are in the process of evaluating the initiation of a new clinical program to develop tesamorelin for a new indication. In our discovery and preclinical groups, we continued to develop new peptides and to advance our preclinical program for acute kidney injury ("AKI"). In fiscal 2009, the expenses incurred were principally associated with completing the Phase 3 clinical trials evaluating tesamorelin in HIV-associated lipodystrophy and the preparation of the NDA, which was submitted to the FDA in May 2009. The significant decline in R&D expenses was in accordance with our projected R&D expenses for fiscal 2010. We expect the amount of our R&D expenses for fiscal 2011 to be similar to those of 2010.

#### **Cost of Sales**

In fiscal 2010, we began producing through our third-party suppliers inventories in anticipation of the launch of *EGRIFTATM* in the United States. Cost of sales in fiscal 2010 related to this activity amounted to \$469,000 which includes a charge of \$192,000, in order to value the inventories at their net realizable value. This write-down was due to raw materials that were not originally bought under the conditions of our current long-term procurement agreements. Cost of sales also included unallocated costs related to the production fees associated with the start-up of the manufacturing process. We expect the cost of sales to increase significantly over the next fiscal

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year as sales of EGRIFTATM grow and as we secure additional suppliers for raw materials and finished products.

#### General and Administrative Expenses

For the year ended November 30, 2010, general and administrative expenses were \$8,002,000, compared to \$6,543,000 for the same period in fiscal 2009.

The higher expenses for the year ended November 30, 2010 are primarily due to the cost and expenses associated with professional fees for the recruitment of the new President and Chief Executive Officer, increased corporate communication associated with the FDA Advisory Committee meeting and FDA approval, and conversion of our financial statements to IFRS, as well as costs and expenses related to variations in share-based compensation expenses. The expenses for the year ended November 30, 2009 include the costs associated with the revision of our three-year business plan which were not repeated in fiscal 2010.

#### Selling and Market Development Expenses

For the year ended November 30, 2010, selling and market development expenses were \$2,670,000, compared to \$6,862,000 in fiscal 2009.

The selling and market development expenses in fiscal 2010 are principally composed of business development expenses and market research outside the United States and the costs of managing the agreement with EMD Serono. In fiscal 2009, we incurred expenses totaling \$4,269,000 in connection with professional fees related to the transaction with EMD Serono.

#### **Net Financial Income**

For the year ended November 30, 2010, interest income was \$1,562,000 compared to \$2,123,000 in fiscal 2009. The year-over-year decline is due to lower average cash positions and a decrease in yield on our bond portfolio. Receipt of the \$25,000,000 milestone payment from EMD Serono in November 2010 strengthened the Company's cash position to a level comparable to that of year-end 2009. Finance costs in fiscal 2010 were a gain of \$493,000 compared to an expense of \$661,000 in fiscal 2009. Finance costs in fiscal 2010 benefited from a net foreign currency gain of \$511,000 compared to a net foreign currency loss of \$635,000 in 2009.

#### **Net Results**

Reflecting the changes in revenue and expenses described above, we realized a net profit of \$8,930,000 (\$0.15 per share) for the year ended November 30, 2010, compared to a net loss of \$15,156,000 (\$0.25 loss per share) for the same period in fiscal 2009. The net profit included revenue of \$31,846,000 related to the collaboration and licensing agreement with EMD Serono.

# **Quarterly Financial Information**

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

(in thousands of Canadian dollars, except per share amounts)

	2010				2009			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Revenue	\$26,717	\$ 1,717	\$ 1,717	\$ 1,717	\$ 1,718	\$12,601	\$ 1,717	\$ 1,432
Net profit (net loss)	\$21,299	\$(3,357)	\$(4,771)	\$(4,241)	\$(4,654)	\$ 5,779	\$(5,454)	\$(10,827)
Basic and diluted earnings (loss) per share	\$ 0.35	\$ (0.06)	\$ (0.08)	\$ (0.07)	\$ (0.08)	\$ 0.10	\$ (0.09)	\$ (0.18)

As described above, the higher revenue in the third quarter of 2009 is related to the milestone payment of \$10,884,000 received from EMD Serono following the FDA's acceptance to file the Company's NDA for *EGRIFTATM*. The higher revenue in the fourth quarter of 2010 is related to the receipt from EMD Serono of a milestone payment of \$25,000,000 following marketing approval of *EGRIFTATM* by the FDA.

### Fourth Quarter Comparison

Consolidated revenue for the three-month period ended November 30, 2010, amounted to \$26,717,000, compared to \$1,718,000 for the same period in fiscal 2009. The higher revenue in the three-month period ended November 30, 2010 is related to the milestone payment of \$25,000,000 received at the end of the fourth quarter, following marketing approval of *EGRIFTATM* by the FDA in the United States.

Consolidated R&D expenses, net of tax credits, totaled \$3,172,000 for the fourth quarter of 2010, compared to \$4,212,000 for the same period in 2009, a decrease of 24.7%. The R&D expenses incurred in 2009 principally included expenses related to preparing for the FDA Advisory Committee meeting, which was held on May 27, 2010. The R&D expenses incurred in the fourth quarter of fiscal 2010 were mainly related to managing responses to the FDA's questions and the FDA approval process, in addition to the advancement of our regulatory filing in Europe and on a new presentation of the existing formulation of *EGRIFTATM*. Furthermore, we are in the process of evaluating the initiation of a new clinical program to develop tesamorelin for a new indication. In our discovery and preclinical groups, we continued to develop new peptides and to advance our preclinical program in AKI.

General and administrative expenses were \$2,036,000 in the fourth quarter of 2010, compared to \$1,563,000 for the same period in 2009. The higher expenses for 2010 are principally related to the conversion of our financial statements to IFRS and FDA approval of *EGRIFTATM* in the United States.

Selling and market development expenses amounted to \$761,000 for the fourth quarter of 2010, compared to \$1,069,000 for the same period in 2009. The sales and market development

expenses in fiscal 2010 are principally composed of business development expenses outside the United States and the costs of performing our obligations under the agreement with EMD Serono. The increased costs in 2009 were principally due to market development costs in Europe to increase the awareness of lipodystrophy as a disease.

Consequently, we recorded a net profit for the three-month period ended November 30, 2010, of \$21,299,000 (\$0.35 per share), compared to a net loss of \$4,654,000 (\$0.08 per share) for the same period in 2009.

In the three-month period ended November 30, 2010, cash flows from operating activities, excluding changes in operating assets and liabilities, was \$22,037,000, compared to a use of cash of \$4,333,000 for the same period in 2009.

# Liquidity and Capital Resources

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

To fund our activities, we have relied primarily on public offerings of common shares in Canada and private placements of our common shares as well as on up-front payments and milestone payments primarily associated with the agreement with EMD Serono. When possible, we try to optimize our liquidity position using non-dilutive sources, including investment tax credits, grants and interest income.

For the year ended November 30, 2010, cash flow from operating activities, excluding changes in operating assets and liabilities, was \$11,160,000 compared to a use of cash of \$13,547,000 in fiscal 2009. The cash flow generated in fiscal 2010 is principally related to payments received under the agreement with EMD Serono as well as decreases in R&D expenses and in selling and market development expenses.

At November 30, 2010, cash and bonds amounted to \$64,550,000 and tax credits and grants receivable amounted to \$332,000, for a total of \$64,882,000.

At this time, apart from our unused \$1,800,000 revolving credit facility, we do not have any additional arrangements for external debt financings, and are not certain whether any proposed debt financing in the future, would be available on acceptable terms, or available at all. We may seek additional capital through the incurrence of debt, the issuance of equity or other financing alternatives.

We invest our available cash in highly liquid fixed income instruments from governmental, municipal and paragovernmental bodies (\$37,542,000 at November 30, 2010) as well as corporate bonds with high credit ratings (\$359,000 at November 30, 2010).

In the year ended November 30, 2010, the Company received share subscriptions amounting to \$15,000 (\$96,000 in fiscal 2009) for the issuance of 2,880 common shares (34,466 in 2009) in connection with the share purchase plan. Under the terms of the agreement with EMD Serono, we issued 2,179,837 common shares for a cash consideration of US\$8,000,000 (C\$9,854,000) during the first quarter of 2009.

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In fiscal 2010, our third-party suppliers began to manufacture inventory of *EGRIFTATM* for commercialization in the United States. We expect to continue to build our inventory until we reach an adequate level of finished goods to meet the needs of our partners and this will significantly increase our working capital needs in fiscal 2011.

## **Contractual Obligations**

### Commitments

We rent our headquarters and main office pursuant to a lease expiring in April 2021. At November 30, 2010 and 2009, and at December 1, 2008, the minimum payments required under the terms of the non-cancellable lease were as follows:

(in thousands of Canadian dollars)	November 30, 2010	November 30, 2009	December 1, 2008
Less than one year	55	340	816
Between one and five years	2,239	2,020	340
More than five years	3,943	4,216	_
	6,237	6,576	1,156

### Long-Term Procurement Agreements

During and after the years ended November 30, 2010 and 2009, we entered into long-term procurement agreements with third-party suppliers in anticipation of the commercialization of *EGRIFTA*<sup>TM</sup>.

### **Credit Facility**

We have a \$1,800,000 revolving credit facility, bearing interest at prime plus 0.5%. Under the term of the revolving credit facility, the market value of investments held must always be equivalent to 150% of amounts drawn under the facility. If the market value falls below \$7,000,000, we will provide the bank with a first rank movable hypothec (security interest) of \$1,850,000 on securities judged satisfactory by the bank. As at November 30, 2010, we did not have any borrowings outstanding under this credit facility.

### **Post-Approval Commitments**

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

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

We have developed a new presentation of *EGRIFTATM* which is more user-friendly than its current presentation because we expect it to be quicker and easier for a patient to manipulate. In the new presentation of the same formulation, *EGRIFTATM* will be available as a single unit dose (one vial containing 2 mg of tesamorelin) of sterile, lyophilized powder to be reconstituted with



sterile water for injection. This new presentation complies with the first of the FDA's post-approval requirements. The FDA requires that this new presentation be available by November 2013.

The purpose of the long-term observational study required by the FDA is to evaluate the safety of long-term administration of *EGRIFTA*TM. The primary purpose of the Phase 4 clinical trial is to assess whether *EGRIFTA*TM has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. The FDA requires that the proposals for the long-term observational safety study and Phase 4 clinical trial be completed within six months of our having received approval to commercialize *EGRIFTA*TM. Under the terms of our collaboration and licensing agreement, EMD Serono is responsible for finalizing such proposals. We will continue to support EMD Serono in developing and finalizing such proposals.

## **Contingent Liability**

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

The Motion has not yet been heard by the Superior Court of Quebec and a date has not been set for the hearing.

The Company has subscribed to insurance covering its potential liability and the potential liability of its directors and officers in the performance of all their duties for the Company subject to a \$200,000 deductible. At November 30, 2010, an amount of \$96,000 in legal fees had been accrued and included in general and administrative expenses, of which \$61,000 was paid during the year and \$35,000 remained in accounts payable and accrued liabilities.

### **Off-Balance Sheet Arrangements**

We were not involved in any off-balance sheet arrangements for the year ended November 30, 2010, with the exception of the lease of our headquarters as described above.

#### Subsequent Events

#### **Distribution and Licensing Agreements**

On December 6, 2010, we announced the signing of a distribution and licensing agreement with Sanofi covering the commercial rights for *EGRIFTATM* in Latin America, Africa, and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

Under the terms of the Agreement, we will sell *EGRIFTATM* to Sanofi at a transfer price equal to the higher of a percentage of Sanofi's net selling price and a predetermined floor price. We have retained all future development rights to *EGRIFTATM* and will be responsible for conducting

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research and development for any additional potential indications. Sanofi will be responsible for conducting all regulatory activities for *EGRIFTATM* in the aforementioned territories, including applications for approval in the different countries for the treatment of excess abdominal fat in HIVinfected patients with lipodystrophy. We also granted Sanofi an option to commercialize tesamorelin for other indications in the territories mentioned above. If such option is not exercised, or is declined, by Sanofi, we may commercialize tesamorelin for such indications on our own or with a third-party.

On February 3, 2011, we entered into a distribution and licensing agreement with Ferrer covering the commercial rights for *EGRIFTATM* for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

Under the terms of the Agreement, we will sell *EGRIFTATM* to Ferrer at a transfer price equal to the higher of a significant percentage of Ferrer's net selling price and a predetermined floor price. We have retained all development rights to *EGRIFTATM* for other indications and will be responsible for conducting research and development for any additional programs. Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with *EGRIFTATM* for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the agreement. We will be responsible for the manufacture and supply of *EGRIFTATM* to Ferrer. We have the option to copromote *EGRIFTATM* for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Ferrer has the option to copromote aco-development and commercialization agreement using tesamorelin relating to any such new indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development.

#### **Deferred Share Unit Plan**

In December 2010, we adopted a deferred share unit plan ("Plan") to provide long-term incentive compensation for our directors and executive officers. Under the Plan, directors must receive their annual remuneration as a board member in fully vested deferred share unites ("DSUs") until they reach a percentage of their annual remuneration and, once such percentage is attained, they have the option to elect to receive part or all of their annual remuneration in DSUs. Under the plan, executive officers have the option of receiving all or a portion of their annual bonus in the form of fully-vested DSUs. The units are only redeemable for cash when a participant ceases to be an employee or member of the Board of Directors. We manage the risk associated with the issuance of the DSU by entering into a yearly forward contract with a third-party. As at February 7, 2011, all of the 99,912 DSUs outstanding were covered by a prepaid forward contract.

#### **Stock Option Plan**

Between December 1, 2010 and February 7, 2011, the Company granted 250,000 options at an exercise price of \$5.65 per share. Also, 27,832 options were forfeited and expired at a weighted exercise average price of \$12.06 per share and 3,000 options were exercised at a weighted exercise average price of \$1.80 per share for a cash consideration of \$5,000.

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# **Financial Risk Management**

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

#### **Credit Risk**

The Company's exposure to credit risk currently relates to accounts receivables with only one customer (see note 4 of the Audited Consolidated Financial Statements). Credit risk is the risk of an unexpected loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. We regularly monitor credit risk exposure and take steps to mitigate the likelihood of this exposure resulting in losses.

Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds. We invest our available cash in highly liquid fixed income instruments from governmental, paragovernmental and municipal bodies (\$37,542,000 as at November 30, 2010) as well as from companies with high credit ratings (\$359,000 as at November 30, 2010). As at November 30, 2010, we were not exposed to any credit risk over the carrying amount of the bonds.

#### Liquidity Risk

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

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

The required payments on the contractual maturities of financial liabilities, as well as the payments required under the terms of the operating lease, as at November 30, 2010, are presented in notes 20 and 23 of the Audited Consolidated Financial Statements.

#### **Currency Risk**

We are exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of our business transactions denominated in currencies other than the Canadian dollar, primarily revenues from milestone payments and expenses for research and development incurred in U.S. dollars, euros and pounds sterling ("GBP"). We do not use derivative financial instruments to reduce our foreign exchange exposure.

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

Exchange rate fluctuations for foreign currency transactions can cause cash flow as well as amounts recorded in consolidated statement of comprehensive income to vary from period to

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

The following table provides significant items exposed to currency risk as at November 30, 2010:

			November 30, 2010
(in thousands of dollars)	\$US	EURO	GBP
Cash	26,424	_	1
Trade and other receivables		—	_
Accounts payable and accrued liabilities	(465)	(26)	(81)
Items exposed to currency risk	25,959	(26)	(80)
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The following exchange rates applied during the year ended November 30, 2010:

	Average rate	Reporting date rate
\$US — C\$	1.0345	1.0266
EURO — C\$	1.3848	1.3326
GBP — C\$	1.6051	1.5969

In fiscal 2010, based on our foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the Canadian dollar would have increased the net profit as follows, assuming that all other variables remained constant:

(in thousands of dollars)	\$US	EURO	GBP
Increase in net profit	1,298	(1)	(4)

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

#### **Interest Rate Risk**

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

Our short-term bonds are invested at fixed interest rates and/or mature in the short-term. Long-term bonds are also instruments that bear interest at fixed rates. The risk that we will realize a

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loss as a result of a decline in the fair value of our bonds is limited because these investments, although they are classified as available for sale, are generally held to maturity. The unrealized gains or losses on bonds are recorded in accumulated other comprehensive income.

Based on the value of our short and long-term bonds at November 30, 2010, 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 \$336,000; an assumed increase in interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

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

Based on the average value of variable interest-bearing cash during year ended November 30, 2010 (\$3,219,000), an assumed 0.5% increase in interest rates during such period would have increased the future cash flow and the net profit by approximately \$16,000; an assumed decrease of 0.5% would have had an equal but opposite effect.

### **Financial Instruments**

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

Bonds are stated at estimated fair value, determined by inputs that are primarily based on broker quotes at the reporting date (level 2 inputs — see note 22 — Determination of fair values).

#### **Critical Accounting Estimates**

#### Use of Estimates and the Exercise of Judgment

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

Information about critical judgments in applying accounting policies and assumption and estimation uncertainties that have the most significant effect on the amounts recognized in the consolidated financial statements is included in the following notes to the Audited Consolidated Financial Statements:

Note 4 — Revenue and deferred revenue Note 15 (iv) — Stock option plan Note 16 — Income taxes Note 18 — Contingent liability

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

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

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

## **Conversion to IFRS**

In February 2008, the Accounting Standards Board of Canada ("AcSB") announced that accounting standards in Canada, as used by public companies, would converge with IFRS, for financial periods beginning on and after January 1, 2011 with the option to early adopt IFRS upon receipt of approval from the Canadian Securities regulatory authorities. In the fourth quarter, we filed a request to adopt IFRS two years in advance of the date required under the AcSB, using December 1, 2008 as the date of transition and December 1, 2009 as the changeover date. Our request was granted and as a result, the consolidated financial statements for the year ended November 30, 2010 are our first annual financial statements prepared in conformity with IFRS.

Because we had previously filed financial statements and MD&As for the first, second and third quarters of 2010 with comparisons to 2009 in accordance with Canadian GAAP, these statements were restated and re-filed on February 8, 2011 to reflect our adoption of IFRS. Periods prior to December 1, 2008 have not been restated.

In preparing these first IFRS financial statements, we used the IFRS accounting policies in effect as at November 30, 2010, including IFRS 1 — *First-time Adoption of International Financial Reporting Standards* ("IFRS 1"). IFRS 1 provides guidance for an entity's initial adoption of IFRS and outlines that, in general, an entity applies the principles under IFRS retrospectively with adjustments arising on conversion from Canadian GAAP to IFRS being directly recognized in retained earnings as of the beginning of the first comparative financial statements presented. IFRS 1 also requires companies adopting IFRS to reconcile equity and net earnings from the previously reported Canadian GAAP amounts to the restated IFRS amounts. Our reconciliation of equity under Canadian GAAP as at December 1, 2008, the date of transition, and as at November 30, 2009 to the restated IFRS amounts are included in note 27 of the consolidated financial statements, as is the reconciliation of comprehensive income for the year-ended November 30, 2009.

IFRS 1 also provides certain optional exemptions from retrospective application of certain IFRS requirements as well as mandatory exceptions which prohibit retrospective application of standards.

We elected to apply the following optional exemptions from full retrospective application:

(*i*) *IFRS 2* — *Share-based Payment*: IFRS 1 encourages the application of IFRS 2, *Share-based Payment* provisions to equity instruments granted on or before November 7, 2002, but permits the application only to equity instruments granted after November 7, 2002 that were not vested by the transition date. As permitted by this exemption, the Company applied IFRS 2 only to equity instruments granted after November 7, 2002 that were not vested by December 1, 2008.

(ii) Designation of financial assets and financial liabilities exemption: we elected to redesignate cash from the held for trading category to loans and receivables.

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We also followed the mandatory exemptions applicable to the Company as described below:

*Estimates* — Hindsight cannot be used to create or revise estimates. Estimates previously made under Canadian GAAP cannot be revised for application of IFRS except where necessary to reflect any difference in accounting policies.

# Impact of IFRS on the Company's Financial Statements

The adoption of IFRS resulted in some changes to our accounting policies that were applied in the recognition, measurement and disclosure of balances and transactions in our financial statements. However, none of the changes to our accounting policies resulted in significant changes to line items within our financial statements.

The following provides a summary of our evaluation of important changes to accounting policies in key areas:

### IFRS 2, Share-based Payment ("IFRS 2")

Under IFRS, when stock option awards vest gradually, each tranche is to be considered as a separate award, while under Canadian GAAP, companies can make a policy choice to consider gradually vested tranches as a single award. Similarly, the IFRS standard requires that forfeiture estimates be established at the time of the initial fair value assessment of share-based payments rather than to account for the forfeitures as they occur. Therefore, the compensation expense will have to be recognized over the expected term of each tranche and take into account the impact of the differences in accounting for forfeitures. As a result of this change, an amount of \$175,000 was recorded to deficit at the transition date, with the counterpart to contributed surplus.

#### IAS 36, Impairment of Assets ("IAS 36")

Under Canadian GAAP impairment standards for non-financial assets, a write-down to estimated fair value is recognized if the estimated undiscounted future cash flows from an asset or group of assets are less than their carrying value. IAS 36 requires a write-down to be recognized if the recoverable amount, determined as the higher of the estimated fair value less costs to sell or value in use, is less than carrying value. We performed impairment testing as of December 1, 2008 and concluded that no impairment charge was required under IFRS. No impairment indicators were identified for the period between the transition date and November 30, 2009 and November 30, 2010. IAS 36 also permits the reversal of certain impairment charges where conditions have changed. We reviewed past impairment charges and concluded that there was no justification for reversal of past impairment charges.

#### IAS 1, Presentation of Financial Statements ("IAS 1")

Financial statement presentation is addressed in conjunction with the related IFRS standards. Certain additional disclosures were required in the notes to the financial statements and the statement of comprehensive income was modified to reflect a presentation by function. The reclassifications required as a result of this change are described in note 27 (c) of the consolidated financial statements.

#### Other Standards

Our examination of all other standards, including for example, IAS 21 — The Effects of Changes in Foreign Exchange Rates, IAS 37 — Provisions, Contingent Liabilities and Contingent Assets, and IAS 18 — Revenue, revealed no significant adjustment was necessary other than enhanced disclosures.



Note 27 of the consolidated financial statements for the year ended November 30, 2010 contains a detailed description of our conversion to IFRS, including a line-by-line reconciliation of our financial statements previously prepared under Canadian GAAP to those under IFRS as at November 30, 2009 and December 1, 2008.

### Impact on the Business

The impact of the conversion to IFRS on the Company was minimal and therefore resulted in a limited number of adjustments. Our systems easily accommodated the required changes. Our internal controls and disclosure controls and procedures did not require significant modification as a result of its conversion to IFRS. Furthermore, there was no impact on our contractual arrangements or compliance thereto.

## Impact on Information Systems and Technology

The transition had minimal impacts on our information systems. The areas where information systems were most impacted were minor modifications to certain general ledger accounts, sub-ledgers and end-user reports to accommodate IFRS accounting adjustments, recording, and heightened disclosures.

# Impact on Internal Control over Financial Reporting and Disclosure Controls and Procedures

Our internal controls over financial reporting were also not significantly affected by the transition to IFRS. The IFRS differences required presentation and process changes to report more detailed information in the notes to the financial statements, as well as certain changes to the recognition and measurement practices. Disclosure controls and procedures were adapted to take into consideration the changes in recognition, measurement and disclosure practices but the impact was minimal as well.

## Impact on Financial Reporting Expertise

Training and education was provided to all members of the finance team who are directly affected by the transition to IFRS. This training focused mainly on the process changes required and an overview of the reasons behind the changes from a standards perspective.

### New accounting policies

Certain pronouncements were issued by the IASB or International Financial Reporting Interpretation Committee that are mandatory for annual periods beginning after January 1, 2010 or later periods. Many of these updates are not applicable or are inconsequential to us and have been excluded from the discussion below. The remaining pronouncements are being assessed to determine their impact on our results and financial position:

## Annual improvements to IFRS

The IASB's improvements to IFRS published in April 2009 contain fifteen amendments to twelve standards that result in accounting changes for presentation, recognition or measurement purposes largely for annual periods beginning on or after January 1, 2010, with early adoption permitted. These amendments were considered by the Company and deemed to be not applicable to the Company other than for the amendment to IAS 17 — Leases relating to leases which include both land and buildings elements. In this case, the Company early adopted this amendment.

The IASB's improvements to IFRS contain seven amendments that result in accounting changes for presentation, recognition or measurement purposes. The most significant features of the IASB's annual improvements project published in May 2010 are included under the specific revisions to standards discussed below.

## (i) IFRS 3:

Revision to IFRS 3, Business Combinations:

Effective for annual periods beginning on or after July 1, 2010 with earlier adoption permitted.

Clarification on the following areas:

- the choice of measuring non-controlling interests at fair value or at the proportionate share of the acquiree's net assets applies only to instruments that represent present ownership interests and entitle their holders to a proportionate share of the net assets in the event of liquidation. All other components of non-controlling interest are measured at fair value unless another measurement basis is required by IFRS.
- application guidance relating to the accounting for share-based payments in IFRS 3 applies to all share-based payment transactions
  that are part of a business combination, including un-replaced awards (i.e., unexpired awards over the acquiree shares that remain
  outstanding rather than being replaced by the acquirer) and voluntarily replaced share-based payment awards.
- (ii) IFRS 7:

Amendment to IFRS 7, Financial Instruments: Disclosures:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted.

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

(iii) IAS 1:

Amendment to IAS 1, Presentation of Financial Statements:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted.

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

(iv) IAS 27:

Amendment to IAS 27, Consolidated and Separate Financial Statements:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted.

The 2008 revisions to this standard resulted in consequential amendments to IAS 21, *The Effects of Changes in Foreign Exchange Rates*, IAS 28, *Investments in Associates*, and IAS 31, *Interests in Joint Ventures*. IAS 27 now provides that these amendments are to be applied prospectively.

(v) IAS 34:

Amendment to IAS 34, Interim Financial Reporting:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption permitted.

The amendments place greater emphasis on the disclosure principles for interim financial reporting involving significant events and transactions, including changes to

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fair value measurements and the need to update relevant information from the most recent annual report.

### New or revised standards and interpretations

In addition, the following new or revised standards and interpretations have been issued but are not yet applicable to the Company:

(i) IAS 24:

Amendments to IAS 24, Related Party Disclosures:

Effective for annual periods beginning on or after January 1, 2011 with earlier adoption is permitted.

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

(ii) IFRS 8:

IFRS 8, Operating Segments:

Effective for annual periods beginning on or after January 1, 2010.

Requires purchase information about segment assets.

(iii) IFRS 9:

New standard IFRS 9, Financial Instruments:

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

As part of the project to replace IAS 39, *Financial Instruments: Recognition and Measurement*, this standard retains but simplifies the mixed measurement model and establishes two primary measurement categories for financial assets. More specifically, the standard:

- deals with classification and measurement of financial assets
- establishes two primary measurement categories for financial assets: amortized cost and fair value
- classification depends on entity's business model and the contractual cash flow characteristics of the financial asset
- eliminates the existing categories: held to maturity, available for sale, and loans and receivables.

Certain changes were also made regarding the fair value option for financial liabilities and accounting for certain derivatives linked to unquoted equity instruments.

### Outstanding share data

At February 7, 2011, the common shares issued and outstanding were 60,515,764 while outstanding options granted under the stock option plan were 3,068,306.



# Disclosure controls and procedures and internal control over financial reporting

As at November 30, 2010, an evaluation of the design and operating effectiveness of our disclosure controls and procedures, as defined in the rules of Canadian Securities Administrators, was carried out. Based on that evaluation, the President and Chief Executive Officer and the Senior Executive Vice-President and Chief Financial Officer concluded that the design and operating effectiveness of those disclosure controls and procedures were effective.

Also as November 30, 2010, an evaluation of the design and operating effectiveness of internal controls over financial reporting, as defined in the rules of the Canadian Securities Administrators, was carried out to provide reasonable assurance regarding the reliability of financial reporting and financial statement compliance with IFRS. Based on that evaluation, the President and Chief Executive Officer and the Senior Executive Vice-President and Chief Financial Officer concluded that the design and operating effectiveness of internal controls over financial reporting were effective.

These evaluations were based on the framework established in *Internal Control —Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, a recognized control model, and the requirements of Multilateral Instrument 52-109 of the Canadian Securities Administrators. A disclosure committee comprised of members of senior management assists the President and Chief Executive Officer and the Senior Executive Vice-President and Chief Financial Officer in their responsibilities.

All control systems, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention or overriding of the controls or procedures. As a result, there is no certainty that our disclosure controls and procedures or internal control over financial reporting will prevent all errors or all fraud. There were no changes in our internal controls over financial reporting that occurred during the year ended November 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

#### **Risks and uncertainties**

Investors should understand that we operate in a high risk industry. We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or operating results. Investors should carefully consider the risks described below before purchasing our securities. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks.



# Risks Related to the Commercialization of our Product and Product Candidates

# Our commercial success depends largely on the commercialization of EGRIFTATM; the failure of EGRIFTATM to obtain commercial acceptance would have a material adverse effect on us.

Our ability to generate revenues in the future is primarily based on the commercialization of *EGRIFTATM* for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. In the short-term, these revenues should be primarily derived from the U.S. market alone. Although we have entered into a collaboration and licensing agreement with EMD Serono for the commercialization of *EGRIFTATM* in the United States, there can be no assurance that *EGRIFTATM* will be successfully commercialized in the United States, or in any other country. Although we are developing other peptides, all of them are at earlier stages of development and none of them may reach the clinical trial phase, obtain regulatory approval or, even if approved, be successfully commercialized.

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

- receipt of regulatory approvals for EGRIFTATM from regulatory agencies in the territories other than the United States in which we wish to expand the commercialization of tesamorelin;
- market acceptance of *EGRIFTATM* by the medical community, patients and third-party payors (such as governmental health administration authorities and private health coverage insurers);
- the amount of resources devoted by our commercial partners to commercialize EGRIFTATM in their respective territories;
- maintaining manufacturing and supply agreements to ensure the availability of commercial quantities of EGRIFTATM through validated processes;
- the number of competitors in our market; and
- protecting and enforcing our intellectual property and avoiding patent infringement claims.

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

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

Although our collaboration and licensing agreements with EMD Serono, Sanofi and Ferrer contain provisions governing their respective responsibilities as partners for the commercialization of *EGRIFTATM* in their respective territories, our dependence on these partners to commercialize *EGRIFTATM* is subject to a number of risks, including:

- our limited control of the amount and timing of resources that our commercial partners will be devoting to the commercialization, marketing and distribution of tesamorelin, including obtaining patient reimbursement for EGRIFTATM, which could adversely affect our ability to obtain or maximize our royalty payments;
- disputes or litigation that may arise between us and our commercial partners, which could adversely affect the commercialization of tesamorelin, all of which would divert our management's attention and our resources;
- our commercial partners not properly defending our intellectual property rights or using them in such a way as to expose us to potential litigation, which could, in both cases, adversely affect the value of our intellectual property rights; and
- corporate reorganizations or changes in business strategies of our commercial partners, which could adversely affect a commercial partner's willingness or ability to fulfill its obligations under its respective agreement.

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

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

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process

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

Our reliance on third-party manufacturers exposes us to a number of risks. We may be subject to delays in or suspension of the manufacturing of *EGRIFTATM* and tesamorelin if a third-party manufacturer:

- becomes unavailable to us for any reason, including as a result of the failure to comply with good manufacturing practices, or GMP, regulations;
- experiences manufacturing problems or other operational failures, such as equipment failures or unplanned facility shutdowns required to comply with GMP or damage from any event, including fire, flood, earthquake, business restructuring or insolvency; or
- fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis.

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

# Even though we have received regulatory approval for EGRIFTA™ in the United States, we still may not be able to successfully commercialize it if we do not gain market acceptance and the revenue that we generate from its sales, if any, may be limited.

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

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- acceptance of the product by physicians and patients as safe and effective treatments and addressing a significant unmet medical need;
- product price;
- the effectiveness of our sales and marketing efforts (or those of our commercial partners);
- storage requirements and ease of administration;
- dosing regimen;
- safety and efficacy;
- prevalence and severity of side effects;
- competitive products;
- the ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness and ability of patients to pay out-of-pocket in the absence of third-party coverage.

If *EGRIFTATM* does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from this product, and we may not be able to achieve profitability. Our efforts, and the efforts of our commercial partners, to educate the medical community and third-party payors on the benefits of tesamorelin may require significant resources and may never be successful.

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

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

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

# We are substantially dependent on revenues from EGRIFTATM.

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

# Our levels of revenues are highly dependent on obtaining patient reimbursement for EGRIFTATM.

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

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

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

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

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

- differing regulatory requirements for drug approvals in foreign countries;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in foreign countries;

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- 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.

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

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

In several countries, including countries which are in Europe, Latin America, Africa, and the Middle East, the pricing of prescription drugs may be subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time and delay the marketing of a product. To obtain reimbursement or pricing approval in some countries, a clinical trial that compares the cost-effectiveness of a product candidate to other available therapies may be required. If reimbursement of our product is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our commercial partners may not be willing to devote resources to market and commercialize *EGRIFTATM* or may decide to cease marketing such product. In such case, our business, prospects and results of operations could be materially adversely affected.

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

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

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products, most of which have substantially greater financial, technical and personnel resources than us. Although we believe that we have no direct competitors for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, we could face indirect competition from other companies developing and/or commercializing metabolic products and/or other products that reduce or eliminate the occurrence of lipodystrophy.

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

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

We import and export products and raw materials from and to several jurisdictions around the world. This process requires us and our commercial partners to operate in a number of jurisdictions with different customs and import/export regulations. The regulations of these countries are subject to change from time to time and we cannot predict the nature, scope or impact of these changes upon our operations. We and our commercial partners are subject to periodic reviews and audits by U.S. and foreign authorities responsible for administering these regulations. To the extent that we or our commercial partners are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties and increased duties, which may, individually or in the aggregate, negatively impact our business, operating results and financial condition.

### Risks Related to the Regulatory Review Process

#### Even after regulatory approval has been obtained regulatory agencies may impose limitations on the indicated uses for which our products may be marketed, subsequently withdraw approval or take other actions against us that would be adverse to our business.

Even though we have obtained marketing approval of *EGRIFTA*<sup>TM</sup> in the United States, the FDA and regulatory agencies in other countries have the ability to limit the indicated use of a product. Also, the manufacture, marketing and sale of our products will be subject to ongoing and extensive governmental regulation in the country in which we intend to market our products. For example, although we obtained marketing approval of *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the United States, the marketing of *EGRIFTA*<sup>TM</sup> will be subject to extensive regulatory requirements administered by the FDA, such as adverse event reporting and compliance with marketing and promotional requirements. The FDA has also requested that we comply with certain post-approval requirements in connection with the approval of *EGRIFTA*<sup>TM</sup> for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, namely, the development of a single vial formulation of *EGRIFTA*<sup>TM</sup> (the development of a new presentation of the same formulation), a long-term observational

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safety study using *EGRIFTATM*; and a Phase 4 clinical trial. Although we have received marketing approval from the FDA of tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, there can be no guarantee that regulatory agencies in other countries will approve tesamorelin for this treatment in their respective countries.

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

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

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

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

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

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

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

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

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

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

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval

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activities and affect our ability to profitably sell EGRIFTATM or any of our other product candidates for which we intend to seek marketing approval.

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

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and sales price that we receive for *EGRIFTATM* or any other approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

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

### **Risks Related to Our Intellectual Property**

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

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

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

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

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

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

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 knowhow, 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 patents at risk of being invalidated or interpreted narrowly, could put one or more of our patents at risk of not issuing, or could facilitate the entry of generic products. Any such litigation could also divert our research, technical and management personnel from their normal responsibilities.

Our ability to defend ourselves against infringement by third parties of our intellectual property in the United States with respect to tesamorelin for the treatment of HIV-related lipodystrophy

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

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

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

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

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

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

If we are involved in patent infringement litigation, we would need to prevail in demonstrating that our products do not infringe the asserted patent claims of the relevant patent, that the patent claims are invalid or that the patent is unenforceable. If we are found to infringe a third-party

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patent or other intellectual property right, we could be required to enter into royalty or licensing agreements on terms and conditions that may not be favourable to us, and/or pay damages, including up to treble damages in the United Sates (for example, if found liable of wilful infringement) and/or cease the development and commercialization of our product candidates. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property and to compete with us.

We have not been served with any notice alleging that we infringe a third-party patent, but there may be issued patents that we are unaware of that our products may infringe, or patents that we believe we do not infringe but ultimately could be found to infringe. We are aware of third-party patents for the reduction of accumulation of fat tissue in HIV patients and, if a patent infringement suit was brought against us, we believe that we should not be found to infringe any valid claims of these patents. If we were to challenge the validity of a competitor's issued United States patent in a United States court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. We cannot guarantee that a court would find in our favour on questions of infringement and validity. Any finding that we infringe or violate a third-party patent or other intellectual property right could materially adversely affect our business, financial condition and operating results.

### Other Risks Related to Our Business

# We have a history of net losses and we may never achieve high profitability.

We have been reporting losses since our inception (except for the financial years ended November 30, 2010, 2001 and 2000) and, as at November 30, 2010, we had an accumulated deficit of \$235,116,000. We do not expect to generate significant recurrent revenues sufficient to cover our overall activities in the immediate future. As a result of the foregoing, we will need to generate significant revenues to achieve profitability.

Our profitability will depend on, among other things, our commercial partners' ability and willingness to successfully commercialize *EGRIFTA*<sup>TM</sup> and to obtain regulatory approval for the use of tesamorelin in the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Latin America, Africa and the Middle East. However, there is no guarantee that our commercial partners will succeed in commercializing *EGRIFTA*<sup>TM</sup> or that our product candidates will ever receive approval for commercialization in any jurisdiction and, accordingly, we may never sustain profitability.

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

We have limited human resources to conduct preclinical studies and clinical trials and must rely on third-party service providers to conduct our studies and trials and carry out certain data gathering and analyses. If our third-party service providers become unavailable for any reason, including as a result of the failure to comply with the rules and regulations governing the conduct of preclinical studies and clinical trials, operational failures such as equipment failures or unplanned facility shutdowns, or damage from any event such as fire, flood, earthquake, business restructuring or insolvency or, if they fail to perform their contractual obligations pursuant to the terms of our agreements with them, such as failing to perform the testing,

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compute the data or complete the reports further to the testing, we may incur delays which may be significant in connection with the planned timing of our trials and studies which could adversely affect the timing of the development program of a product candidate or the filing of an application for marketing approval in a jurisdiction where we rely on third-party service providers to make such filing. In addition, where we rely on such third-party service provider to help in answering any question raised by a regulatory agency during its review of one of our files, the unavailability of such third-party service provider may adversely affect the timing of the review of an application and, could ultimately delay the approval. If the damages to any of our third-party service providers are material, or, for any reason, such providers do not operate in compliance with Good Laboratory Practices, or GLP, or are unable or refuse to perform their contractual obligations, we would need to find alternative thirdparty service providers.

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

Any selection of new third-party service providers to carry out work related to preclinical studies and clinical trials would be time-consuming and would result in additional delays in receiving data, analysis and reports from such third-party service providers which, in turn, would delay the filing of any new drug application with regulatory agencies for the purposes of obtaining regulatory approval to commercialize our product candidates. Furthermore, such delays could increase our expenditures to develop a product candidate and materially adversely affect our financial condition and operating results.

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

The conduct of clinical trials requires the enrolment of patients. We may have difficulties enrolling patients for the conduct of our future clinical trials as a result of design protocol, the size of the patient population, the eligibility criteria to participate in the clinical trials, the availability of competing therapies, the patient referral practices of physicians and the availability of clinical trial sites. Difficulty in enrolling patients for our clinical trials could result in the cancellation of clinical trials or delays in completing them. Once patients are enrolled in a clinical trial, the occurrence of any adverse drug effects or side effects observed during the trial could result in the clinical trial being cancelled. Any of these events would have material adverse consequences on the timely development of our product candidates, the filing of an NDA, or its equivalent, with regulatory agencies and the commercialization of such product candidates.

# We may require additional funding and may not be able to raise the capital necessary to fund all or part of our capital requirements, including to continue and complete the research and development of our product candidates and their commercialization.

We do not generate significant recurrent revenues and may need financing in order to fund all or part of our capital requirements to sustain our growth, to continue research and development of new product candidates, to conduct clinical programs, to develop our marketing and commercial capabilities and to meet our compliance obligations with various rules and regulations to which

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

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

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

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

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

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

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

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

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

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

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

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

# We may not achieve our publicly announced milestones on time.

From time to time, we publicly announce the timing of certain events to occur. 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 may differ from what has been publicly disclosed. Events such as completion of a clinical program, discovery of a new product candidate, filing of an application to obtain regulatory approval, beginning of commercialization of our products or announcement of additional clinical programs for a product candidate may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including the nature of the results obtained during a clinical trial or during a research phase, problems with a supplier or a commercial partner or any other event having the effect of delaying the publicly announced timeline. Our policy on disclosure of forward-looking information consists of not updating it if the publicly disclosed timeline varies, except as may be required by law. Any variation in the timing of certain events having the effect of postponing such events could have an adverse material effect on our business plan, financial condition or operating results.

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

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

# **Risks Related to our Common Shares**

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

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

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

# Our quarterly operating results may fluctuate significantly.

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

- variations in the level of revenues and royalties received related to our development programs;
- variations in the level of expenses related to our development programs;
- addition or termination of clinical trials;



- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- the achievement and timing of milestone payments under our existing strategic partnership agreements.

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

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

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

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

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

- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize the product candidates;
- the outcome of any litigation;
- changes in foreign currency fluctuations;
- the timing of achievement and the receipt of milestone payments from current or future third parties;

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- failure to enter into new or the expiration or termination of current agreements with third parties; and
- failure to introduce the product candidates to the market in a manner that generates anticipated revenues.

#### We may be adversely affected by currency fluctuations.

A substantial portion of our revenue is earned in U.S. dollars, but a substantial portion of our operating expenses are incurred in Canadian dollars. Fluctuations in the exchange rate between the U.S. dollar and other currencies, such as the Canadian dollar, may have a material adverse effect on our business, financial condition and operating results. We do not currently engage in transactional hedging schemes but we do attempt to hedge or mitigate the risk of currency fluctuations by actively monitoring and managing our foreign currency holdings relative to our foreign currency expenses.

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

On February 10, 2010, we entered into a shareholder rights plan agreement. In the event of certain change of control transactions, the plan entitles a rights holder, other than the person or group acquiring control, to subscribe to our common shares at a discount of 50 percent to the market price at that time, subject to certain exceptions.

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

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

# Further information on Theratechnologies

Further information on Theratechnologies, including the Company's Annual Information Form, is available on the SEDAR site at www.sedar.com.

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NOTICE OF ANNUAL AND SPECIAL MEETING OF SHAREHOLDERS TO BE HELD ON THURSDAY, MARCH 25, 2010

AND

# MANAGEMENT PROXY CIRCULAR

**FEBRUARY 23, 2010** 



# NOTICE OF ANNUAL AND SPECIAL MEETING OF SHAREHOLDERS

To the shareholders of Theratechnologies Inc. (the "Company"):

NOTICE IS HEREBY GIVEN that an annual and special meeting of shareholders (the "**Meeting**") of the Company will be held at the Centre Mont-Royal, 2200 Mansfield, Salon International, Montreal, Québec, on Thursday, March 25, 2010 at 10:00 a.m., local time, for the following purposes:

- (1) to receive the consolidated financial statements for the fiscal year ended November 30, 2009, as well as the auditors' report thereon;
- (2) to elect directors for the ensuing year;
- (3) to appoint auditors for the ensuing year and authorize the directors to set their compensation;
- (4) to consider, and if deemed advisable, to pass Resolution 2010-1 (the text of which is attached as Appendix A to the accompanying Management Proxy Circular), with or without amendments, approving the shareholder rights plan, the whole as described in the accompanying Management Proxy Circular; and
- (5) to transact such other business as may properly come before the Meeting.

DATED at Montreal, Québec, Canada, February 23, 2010.

# BY ORDER OF THE BOARD OF DIRECTORS

Jocelyn Lafond Corporate Secretary



# MANAGEMENT PROXY CIRCULAR

The information contained in this management proxy circular (the "**Circular**") is given as at February 23, 2010, except as otherwise noted. All dollar amounts set forth herein are expressed in Canadian dollars and the symbol "\$" refers to the Canadian dollar, unless otherwise indicated.

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APPENDIX B — Compensation Committee Charter APPENDIX C — Mandate of the Board of Directors APPENDIX D — Director Orientation and Continuing Education Policy APPENDIX E — Nominating and Corporate Governance Committee Charter

# ITEM I. INFORMATION RELATING TO THE ANNUAL AND SPECIAL MEETING

### 1. Voting

You may vote your shares either through a proxy or in person at the annual and special meeting of shareholders of the Company (the "Meeting").

# A. By Proxy

#### Solicitation of Proxies

This Circular is furnished in connection with the solicitation by the management of Theratechnologies Inc. (the "**Company**" or "**Theratechnologies**") of proxies to be used at the Meeting of the Company to be held on Thursday, March 25, 2010, at the time, place and for the purposes set forth in the attached Notice of Annual and Special Meeting of Shareholders (the "**Notice of Meeting**") and at any continuation of the Meeting after adjournment thereof.

The solicitation of proxies is being primarily made by mail but proxies may also be solicited by telephone, telecopier or other personal contact by officers or other employees of the Company. The entire cost of the solicitation will be borne by the Company.

#### Terms of Proxy Grant

By completing the enclosed form of proxy, or the one provided by your intermediary, you appoint the persons proposed in that form to represent your interests and vote your shares on your behalf at the Meeting. The persons named in the enclosed form of proxy are directors or officers of the Company. **However, you have the right to appoint a person or company other than the ones designated in the form of proxy to represent you at the Meeting**. To do this, you must insert such person's name in the blank space provided in the form of proxy enclosed hereto or complete another form of proxy. It is not necessary to be a shareholder of the Company in order to act as a proxy.

**If you hold your shares through an intermediary** (a stockbroker, a bank, a trust, a truste, etc.), you are not a registered shareholder in the registry of shareholders of the Company held by Computershare Trust Company of Canada ("**Computershare**"). Therefore, you cannot vote your shares directly at the Meeting. If this is your situation, you will receive from your intermediary explanation as to how to appoint proxies and have them vote your shares. To ensure that your instructions are respected, you must deliver them to your intermediary within the prescribed deadline. For any questions, please contact your intermediary directly.

## Proxy Voting

The persons named or appointed in the form of proxy will, on a show of hands or any ballot that may be called, vote (or withhold from voting) your shares in respect of which they are appointed as proxies in accordance with the instructions given in the form of proxy. **In the absence of instructions, the voting rights attached to the shares referred to in your form of proxy will be exercised FOR the matters mentioned in the attached Notice of Meeting.** 

Furthermore, the enclosed form of proxy confers upon the proxy holder a discretionary power with respect to amendments or variations to matters identified in the Notice of Meeting and with respect to all other matters which may properly come before the Meeting, or any continuation after adjournment thereof.

INFORMATION RELATING TO THE MEETING MANAGEMENT PROXY CIRCULAR Page 1 Theratechnologies Inc. However, to our knowledge, all matters to be brought before the Meeting are mentioned in appropriate fashion in the Notice of Meeting.

#### Delivery of Form of Proxy and Deadlines

If you hold your shares personally and are a registered shareholder in the registry of shareholders of the Company, please send the completed form of proxy to the Secretary of the Company, c/o Computershare Trust Company of Canada, 1100 University Street, 12<sup>th</sup> Floor, Montreal, Québec H3B 2G7, prior to 5:00 p.m. (Eastern time) on March 23, 2010 (unless you attend the Meeting in person). All shares represented by proper proxies accompanied by duly completed declarations received by Computershare at the latest on such date and prior to such time will be voted in accordance with your instructions as specified in the proxy form on any ballot that may be called at the Meeting.

If you hold your shares through an intermediary, please proceed as indicated in the documentation sent by your intermediary and within the deadlines specified therein. For any questions, please contact your intermediary directly.

### **Revocation of a Proxy**

You may, at any time, including any continuation of the Meeting after adjournment thereof, revoke a proxy for any business with respect to which said proxy confers a vote that has not already been cast.

**If you hold your shares personally and are a registered shareholder in the registry of shareholders of the Company,** please send a written notice to revoke a proxy bearing your signature or that of your proxy (or a representative of your proxy if your proxy is a company) to the Secretary of the Company, c/o Computershare Trust Company of Canada, 1100 University Street, 12<sup>th</sup> Floor, Montreal, Québec H3B 2G7, prior to 5:00 p.m. (Eastern time) on March 23, 2010. You may also revoke a proxy in person at the Meeting by making a request to that effect to the Secretary of the Company.

If you hold your shares through an intermediary, please proceed as indicated in the documentation sent by your intermediary and within the deadlines specified therein. For any questions, please contact your intermediary directly.

#### **B. In Person**

If you hold your shares personally and are a registered shareholder in the registry of shareholders of the Company, you may present yourself on the date, at the time and place set forth in the Notice of Meeting and register with the representatives of Computershare who will be at the Meeting. You should then follow voting instructions given by the Chairman of the Meeting.

If you hold your shares through an intermediary and you wish to vote your shares in person at the Meeting, please proceed as indicated in the documentation sent by your intermediary. For any questions, please contact your intermediary directly.

#### C. Voting Securities and Principal Holders

As at February 22, 2010, there were 60,449,891 common shares (the "**Common Shares**") of the Company issued and outstanding. The Common Shares are the only securities with respect to which a voting right may be exercised at the Meeting. Each Common Share entitles its holder to one vote with respect to the matters voted on at the Meeting.

Information Relating to the Meeting Management Proxy Circular

Page 2 Theratechnologies Inc. Holders of Common Shares whose names are registered on the lists of shareholders of the Company as at 5:00 p.m. (Eastern time) on February 22, 2010, being the date fixed by the Company for determination of the registered holders of Common Shares who are entitled to receive notice of the Meeting (the "**Record Date**"), will be entitled to exercise their voting rights attached to the Common Shares in respect of which they are so registered at the Meeting, or any continuation after adjournment thereof, if present or represented by proxy thereat. However, even if you have acquired Common Shares after the Record Date, you will be entitled to vote at the Meeting if, at least twenty-four (24) hours prior to the Meeting, you produce certificates for such Common Shares properly endorsed by the seller, or if you otherwise establish that you own such Common Shares and have requested that your name be included on the list of shareholders entitled to receive the Notice of Meeting.

To our knowledge, no person beneficially owns, or controls or directs control, directly or indirectly, over more than ten percent (10%) of the outstanding Common Shares of the Company.

# 2. Subjects To Be Treated at the Meeting

Please find below a description of the items listed in the Notice of Meeting.

#### A. Receipt of Financial Statements

The consolidated financial statements for the fiscal year ended November 30, 2009 together with the auditors' report thereon will be presented at the Meeting. The financial statements are included in the Company's 2009 annual report, which has been mailed to you if you requested it, along with this Circular. The financial statements are also available on SEDAR at <u>www.sedar.com</u>. No vote is required on this matter.

#### **B. Election of Directors**

The shareholders at the Meeting will appoint the directors of the Company for the coming year.

### Composition of the Board of Directors

The articles of the Company provide that the board of directors of the Company (the "**Board of Directors**") must consist of a minimum of three (3) and a maximum of twenty (20) directors. The Board of Directors has established that a number of nine (9) directors was well adapted to its size and activities.

#### Nominees

All of the nominees for the director positions of the Company are elected for a one year term ending at the next annual meeting of shareholders or when his successor is elected, unless he resigns or the position becomes vacant as a result of death, dismissal or otherwise, prior to the said meeting. We do not contemplate that any of the nominees will be unable to fulfill his mandate as director. **Unless instructions are given to abstain from voting with regard to the election of directors, the persons whose names appear on the enclosed form of proxy will vote FOR the election of the nominees whose names are set out in the table below.** 

At the Meeting, shareholders are asked to vote on a slate of directors. However, at a meeting of the Nominating and Corporate Governance Committee held in December 2009, the members of this committee agreed to review the election mode of directors for the next annual meeting of the Company. The members of the committee will examine the opportunity to move from a bundled slate of directors to an election of directors on an individual basis.

INFORMATION RELATING TO THE MEETING MANAGEMENT PROXY CIRCULAR PAGE 3 THERATECHNOLOGIES INC. The following table states the names of all persons proposed for election as directors, their province or state and country of residence, their principal occupation, the position held in the Company (if any), the year in which they first became directors of the Company and the number of Common Shares they own, directly or indirectly, or over which they exercise control or direction. To obtain additional information regarding the biographical notes of the nominees, shareholders can consult item 4.1 of the Company's 2009 annual information form dated February 23, 2010 available on SEDAR at <u>www.sedar.com</u>.

The information relating to the number of Common Shares held by the nominees in the table below and under "Cease Trade Orders, Bankruptcies, Penalties or Sanctions" is based on the statements made by the nominees.

Name, Province or State and Country of Residence	Principal Occupation	Director Since	Number of Common Shares of the Company Owned, Directly or Indirectly, or Over Which Control or Direction is Exercised
Paul Pommier(1) (2) (3) (4) (5)	Chairman of the Board of the		
Québec, Canada	Company	1997	190,100
Gilles Cloutier <sup>(3)</sup> <sup>(5)</sup> North Carolina, United States	Corporate Director	2003	51,000
A. Jean de Grandpré(2) (3) (4) (5) Québec, Canada	Corporate Director	1993	200,000
Robert G. Goyer <sup>(3)</sup> Québec, Canada	Emeritus Professor Faculty of Pharmacy Université de Montreal	2005	10,000
Gérald A. Lacoste(1) (3) (5) Québec, Canada	Corporate Director	2006	11,000
Bernard Reculeau(2) Paris, France	Corporate Director	2005	18,100
Yves Rosconi <sup>(4)</sup> Québec, Canada	President and Chief Executive Officer of the Company	2004	67,093
Jean-Denis Talon(1) (2) Québec, Canada	Chairman of the Board AXA Canada (Insurance Company)	2001	60,000
Luc Tanguay(4) Québec, Canada	Senior Executive Vice President and Chief Financial Officer of the Company	1993	83,000
(1) Member of the Audit Committee			

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

(4) Member of the Financing Committee

(5) Member of the Strategic Review Committee

INFORMATION RELATING TO THE MEETING MANAGEMENT PROXY CIRCULAR PAGE 4 THERATECHNOLOGIES INC.

### Cease Trade Orders, Bankruptcies, Penalties or Sanctions

Except as described below, to the knowledge of management of the Company, no nominee (a) is, as at the date of the Circular, or has been within the ten (10) years before the date of the Circular, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, (i) was the subject of a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty consecutive days; (ii) was subject to an event that resulted, after the director or executive officer ceased to be a director or executive officer, in the company being the subject of a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, for a period of more than thirty consecutive days; or (iii) within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or (b) has, within the ten (10) years before the date of the Circular, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his assets.

Paul Pommier was a member of the board of directors of Royal Aviation Inc. from September 1996 until it was acquired by Canada 3000 Inc. in March 2001. Subsequently, at the end of 2001, Canada 3000 Inc. and its subsidiaries, including Royal Aviation Inc., made assignments in bankruptcy under Section 49 of the *Bankruptcy and Insolvency Act (R.S. 1985, c. B-3)* (the "**Bankruptcy Act**").

Yves Rosconi was a member of the board of directors of Mistral Pharma Inc. from September 2007 until May 2008. On June 13, 2008, Mistral Pharma Inc. filed a notice of intention to make a proposal to its creditors under the Bankruptcy Act and, on August 19, 2008, Mistral Pharma Inc. filed a proposal under the Bankruptcy Act.

Luc Tanguay is currently a member of the board of directors of Ambrilia Biopharma Inc. (hereafter "**Ambrilia**") and has been a member since August 22, 2006. On July 31, 2009, Ambrilia obtained court protection from its creditors under the *Companies' Creditors Arrangement Act* (Canada). The purpose of the order issued by the court granting Ambrilia protection from its creditors is to provide Ambrilia and its subsidiaries the opportunity to restructure its affairs. Ambrilia is still under court protection. In addition, on July 31, 2009, the Toronto Stock Exchange halted the trading of Ambrilia's shares pending its review of Ambrilia's meeting the requirements for continuous listing. On August 5, 2009, Ambrilia announced that its shares would resume trading.

#### **C.** Appointment of Auditors

The Company's auditors for the current fiscal year must be appointed at the Meeting. We propose the appointment of KPMG LLP, chartered accountants from Montréal, who have been the Company's auditors since October 19, 1993. They will hold office until the next annual meeting of shareholders or until their successors are appointed.

The table below sets forth the fees paid to the auditors of the Company for the financial years ended November 30, 2009 and November 30, 2008.

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		Financial Year Ended November 30, 2009			
Audit Fees	\$	80,000	\$	77,000	
Audit-Related Fees (1)	\$	17,500	\$	71,300	
Tax Fees (2)	\$	39,626	\$	40,064	
All Other Fees					

(1) Audit-related fees relate principally to services rendered in connection with the Company's quarterly financial statements. For the financial year ended November 30, 2008, audit-related fees paid to KPMG also included fees related to services rendered in connection with the Company's public offering.

(2) Tax fees relate to services rendered in connection with the preparation of corporate tax returns and general tax advice.

# Unless instructions are given to abstain from voting with regard to the appointment of auditors, the persons whose names appear on the enclosed form of proxy will vote FOR the appointment of KPMG LLP, chartered accountants, as auditors of the Company, and authorize that compensation for their services be determined by the Board of Directors.

#### D. Approval of Shareholder Rights Plan

On February 10, 2010, the Board of Directors implemented a shareholder rights plan (the "**Rights Plan**"), the terms and conditions of which are set out in a shareholder rights plan agreement (the "**Rights Agreement**") dated February 10, 2010 with Computershare Trust Services of Canada, as rights agent. The Rights Plan is currently effective but is subject to approval by a majority of the votes cast by shareholders, in person or by proxy, at the Meeting. If shareholders of the Company do not approve the Rights Plan, it will cease to be effective and will terminate.

### Purpose of the Rights Plan

The purpose of the Rights Plan is to ensure equal treatment of shareholders and to give adequate time for shareholders to properly assess the merits of a bid without undue pressure, and to allow competing bids to emerge. The Rights Plan is designed to give the Board of Directors time to consider alternatives, allowing shareholders to receive full and fair value for their shares. The Rights Plan was not adopted by the Board of Directors in response to any acquisition proposal and is not designed to secure the continuance in office of the current management or the directors of the Company. The adoption of the Rights Plan does not in any way lessen the duties of the directors to fully and fairly examine all bids which may be made to acquire the Common Shares of the Company and to exercise such duties with a view to the best interest of the shareholders and the Company.

Before deciding to adopt the Rights Plan, the Board of Directors considered the current shareholdings of the Company and the legislative framework in Canada governing takeover bids. To our knowledge, there is currently no person who beneficially owns, or controls or directs control, directly or indirectly, over more than ten percent (10%) of the outstanding Common Shares of the Company. Therefore, a person could acquire a *de facto* control of the Company through the purchase of a number of Common Shares that would represent a percentage of Common Shares below 50% by entering into private acquisition agreements without having to make an offer to all of the shareholders.

Under provincial securities legislation, a takeover bid generally means an offer to acquire voting or equity voting shares of a corporation that, together with shares already owned by the bidder and certain parties related thereto, amount to 20% or more of the outstanding shares of that class.

The existing legislative framework for takeover bids in Canada presents the following concerns for shareholders:

INFORMATION RELATING TO THE MEETING MANAGEMENT PROXY CIRCULAR Page 6 Theratechnologies Inc.

# 1. Time

Current legislation permits a takeover bid to expire 35 days after it is initiated. The Board of Directors is of the view that this is not sufficient time to permit shareholders to adequately consider a takeover bid and make a reasoned and unhurried decision.

# 2. Pressure to Tender

A shareholder may feel compelled to tender his Common Shares pursuant to a takeover bid which he considers to be inadequate, out of a concern that in failing to do so, the shareholder may be left with illiquid or minority discounted Common Shares. The Rights Plan provides shareholders with a mechanism which is intended to ensure that they can separate the decision to tender, based on the merits of a bid, from the approval or disapproval of a particular takeover bid.

# 3. Unequal Treatment

Shareholders may not be treated equally if, as current securities legislation provides, an important number of Common Shares is acquired pursuant to a private agreement in which a small group of shareholders or a shareholder disposes of its Common Shares at a premium to market price, which premium is not shared with the other shareholders of the Company. In addition, a person may gradually accumulate Common Shares through stock exchange acquisitions which results in an acquisition of control of the Company, without payment of fair value for control or a fair sharing of a control premium amongst all shareholders. The Rights Plan addresses these concerns by applying to all acquisitions of 20% or more of the Common Shares of the Company, ensuring that shareholders receive equal treatment.

The issue of rights (the "**Rights**") will not in any way adversely alter the financial condition of the Company and will not change the way in which shareholders trade their Common Shares. However, by permitting holders of Rights other than an "Acquiring Person" (as defined below) to acquire additional Common Shares of the Company at a discount to market value, the Rights may cause substantial dilution to a person or group that acquires 20% or more of the outstanding Common Shares other than by way of a "Permitted Bid" (as defined below). A potential bidder can avoid the dilutive features of the Rights Plan by making a bid that conforms to the requirements of a Permitted Bid.

The Company has reviewed the Rights Plan for conformity with current practices of Canadian companies with respect to shareholder protection rights plans. We believe that the Rights Plan preserves the fair treatment of shareholders, is consistent with best Canadian corporate practices and addresses institutional investor guidelines.

# Terms of the Rights Plan

The following is a summary of the principal terms of the Rights Agreement and is provided subject to the terms and conditions thereof. A complete copy of the Rights Agreement has been filed and is available on the System for Electronic Document Analysis and Retrieval (SEDAR) at <u>www.sedar.com</u>.

# Issue of Rights

In order to implement the Rights Plan, the Board of Directors authorized the Company to issue one right in respect of each Common Share outstanding as of 6:00 p.m. (Montreal time) on February 9, 2010 (the "Effective Date"). One Right will also be issued and attached to each subsequently issued Common Share.

INFORMATION RELATING TO THE MEETING MANAGEMENT PROXY CIRCULAR Page 7 Theratechnologies Inc.

### Rights-Exercise Privilege

The Rights will be separate from the Common Shares to which they are attached and will become exercisable at the time (the "**Separation Time**") that is ten (10) business days after the earlier of: (i) the first date of public announcement that an "Acquiring Person" (as defined below) has become such; (ii) the date of commencement of, or first public announcement in respect of, a takeover bid which will permit an offeror to hold 20% or more of the Common Shares, other than by an acquisition pursuant to a takeover bid permitted by the Rights Plan (a "**Permitted Bid**" as defined below); (iii) the date upon which a Permitted Bid ceases to be a Permitted Bid; or (iv) such other date as may be determined in good faith by the Board of Directors.

The acquisition permitting a person (an "**Acquiring Person**"), including others acting jointly or in concert with such person, to hold 20% or more of the outstanding Common Shares, other than by way of a Permitted Bid, is referred to as a "**Flip-in Event**." Any Rights held by an Acquiring Person on or after the earlier of the Separation Time or the first date of a public announcement (the "**Common Share Acquisition Date**") by the Company or an Acquiring Person that an Acquiring Person has become such will become null and void upon the occurrence of a Flip-in Event. Ten (10) trading days after the occurrence of the Common Share Acquisition Date, each Right (other than those held by the Acquiring Person) will permit the holder to purchase for the exercise price that number of Common Shares determined as follows: a value of twice the exercise price divided by the average weighted market price for the last 20 trading days preceding the Common Share Acquisition Date. The exercise price is currently \$25 per Right, subject to adjustment provisions described in the Rights Plan.

Upon the occurrence of a Flip-in Event and the separation of the Rights from the Common Shares, reported earnings per share on a fully diluted or non-diluted basis may be affected. Holders of Rights who do not exercise their Rights upon the occurrence of a Flip-in Event may suffer substantial dilution.

#### Lock-Up Agreements

A bidder may enter into lock-up agreements with the shareholders of the Company whereby such shareholders agree to tender their Common Shares to the takeover bid (the "**Lock-up Bid**") without a Flip-in Event occurring. Any such agreement must permit or must have the effect to permit the shareholder to withdraw the Common Shares to tender to another takeover bid or to support another transaction that exceeds the value of the Lock-up Bid.

#### Certificates and Transferability

Prior to the Separation Time, the Rights will be evidenced by a legend imprinted on certificates for Common Shares issued after the Effective Date. Rights are also attached to Common Shares outstanding on the Effective Date, although share certificates will not bear such a legend. Prior to the Separation Time, Rights will not be transferable separately from the Common Shares. From and after the Separation Time, the Rights will be evidenced by Rights certificates, which will be transferable and traded separately from the Common Shares.

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#### "Permitted Bid" Requirements

A "**Permitted Bid**" is a takeover bid that does not trigger the exercise of Rights. A "**Permitted Bid**" is a bid that aims to acquire shares which, together with the other securities beneficially owned by the bidder, represent not less than 20% of the outstanding Common Shares, which bid is made by means of a takeover bid circular and satisfies the following requirements:

- (i) the bid must be made to all holders of Common Shares;
- (ii) the bid must include a condition without reservation providing that no share tendered pursuant to the bid will be taken up prior to the expiry of a period of not less than 60 days and only if at such date more than 50% in aggregate of the outstanding shares held by the shareholders other than the bidder, its associates and affiliates, and persons acting jointly or in concert with such persons (the "Independent Shareholders"), have been tendered pursuant to the bid and not withdrawn;
- (iii) if more than 50% in aggregate of the shares held by Independent Shareholders are tendered to the bid within the 60-day period, the bidder must make a public announcement of that fact and the bid must remain open for deposits of shares for an additional ten (10) business days from the date of such public announcement.

#### Waiver and Redemptions

The Board of Directors acting in good faith may, prior to a Flip-in Event, waive the dilutive effects of the Rights Plan in respect of a particular Flip-in Event that would result from a takeover bid made by way of takeover bid circular to all holders of Common Shares, in which event such waiver would be deemed also to be a waiver in respect of any other Flip-in Event. The Board of Directors may also waive the Rights Plan in respect of a particular Flip-in Event that has occurred through inadvertence, provided that the Acquiring Person that inadvertently triggered such Flip-in Event reduces its beneficial holdings to less than 20% of the outstanding Common Shares within 14 days or any other period that may be specified by the Board of Directors. At any time prior to the occurrence of a Flip-in Event, the Board of Directors may, subject to the prior approval of the holders of Common Shares, elect to redeem all, but not less than all, of the outstanding Rights at a price of \$0.0001 per right.

#### Exemption for Investment Managers

Investment managers (for client accounts), trust companies and pension funds (acting in their capacity as trustees and administrators) acquiring shares permitting them to hold 20% or more of the Common Shares are exempt from triggering a Flip-in Event, provided that they are not making, or are not part of a group making, a takeover bid.

#### Supplements and Amendments

The Company is authorized to make amendments to the Rights Plan to correct any clerical or typographical error or to maintain the validity of the Rights Plan as a result of changes in laws or regulations. Prior to the Meeting, the Company is authorized to amend or supplement the Rights Plan as the Board of Directors may in good faith deem necessary or advisable. The Company will issue a press release relating to any material amendment made to the Rights Plan prior to the Meeting and will advise the shareholders of any such amendment at the Meeting. Material amendments or supplements to the Rights Plan will require, subject to the regulatory authorities, the prior approval of the shareholders or, after the Separation Time, holders of Rights.

INFORMATION RELATING TO THE MEETING MANAGEMENT PROXY CIRCULAR PAGE 9 THERATECHNOLOGIES INC.

### Canadian Income Tax Consequences of the Rights Plan

Under the *Income Tax Act* (Canada) (the "**Tax Act**"), while the matter may be debated, the issue of the Rights under the Rights Plan may be a taxable benefit, the fair market of value of which must be included in the income of a recipient. The Company considers that the Rights, when issued, will have no or negligible monetary value, there being only a remote possibility that the Rights will ever be exercised. The Rights will be considered to have been acquired at no cost. The holder of Rights may realize income or be subject to withholding tax under the Tax Act if the Rights become exercisable, are exercised and are otherwise disposed of.

The information provided above is of a general nature and is not intended to constitute, nor should it be construed as, legal or tax advice to any particular holder of Common Shares. Such holders are advised to consult their own tax advisors regarding the consequences of acquiring, holding, exercising or otherwise disposing of their Rights, taking into account their own particular circumstances and applicable federal, provincial, territorial or foreign legislation.

#### **Recommendation of the Board of Directors**

At the Meeting, shareholders will be asked to consider and, if deemed advisable, to approve the Rights Plan by passing Resolution 2010-1, substantially in the form of the resolution attached as Appendix A to this Circular. Resolution 2010-1 must be passed by a majority of the votes cast by shareholders entitled to vote who are represented in person or by proxy at the Meeting and who vote in respect of that resolution.

The Board of Directors considers the approval of the Rights Plan to be appropriate and in the best interests of the Company and recommends that shareholders vote in favour of Resolution 2010-1 to approve the Rights Plan.

# Unless instructions are given to vote against, or abstain from voting on, Resolution 2010-1, the persons whose names appear in the enclosed form of proxy will vote FOR the passing of Resolution 2010-1.

### E. Other Matters to be Acted Upon

The Company will consider and transact such other business as may properly come before the Meeting or any adjournment thereof. Management of the Company knows of no other matters to come before the Meeting other than those referred to in the Notice of Meeting. Should any other matters properly come before the Meeting, the Common Shares represented by the proxy solicited hereby will be voted on such matter in accordance with the best judgment of the persons voting the proxy.

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# **ITEM II. COMPENSATION**

The compensation of the executive officers and directors of the Company is determined by the compensation committee of the Company (the "**Compensation Committee**"). The Compensation Committee is composed of four (4) independent directors, namely A. Jean de Grandpré, who is the chair of the Compensation Committee, Paul Pommier, Bernard Reculeau and Jean-Denis Talon. The mandate, obligations and duties of the Compensation Committee are described in Appendix B to this Circular. The Compensation Committee reviews the compensation of executive officers at a meeting held after the end of the Company's financial year. At this meeting, the Compensation Committee reviews the compensation of executive officers for the past financial year and determines the compensation for the ensuing year.

# 1. Executive Compensation

### A. Compensation Discussion & Analysis

### **Objectives of the Compensation Program**

To achieve its business plan, the Company requires a strong and capable executive team. This justifies the need for an executive program that will attract, retain, motivate and reward its executive officers. The Company is committed to a compensation policy that is competitive and drives business performance.

#### What the Compensation Program is Designed to Reward

The compensation program of the Company (the "**Compensation Program**") is designed to reward the executive officers for implementing strategies, both in the short and the long term, to realize the business plan of the Company to advance its drug development and commercialization programs. It is also designed to enhance its share value and, thereby, create economic value.

The Compensation Program provides reasonable and competitive total executive compensation. Remuneration and incentive components are established to compete with remuneration practices of similar companies that are involved in the biopharmaceutical and pharmaceutical industries.

To establish base salary and bonus compensation levels, the Company generally studies, among other things, the competitive market environment and reviews information published in the Rx & D Compensation Survey and the proxy circulars of other publicly listed biotechnology companies whose stage of development and market capitalization are similar or more advanced than those of the Company. The Compensation Committee also takes into consideration the financial needs of the Company, its business plan and the Company's annual corporate objectives before determining the Company's own Compensation Program.

At the beginning of the financial year 2009, the Compensation Committee met to determine the base salary of each executive officer. In order to set the base salary of its executive officers for that financial year, the Compensation Committee considered publicly available economic data regarding the variation of the Consumer Price Index and publicly available data regarding forecasted salary percentage increase for that year. The Compensation Committee also considered the importance of the objectives to be attained by the executive officers and the Company during that year. No independent third-party report was prepared. However, at the end of the financial year 2009, the Compensation Committee retained the services of Towers Perrin, an independent third-party

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR Page 11 Theratechnologies Inc. consulting firm, to conduct an annual comparative analysis of the compensation paid to its executive officers against the compensation paid to executive officers in various companies. Towers Perrin's analysis was based on a reference market of the following 19 companies (the "**Benchmarked Companies**"):

- AEterna Zentaris Inc.
- Angiotech Pharmaceuticals Inc.
- AstraZeneca Canada Inc.
- Bayer Inc.
- Beckman Coulter Canada Inc.
- Biogen Idec Canada Inc.
- BioMS Medical Corp.
- Cardiome Pharma Corp.
- Eli Lilly Canada Inc.
- Hoffman La Roche Limited
- Labopharm Inc.
- Life Technologies Corporation
- MDS Inc.
- Methylgene Inc.
- Bellus Health Inc.
- Patheon Inc.
- QLT Inc.
- Sanofi Pasteur Limited
- Transition Therapeutics Inc.

The Benchmarked Companies were reviewed and agreed to by the Compensation Committee.

Overall, Towers Perrin's report concluded that the aggregate compensation paid to the Named Executive Officers (as defined below) of the Company was below the median and, in certain circumstances, at the median of the aggregate compensation paid by the Benchmarked Companies to individuals holding the same position as those of the Named Executive Officers.

## **Decision-Making Process**

The proposed annual compensation for each of the executive officers, other than for the President and Chief Executive Officer, is presented by the President and Chief Executive Officer to the Compensation Committee and reviewed by the Compensation Committee. The compensation for the President and Chief Executive Officer is determined by the Compensation Committee. The Compensation Committee reports and makes a recommendation to the Board of Directors on the proposed compensation of executive officers. The Board of Directors approves grants of options if, upon the recommendation of the Compensation Committee, it deems it advisable.

# Elements of Compensation Program

The major elements of the Company's executive Compensation Program are base salary, short-term performance reward program that takes the form of cash bonuses, and long-term incentives through the granting of stock options. All proposed changes to any compensation component of an executive officer are first reviewed internally by the President and Chief Executive Officer and the Senior Executive Vice President and Chief Financial Officer. The proposed changes are then presented to the Compensation Committee.

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR Page 12 Theratechnologies Inc.

### **Base Salary**

Base salaries for each of the executive officers are based on the experience, expertise and competencies of each executive officer. In reference to the Benchmarked Companies used for comparison, the salaries of the Named Executive Officers and other executive officers are generally at the median (50<sup>th</sup> percentile). However, the Compensation Committee has no firm policy on setting the base salary at the median and, accordingly, base salaries may be set below or above the median.

### Performance Reward Program

The short-term performance reward program is designed to recognize the contribution of each executive officer in helping the Company to attain its corporate objectives and to increase its value. Bonuses are granted if the annual corporate objectives are met by the Company and in accordance with the individual performance and the results achieved or surpassed by such individual in connection with such corporate objectives. When and if the Company generates significant revenues from the sale of his products, financial criteria will also be factored into the determination of this program.

The target bonus payment for each of the President and Chief Executive Officer and the Senior Executive Vice President and Chief Financial Officer is set at 50% of their respective base salary. For the other three Named Executive Officers, the target bonus payment is set at 33 1/3% of their respective base salary. These target bonus payments are at the 75<sup>th</sup> percentile when compared against the Benchmarked Companies, except for the target bonus payment of the President and Chief Executive Officer which is at the median.

For the year ended November 30, 2009, the Company's principal objective was to file a complete New Drug Application to the Food and Drug Administration in the United States and to file it by the end of the second quarter. The second corporate objective of the Company consisted in organizing working committees with our commercial partner in the United States for the preparation of the commercialization of tesamorelin in such country further to the execution of our collaboration and licensing agreement with EMD Serono, Inc. at the beginning of our fiscal year 2009. The third corporate objective of the Company was related to the negotiations of supply agreements with third-party service providers to ensure that the Company would have the manufacturing capacity to supply tesamorelin to its commercial partner in the United States for commercial sale in this country. The fourth corporate objective of the Company consisted in exploring the potential of tesamorelin to be approved in countries other than the United States for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy while seeking partners to commercialize tesamorelin in those countries. The fifth corporate objective of the Company consisted in pursuing the evaluation of other clinical programs in which tesamorelin could be developed. Finally, the last objective was to meet each of these objectives in a cost-efficient manner to conserve the Company's cash position and to manage its burn rate.

The objectives of the Named Executive Officers were aligned with those of the Company. The Compensation Committee did not mathematically weight the objectives of the Company against each other and the objectives of the Named Executive Officers against those of the Company in determining the compensation of the Named Executive Officers for the last financial year. The Compensation Committee rather considered all objectives with the attainment of the first corporate objective as being the most relevant one in order to set the compensation of the Named Executive Officers for the last financial year.

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#### Long-Term Incentive Program

The Company's long-term incentive program is composed of its share option plan (the "**Share Option Plan**") which was originally adopted on December 6, 1993, and subsequently amended from time to time, in order to attract, retain, motivate employees in key positions and align their interests with those of the Company's shareholders by allowing optionees to participate in the increased value of the Common Shares. The Company has no share-based award. The Company has a share purchase plan but the share purchase plan is available to all employees of the Company and the decision to subscribe for Common Shares under this plan rests with each employee. For a description of the share purchase plan, see "Other Information — Description of the Share Purchase Plan" below.

The number of options granted is determined on the basis of the position of each executive officer, the attainment of corporate objectives and the value of the options at the time of grant as part of the total compensation of an executive officer. When assessing whether options should be granted to an executive officer, the Compensation Committee also factors in the number of options held by an executive officer, their vesting periods, expiry dates and exercise prices. When compared against the value of options granted by the Benchmarked Companies to individuals holding the same positions as those of the Named Executive Officers, the estimated annualized value of the options granted by the Company during the last five (5) years to its Named Executive Officers is below and, in certain circumstances, at the median.

#### Description of the Share Option Plan

A maximum of 5,000,000 Common Shares have been reserved for stock option grants under the Share Option Plan, of which, as at the date of the Circular, 999,001 options remain available for issuance.

The Board of Directors administers the Share Option Plan. The Board of Directors designates the optionees and determines the number of Common Shares underlying these options, the vesting period, the exercise price and the expiry date of each option, as well as all other related matters, the whole in compliance with the terms of the Share Option Plan and applicable legislative provisions established by the securities regulatory authorities. Options granted to executive officers generally vest as to 33 1/3% on each year starting twelve (12) months after the date of grant. The Board of Directors can modify or terminate the Share Option Plan subject to compliance with the rules set forth by regulatory authorities. However, certain amendments require the approval of a majority of the voting shareholders of the Company.

Unless otherwise determined by the Board of Directors, the options granted pursuant to the Share Option Plan may be exercised within a maximum period of ten (10) years following their date of grant, unless the optionee's employment is terminated, other than for death, in which case the optionee's unexercised vested options, if any, may be exercised within a period of one hundred eighty (180) days following the date of the employee's termination. In the event of the death of an optionee prior to the expiry date of his options, the optionee's legal personal representative may exercise the optionee's unexercised vested options within twelve (12) months after the date of the optionee's death. The options granted in accordance with the Share Option Plan cannot be transferred or assigned.

The exercise price at which the options may be granted pursuant to the Share Option Plan cannot be less than the closing price of the Common Shares on the TSX on the day preceding the date of grant of the options.

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR Page 14 Theratechnologies Inc. In addition, the Share Option Plan states that the number of Common Shares that may be issued to insiders, at any time, under all security based compensation arrangements of the Company, cannot exceed 10% of the outstanding Common Shares of the Company, and the number of Common Shares issued to insiders, within any one year period, under all security based compensation arrangements, cannot exceed 10% of the outstanding Common Shares that may be issued to non-employee directors, within any one year period, under all security based compensation arrangements, cannot exceed 0.5% of the outstanding Common Shares of the Company.

During the financial year ended November 30, 2009, the Company granted options under the Share Option Plan providing for the purchase of 680,500 Common Shares. From December 1, 2009 to February 22, 2010, the Company granted 265,000 options under the Share Option Plan, 155,000 of which were granted to the Named Executive Officers as part of their compensation for the last financial year ended November 30, 2009.

The following table sets forth the information regarding the equity compensation plan of the Company as at November 30, 2009.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options (% of Issued and Outstanding Share Capital)	Exerci	ed-average se Price of ding Option	Number of Securities Remaining Available for Future Issuance under Equity Compensation Plan
Equity Compensation				
Plan Approved by	2,665,800			
Shareholders	(4.41%)	\$	5.20	1,244,834
Equity Compensation Plans Not Approved by Shareholders	_			_
Total	2,665,800	\$	5.20	1,244,834

#### **B.** Summary Compensation Table

The summary compensation table below details compensation for the financial year ended November 30, 2009 for each of the President and Chief Executive Officer, the Senior Executive Vice President and Chief Financial Officer, and the three other most highly compensated executive officers of the Company (collectively the "**Named Executive Officers**") for services rendered in all capacities.

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					Non-equity incentive pla	n compensation (\$)			
Name and principal position	Year	Salary (\$)	Share-based awards (\$)	Option- based awards(1) (2) (\$)	Annual incentive plans	Long-term incentive plans	Pension value (\$)	All other compen- sation(13) (\$)	Total compensation (\$)
Yves Rosconi President and Chief Executive	2000	406 605		00.000	225.000				
Officer	2009	426,635	—	80,820 <sub>(3)</sub>	225,000 <sub>(8)</sub>		—	—	732,455
Luc Tanguay Senior Executive Vice President and Chief Financial Officer	2009	353,354	_	67,350 <sub>(4)</sub>	176,000 <sub>(9)</sub>	_	_	_	596,704
Christian Marsolais Vice President, Clinical Research and Medical Affairs	2009	220,846	_	156,040(5)	100,000(10)	_	_	_	476,886
Martine Ortega Vice President, Compliance and Regulatory Affairs	2009	215,827	_	125,165 <sub>(6)</sub>	110,000(11)	_	_	_	450,992
Jocelyn Lafond Vice President, Legal Affairs, and Corporate Secretary	2009	200,769	_	142,570 <sub>(7)</sub>	66,000 <sub>(12)</sub>	_	_	_	409,339

(1) The value of the awards is comprised of two grants that occurred during the last financial year. The first grant was made on December 18, 2008 (the "December 2008 Grant") and the second occurred on December 8, 2009 (the "December 2009 Grant"). Only the value of the options received by Ms. Ortega, Mr. Marsolais and Mr. Lafond as part of the December 2008 Grant and resulting as compensation for the financial year ended November 30, 2009 has been included in this table. The value of the option-based awards was calculated using the Black-Scholes-Merton model using the following assumptions:

- (a) December 2008 Grant:
  - (i) Risk-free interest rate: 1.79%;
  - (ii) Expected volatility in the market price of the Common Shares: 79.33%;
  - (iii) Expected dividend yield: 0%; and
  - (iv) Expected life: 6 years.

Fair value per option: \$1.235.

- (b) December 2009 Grant:
  - (i) Risk-free interest rate: 2.46%;
  - (ii) Expected volatility in the market price of the Common Shares: 80.96%;
  - (iii) Expected dividend yield: 0%; and
  - (iv) Expected life: 6 years.

Fair value per option: \$2.694

- (2) The options granted as part of the December 2008 Grant vest over a three (3) year period as to 33 1/3% beginning December 18, 2009. The options granted as part of the December 2009 Grant vest over a three (3) year period as to 33 1/3% beginning on December 8, 2010.
- (3) Mr. Rosconi was granted 30,000 options as part of the December 2009 Grant.
- (4) Mr. Tanguay was granted 25,000 options as part of the December 2009 Grant.

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- (5) Mr. Marsolais was granted 35,000 options as part of the December 2009 Grant. Mr. Marsolais was also granted 50,000 options as part of the December 2008 Grant, of which 25,000 were granted pursuant to the terms of his employment agreement and 25,000 were granted further to his appointment as Vice President in August 2007. Subject to Mr. Marsolais being employed by the Company, these 50,000 options were scheduled to be granted in the financial year 2008. However, as a result of the strategic review process that was ongoing during this financial year, the Board of Directors decided to defer the grant of those options until completion of the strategic review process.
- (6) Ms. Ortega was granted 35,000 options as part of the December 2009 Grant. Ms. Ortega was also granted 25,000 options as part of the December 2008 Grant further to her appointment as Vice President in August 2007. Subject to Ms. Ortega being employed by the Company, these 25,000 options were scheduled to be granted in the financial year 2008. However, as a result of the strategic review process that was ongoing during this financial year, the Board of Directors decided to defer the grant of those options until completion of the strategic review process.
- (7) Mr. Lafond was granted 30,000 options as part of the December 2009 Grant. Mr. Lafond was also granted 50,000 options as part of the December 2008 Grant, of which 25,000 were granted pursuant to the terms of his employment agreement and 25,000 were granted further to his appointment as Vice President in August 2007. Subject to Mr. Lafond being employed by the Company, these 50,000 options were scheduled to be granted in the financial year 2008. However, as a result of the strategic review process that was ongoing during this financial year, the Board of Directors decided to defer the grant of those options until completion of the strategic review process.
- (8) The amount received by Mr. Rosconi represents 106% of his targeted bonus (\$212,873). As President and Chief Executive Officer of the Company, Mr. Rosconi's objectives were aligned with the Company's objectives. The Compensation Committee determined that he had exceeded his objectives by leading the scientific and regulatory teams in filing a New Drug Application to the Food and Drug Administration in the United States before the end of the second quarter.
- (9) The amount received by Mr. Tanguay represents 100% of his targeted bonus (\$176,000). As Senior Executive Vice President and Chief Financial Officer of the Company, Mr. Tanguay's objectives were aligned with those of the Company and included (i) managing the Company's liquidities to ensure the corporate objectives would be attained in a cost-efficient manner and according to the annual budget; (ii) supervising the negotiation of supply agreements with third parties for the manufacture of tesamorelin on a commercial scale; (iii) overseeing the internal controls and process of the Company for compliance with securities regulation; (iv) supervising the process regarding the preparation of the Company to the new IFRS accounting rules; and (v) overseeing the investors' relations programme.
- (10) The amount received by Mr. Marsolais represents 135% of his targeted bonus (\$73,615). As Vice President, Clinical Research and Medical Affairs, of the Company, Mr. Marsolais's objective were aligned with those of the Company and consisted in the preparation and completion of the New Drug Application to be filed with the Food and Drug Administration of the United States.
- (11) The amount received by Ms. Ortega represents 153% of her targeted bonus (\$71,942). As Vice President, Compliance and Regulatory Affairs, of the Company, Ms. Ortega's objectives were aligned with those of the Company and included (i) leading the preparation of the New Drug Application to ensure compliance with the *Federal Food*, *Drug*, *and Cosmetic Act* (United States); and (ii) managing the filing process of the New Drug Application with the Food and Drug Administration in the United States.
- (12) The amount received by Mr. Lafond represents 99% of his targeted bonus (\$66,922). As Vice President, Legal Affairs, and Corporate Secretary, of the Company, Mr. Lafond's objectives were aligned with those of the Company. The main objective of Mr. Lafond consists in overseeing the legal needs of the Company. In addition, the Compensation Committee determined that he had achieved the following objectives (i) overseeing the anti-trust issues regarding the execution of the collaboration and licensing agreement with EMD Serono, Inc.; (ii) assisting with the negotiations of the supply agreements to manufacture tesamorelin on a commercial scale; and (iii) supporting the legal needs of both the clinical research and regulatory teams.
- (13) Perquisites for each Named Executive Officer have not been included as they do not reach the prescribed threshold of the lesser of \$50,000 and 10% of each of the respective Named Executive Officer's salary for the last financial year.

## C. Incentive Plan Awards

## **Outstanding Option-Based Awards and Share-Based Awards**

The table below details the outstanding option-based awards and share-based awards as at November 30, 2009 for each of the Named Executive Officers.

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		<b>Option-Based</b> Awar	ds		Share-Based Awards	
Name	Number of securities underlying unexercised options (#)	Option exercice price (\$)	Option expiration date	Value of unexercised in-the-money options (1) (\$)	Number of shares or units of shares that have not vested (#)	Market or payout value of share-based awards that have not vested (\$)
Yves Rosconi	133,334	2.61	2014.10.01	90,667	—	—
President and	133,334	1.24	2015.10.01	273,335		
Chief Executive Officer	25,000	8.23	2017.01.12	—		
	25,000	1.80	2018.12.18	37,250		
Luc Tanguay Senior Executive Vice President and Chief Financial Officer Christian Marsolais Vice President,	200,000 200,000 125,000 25,000 25,000 25,000 25,000	10.40 8.00 1.94 8.23 1.80 11.48 10.60	2011.10.30 2012.10.30 2016.02.08 2017.01.12 2018.12.18 2017.07.11 2017.08.06 2018.01 20	 168,750  29,800 	_	_
Clinical Research and Medical Affairs	1,000 65,000	8.50 1.80	2018.01.30 2018.12.18	 96,850		
Martine Ortega Vice President, Compliance and Regulatory Affairs	25,000 10,000 25,000 25,000 1,000 40,000	$1.42 \\ 8.23 \\ 11.48 \\ 10.60 \\ 8.50 \\ 1.80$	2016.07.06 2017.01.12 2017.07.11 2017.08.06 2018.01.30 2018.12.18	46,750 — — — 59,600	_	_
Jocelyn Lafond Vice President, Legal Affairs, and Corporate Secretary	25,000 25,000 65,000	8.29 10.60 1.80	2017.03.29 2017.08.06 2018.12.18	 96,850	_	_

(1) The value of unexercised in-the-money options at financial year end is the difference between the closing price of the Common Shares on November 30, 2009 (\$3.29) on the TSX and the respective exercise prices of the options. The value shown in this table does not represent the actual value that a Named Executive Officer would have received if the options had been exercised as at November 30, 2009 since some of these options were not fully vested as of that date and, therefore, were not exercisable.

# Incentive Plan Awards — Value vested or earned during the year

The table below shows the value vested or earned during the year under each incentive plan as at November 30, 2009 for each of the Named Executive Officers.

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Name	Option-based awards Value vested during the year(1) (\$)	Share-based awards Value vested during the year (\$)	Non-equity incentive plan compensation Value earned during the year (\$)
Yves Rosconi President and Chief Executive Officer	_	_	225,000
Luc Tanguay Senior Executive Vice President and Chief Financial Officer	_	_	176,000
Christian Marsolais Vice President, Clinical Research and Medical Affairs	_	_	100,000
Martine Ortega Vice President, Compliance and Regulatory Affairs	7,167 (2)	_	110,000
Jocelyn Lafond Vice President, Legal Affairs, and Corporate Secretary	_	_	66,000

(1) The value is determined by assuming that the options vested during the financial year would have been exercised on the vesting date. The value corresponds to the difference between the closing price of the Common Shares on the TSX on the vesting date and the exercise price of the options on that date.

(2) 8,334 options having an exercise price of \$1.42 vested on July 6, 2009. On that date, the closing price of the Common Shares on the TSX was \$2.28.

## D. Termination and Change of Control Provisions

Below is a summary of the employment agreements of each of the Named Executive Officers together with a table detailing the value of the severance payment that would be payable by the Company to each Named Executive Officer pursuant to his employment agreement if one of the events described in the table had occurred on November 30, 2009.

## Yves Rosconi

### President and Chief Executive Officer

On October 21, 2004, the Company entered into an employment agreement for an indeterminate term with Mr. Yves Rosconi. In addition to his base salary, Mr. Rosconi is entitled to the Company's benefits program and is eligible to receive an annual bonus based on attainment of objectives set annually by the Company's Board of Directors. Mr. Rosconi was also entitled to stock options, which have all been granted. These options vested over a three-year period from the date of grant. Under the terms of the agreement, Mr. Rosconi agreed to non-competition, non-solicitation, non-disclosure and assignment of intellectual property provisions in favour of the Company. If the Company terminates Mr. Rosconi's employment without just and sufficient cause, he will receive an

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR PAGE 19 THERATECHNOLOGIES INC. amount equal to twelve (12) months of compensation (including bonus — based on the last granted — and the value of the Company's benefits to which he was then entitled). The payment of this amount will be the sole monetary obligation of the Company. Furthermore, in the event of a "Change of Control" (as defined below), his employment agreement provides for an indemnity equal to twenty-four (24) months of compensation (including bonus — based on the last granted — and the value of the Company's benefits to which he was then entitled) if Mr. Rosconi's employment is terminated by the Company, and twelve (12) months if Mr. Rosconi resigns on his own free will. In Mr. Rosconi's agreement, a "Change of Control" is defined as a successful take-over bid, as such term is defined in the *Securities Act* (Québec).

Events	Severance (\$)	Value of Stock Options(1) (\$)
Retirement (2)		364,002
Termination of Employment without Just Cause (2)	678,535 <sub>(4)</sub>	364,002
Termination of Employment in the event of a Change of Control <sup>(3)</sup>	1,357,070 <sub>(4)</sub>	401,252
Voluntary Resignation in the event of a Change of Control (3)	678,535 <sub>(4)</sub>	401,252
Voluntary Resignation (2)	—	364,002

- (1) The value assumes that upon the occurrence of an event, all vested options would be exercised. The value is the difference between the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) and the respective exercise price of each vested option as at November 30, 2009.
- (2) Under the Share Option plan, the termination of a person's employment with the Company entitles him to exercise his vested options over a six-month period after the termination date.
- (3) Given the different definitions of "Change of Control" used in the employment agreements of the Named Executive Officers, in computing the value of the stock options in the event of a Change of Control, the Company assumed that all unvested options would vest as per the terms of Section 5.5 of its Share Option Plan and that all vested options having an exercise price lower than the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) would be exercised.
- (4) As at November 30, 2009, the last bonus paid to Mr. Rosconi was the bonus he received for the financial year 2008 which amounted to \$230,000.

### Luc Tanguay

#### Senior Executive Vice President and Chief Financial Officer

The Company entered into an employment agreement for an indeterminate term with Mr. Luc Tanguay on October 30, 2001. His agreement was subsequently amended on May 9, 2002, June 7, 2004 and February 8, 2006. In addition to his base salary, Mr. Tanguay is entitled to the Company's benefits program and is eligible to receive an annual bonus based on the attainment of annual objectives. Mr. Tanguay was also entitled to stock options, which have all been granted. Under the terms of the agreement, Mr. Tanguay agreed to non-competition, non-solicitation, non-disclosure and assignment of intellectual property provisions in favour of the Company. If the Company terminates the employment of Mr. Tanguay without just and sufficient cause, he will receive an amount equal to twenty-four (24) months of compensation (including bonus — based on the last granted — and the value of the Company's benefits to which he was then entitled). The payment of this amount will be the sole monetary obligation of the Company. In addition, in the event the employment of Mr. Tanguay is terminated for any reason, including death, he will be entitled to exercise his stock options over a 24-month period, subject to the prior expiry of his stock

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR PAGE 20 THERATECHNOLOGIES INC. options in accordance with their terms. Furthermore, in the event of a "Change of Control" (as defined below), his employment agreement provides for an indemnity equal to twenty-four (24) months of compensation (including bonus — based on the last granted — and the value of the Company's benefits to which he was then entitled) if Mr. Tanguay's employment is terminated by the Company, and twelve (12) months if Mr. Tanguay resigns on his own free will. In Mr. Tanguay's agreement, a "Change of Control" is defined as a successful take-over bid, as such term is defined in the *Securities Act* (Québec).

Events Retirement (2)	Severance (\$)	Value of Stock Options(1) (\$) 168,750
Remement (2)	—	100,750
Termination of Employment without Just Cause (2)	1,140,508(4)	168,750
Termination of Employment in the event of a Change of Control (3)	1,140,508(4)	198,550
	(-)	,
Voluntary Resignation in the event of a Change of Control (3)	570,254 <sub>(4)</sub>	198,550
Voluntary Resignation (2)		168,750
·		

- (1) The value assumes that upon the occurrence of an event, all vested options would be exercised. The value is the difference between the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) and the respective exercise price of each vested option as at November 30, 2009.
- (2) Under the Share Option plan, the termination of a person's employment with the Company entitles him to exercise his vested options over a six-month period after the termination date.
- (3) Given the different definitions of "Change of Control" used in the employment agreements of the Named Executive Officers, in computing the value of the stock options in the event of a Change of Control, the Company assumed that all unvested options would vest as per the terms of Section 5.5 of its Share Option Plan and that all vested options having an exercise price lower than the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) would be exercised.
- (4) As at November 30, 2009, the last bonus paid to Mr. Tanguay was the bonus he received for the financial year 2008 which amounted to \$195,000.

## Christian Marsolais

## Vice President, Clinical Research and Medical Affairs

The Company entered into an employment agreement for an indeterminate term with Mr. Christian Marsolais on April 13, 2007. In addition to his base salary, Mr. Marsolais is entitled to the Company's benefits program and is eligible to receive an annual bonus based on attainment of objectives set annually by the President and Chief Executive Officer. Mr. Marsolais was also entitled to stock options, which have all been granted. These stock options vest over a three-year period from the date of grant. Under the terms of the agreement, Mr. Marsolais agreed to non-competition, non-solicitation, non-disclosure and assignment of intellectual property provisions in favour of the Company. If the Company terminates Mr. Marsolais' employment without just and sufficient cause, he will receive an amount equal to nine (9) months of his annual base salary. The payment of this amount will be the sole monetary obligation of the Company.

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Events Retirement (2)	Severance (\$)	Value of Stock Options(1) (\$)
Termination of Employment without Just Cause (2)	165,634	_
Termination of Employment in the event of a Change of Control (3)	165,634	96,850
Voluntary Resignation in the event of a Change of Control (3)	_	96,850
Voluntary Resignation (2)	—	—

<sup>(1)</sup> The value assumes that upon the occurrence of an event, all vested options would be exercised. The value is the difference between the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) and the respective exercise price of each vested option as at November 30, 2009.

## Martine Ortega

#### Vice President, Compliance and Regulatory Affairs

The Company entered into an employment agreement for an indeterminate term with Ms. Martine Ortega on May 11, 2006. In addition to her base salary, Ms. Ortega is entitled to the Company's benefits program and is eligible to receive an annual bonus based on attainment of objectives set annually by the President and Chief Executive Officer. Ms. Ortega was also entitled to stock options, which have all been granted. These stock options vest over a three-year period from the date of grant. Under the terms of the agreement, Ms. Ortega agreed to non-solicitation, non-disclosure and assignment of intellectual property provisions in favour of the Company. If the Company terminates Ms. Ortega's employment without just and sufficient cause, she will receive an amount equal to nine (9) months of her annual base salary, if her termination occurs: (i) in the context of an internal reorganization of the Company or (ii) within two (2) years from the date there occurs a "Change of Control" (as defined below) of the Company. The payment of this amount will be the sole monetary obligation of the Company. In Ms. Ortega's agreement, a "Change of Control" is defined as a transaction resulting in the liquidation or winding-up of the Company, delisting of the Company's Common Shares on a stock exchange, the acquisition by a third party of the control of the Company, the sale of all or substantially all of the assets of the Company or the privatization or a merger of the Company.

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<sup>(2)</sup> Under the Share Option plan, the termination of a person's employment with the Company entitles him to exercise his vested options over a six-month period after the termination date.

<sup>(3)</sup> Given the different definitions of "Change of Control" used in the employment agreements of the Named Executive Officers, in computing the value of the stock options in the event of a Change of Control, the Company assumed that all unvested options would vest as per the terms of Section 5.5 of its Share Option Plan and that all vested options having an exercise price lower than the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) would be exercised.

Events Retirement (2)	Severance (\$)	Value of Stock Options(1) (\$) 46,750
Termination of Employment without Just Cause (2)	161,870	46,750
Termination of Employment in the event of a Change of Control (3)	161,870	106,350
Voluntary Resignation in the event of a Change of Control <sup>(3)</sup>	_	106,350
Voluntary Resignation (2)	—	46,750

<sup>(1)</sup> The value assumes that upon the occurrence of an event, all vested options would be exercised. The value is the difference between the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) and the respective exercise price of each vested option as at November 30, 2009.

#### Jocelyn Lafond

### Vice President, Legal Affairs, and Corporate Secretary

The Company entered into an employment agreement for an indeterminate term with Mr. Jocelyn Lafond on March 27, 2007. In addition to his base salary, Mr. Lafond is entitled to the Company's benefits program and is eligible to receive an annual bonus based on attainment of objectives set annually by the Senior Executive Vice President and Chief Financial Officer. Mr. Lafond was also entitled to stock options, which have all been granted. These stock options vest over a three-year period from the date of grant. Under the terms of the agreement, Mr. Lafond agreed to non-disclosure and assignment of intellectual property provisions in favour of the Company. If the Company terminates Mr. Lafond's employment without just and sufficient cause, he will receive an amount equal to 12 months of his annual base salary. The payment of this amount will be the sole monetary obligation of the Company. Furthermore, in the event of a "Change of Control", his employment agreement provides for an indemnity equal to 12 months of his annual base salary if his employment is terminated or if he resigns of his own free will within 24 months from such "Change of Control". In Mr. Lafond's agreement, a "Change of Control" is defined as a take-over bid, as such term is defined in the *Securities Act* (Québec), and as any transaction pursuant to which a person acquires the control of the Company.

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<sup>(2)</sup> Under the Share Option plan, the termination of a person's employment with the Company entitles him to exercise his vested options over a six-month period after the termination date.

<sup>(3)</sup> Given the different definitions of "Change of Control" used in the employment agreements of the Named Executive Officers, in computing the value of the stock options in the event of a Change of Control, the Company assumed that all unvested options would vest as per the terms of Section 5.5 of its Share Option Plan and that all vested options having an exercise price lower than the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) would be exercised.

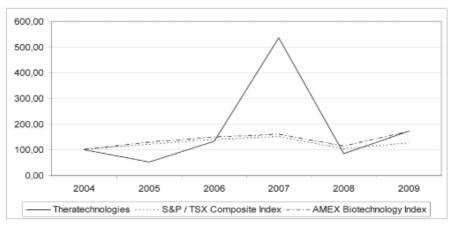
Events Retirement (2)	Severance (\$)	Value of Stock Options(1) (\$) ——————————————————————————————————
Termination of Employment without Just Cause <sup>(2)</sup>	200,769	_
Termination of Employment in the event of a Change of Control (3)	200,769	96,850
Voluntary Resignation in the event of a Change of Control (3)	200,769	96,850
Voluntary Resignation (2)	—	_

<sup>(1)</sup> The value assumes that upon the occurrence of an event, all vested options would be exercised. The value is the difference between the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) and the respective exercise price of each vested option as at November 30, 2009.

- (2) Under the Share Option plan, the termination of a person's employment with the Company entitles him to exercise his vested options over a six-month period after the termination date.
- (3) Given the different definitions of "Change of Control" used in the employment agreements of the Named Executive Officers, in computing the value of the stock options in the event of a Change of Control, the Company assumed that all unvested options would vest as per the terms of Section 5.5 of its Share Option Plan and that all vested options having an exercise price lower than the closing price of the Common Shares on November 30, 2009 on the TSX (\$3.29) would be exercised.

#### E. Performance Graph

The following graph compares a cumulative annual total shareholder return on a \$100 investment in the Common Shares of the Company ("**TH**") with a cumulative total shareholder return on the composite index S&P/TSX (previously known as the Toronto Stock Exchange 300 (TSE 300 Index)) assuming that all dividends are reinvested ("**S&P**") and the AMEX biotech index ("**AMEX Biotech**").



## Return on a \$100 Investment from November 30, 2004 to November 30, 2009

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR PAGE 24 THERATECHNOLOGIES INC.

	2004	2005	2006	2007	2008	2009
Theratechnologies	100,00	53,44	133,33	537,04	85,19	174,07
S&P / TSX Composite Index	100,00	119,87	141,22	151,60	102,66	126,77
AMEX Biotechnology Index	100,00	129,84	148,42	159,78	114,91	171,25

The trend shown in the above performance graph indicates that, as at November 30 of each of the 2005, 2006, 2007, 2008 and 2009 year, the annual total shareholder return on a \$100 investment in the Common Shares of the Company was above the S&P and approximately the same as the AMEX Biotech. The base salaries of the Named Executives Officers were not linked to the trend regarding the annual total shareholder return over the last five years. For the same period, shareholder return was one of the parameters taken into consideration in establishing the value of the short-term performance reward for the Named Executive Officers.

## F. Other Information

#### Description of the Share Purchase Plan

On February 16, 1999, the Board of Directors adopted a common share purchase plan (the "**Share Purchase Plan**"). The Share Purchase Plan was thereafter amended from time to time and, more recently, by the Board of Directors on February 24, 2009. The last amendments to the Share Purchase Plan were approved by the shareholders on March 26, 2009 at the Company's last annual and special meeting of shareholders.

The Share Purchase Plan entitles full-time and part-time employees of the Company who, on a Participation Date (as defined below), are residents of Canada, are not under a probationary period and do not hold, directly or indirectly, five percent (5%) or more of the Company's outstanding Common Shares, to directly subscribe for Common Shares of the Company. The Share Purchase Plan provides that a maximum of 550,000 Common Shares (0.91% of the issued and outstanding Common Shares as at January 31, 2010) may be offered to employees. During the fiscal year ended November 30, 2009, the Company issued 34,466 Common Shares under the Share Purchase Plan (0.06% of the issued and outstanding Common Shares as at January 31, 2010). As at the date of the Circular, 210,186 Common Shares remain available for issuance.

On May 1<sup>st</sup> and November 1<sup>st</sup> of each year (the "**Participation Dates**"), an employee may subscribe for a number of Common Shares under the Share Purchase Plan for an amount that does not exceed during such year 10% of his annual gross salary during said year. Under the Share Purchase Plan, the Board of Directors has the authority to suspend, differ or determine that no subscription of Common Shares will be allowed on a Participation Date if it is in the best interest of the Company.

The Share Purchase Plan provides that the number of Common Shares that may be issued to insiders, at any time, under all security based compensation arrangements of the Company, cannot exceed 10% of the outstanding Common Shares, and the number of Common Shares issued to insiders, within any one-year period, under all security based compensation arrangements, cannot exceed 10% of the outstanding Common Shares.

The subscription price for each new Common Share subscribed pursuant to the Share Purchase Plan is equal to the weighted average closing price of the Common Shares on the Toronto Stock Exchange during a period of five (5) days prior to a Participation Date. Employees cannot assign or otherwise alienate their rights in the Share Purchase Plan.

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR Page 25 Theratechnologies Inc. At the election of an employee, the subscription price for Common Shares may be paid in cash or through an interest-free loan provided by the Company. The loans provided by the Company under the Share Purchase Plan may be repayable by equal withholdings from a participant's salary for a period not exceeding two (2) years. All loans may be prepaid at all times. The loans granted to any employee at any time must not exceed 10% of his current annual gross salary. All Common Shares subscribed for through an interest-free loan are hypothecated to secure the full and final repayment of the loan and are held by the trustee, Computershare, until such full repayment. Loans are immediately due and repayable upon the occurrence of one of the following events: (i) the termination of the employment of an employee; (ii) the sale or seizure of the Common Shares being subject to a hypothec; (iii) the bankruptcy or insolvency of an employee; or (iv) the suspension of the payment of an employee's salary or the revocation of his right to salary withholdings.

Shareholder approval is not required for all amendments to the Share Purchase Plan. For example, the Board of Directors may, without shareholder approval, make certain amendments of the following nature to the Share Purchase Plan such as: (i) formal minor or technical amendments to any provision of the Share Purchase Plan; (ii) corrections to any provision of the Share Purchase Plan containing an ambiguity, defect, error or omission; or (iii) changes that do not require shareholder approval as hereafter described. However, the following amendments require the approval by a majority of the shareholders present at a duly called shareholders' meeting:

- (a) any extension of the term of the Share Purchase Plan;
- (b) any increase in the number of Common Shares reserved for issuance under the Share Purchase Plan;
- (c) any increase in the number of Common Shares that may be purchased annually by an employee;
- (d) any change in the formula to determine the subscription price of Common Shares; and
- (e) any increase in the amount an employee is authorized to borrow from the Company to purchase Common Shares under the Share Purchase Plan.

#### Indebtedness of Executive Officers

As at the date of the Circular, none of the executive officers was indebted to the Company, other than for "Routine Indebtedness" (as defined in *Regulation 51-102 respecting Continuous Disclosure Obligations* (Québec)). During the financial year ended on November 30, 2009, none of the executive officers of the Company was indebted to the Company, other than for "Routine Indebtedness".

#### 2. Director Compensation

### A. Determination of Director Compensation

The Company has adopted a compensation policy for its directors who are not employed on a full-time basis by the Company under which they are paid an annual retainer fee as well as attendance fees. In addition, the Company reimburses the reasonable expenses incurred by each director to attend meetings of the board or meetings of committees. In January 2008, the Compensation Committee met and reassessed the compensation paid to all board members, committee members and to the chairs of each committee. The last assessment of the compensation paid to individuals acting as board members, committee members and chairs of such committees had occurred in 2004. The assessment was based on a review of public documents filed by Canadian companies listed on the TSX or NASDAQ market. Criteriae such as fields of operation, market

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR PAGE 26 THERATECHNOLOGIES INC. capitalization, number of employees, stage of development, where applicable, and level of revenue were taken into consideration by the Compensation Committee in reviewing in 2008 the compensation paid to board members, committee members and to chairs of each committee. Based on the recommendation of the Compensation Committee, effective January 1, 2008, the Board of Directors approved the compensation described in the table below for individuals who are not employees of the Company who act as board members, committee members and chairs of those committees.

Position at Board Level or		
Committee Level	Co	mpensation
Annual Retainer to Chair of the Board	\$	100,000
Annual Retainer to Board Members	\$	20,000
Annual Grant of Options (1)		$10,000_{(2)}$
Attendance Fees Paid for Each Meeting of the Board of Directors		
in person	\$	2,000
- by conference call	\$	1,200
Annual Retainer to Chair of the Audit Committee	\$	10,000
Annual Retainer to Chair of each Committee (other than the Audit Committee)	\$	6,000
Annual Retainer to Committee Members	\$	4,000
Attendance Fees Paid for Each Meeting of a Committee <sup>(3)</sup>		
in person	\$	1,500
- by conference call	\$	1,200

(1) Options are usually granted at the board meeting following the annual meeting of shareholders.

(2) At the time of the 2008 review, the Compensation Committee had set the annual grant of options to each director at 10,000. However, as a result of the strategic review process that was ongoing, the Board of Directors decided that the number of options that each director was entitled to receive annually was to remain at 5,000. Further to the completion of the strategic review process, during the last financial year, the Board of Directors passed a resolution in order to change that number from 5,000 to 10,000.

(3) No attendance fee is paid for meetings of the Finance Committee.

## **B. Director Compensation Table**

The following table details all components of the compensation provided to the directors of the Company in the last financial year and the value thereof.

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR PAGE 27 THERATECHNOLOGIES INC.

Fees earned (\$)	Share-based awards (\$)	Option-based awards(2) (\$)	Non-equity incentive plan compensation (\$)	Pension value (\$)	All other compensation (\$)	Total (\$)
46,767	—	12,740	—		1,500 <sub>(3)</sub>	61,007
62,300	_	12,740	_	_	_	75,040
38,267	—	12,740	—		1,500 <sub>(3)</sub>	52,507
58,200	_	12,740	_	_	_	70,940
179,200	—	12,740	—		—	191,940
39,400	_	12,740	—		—	52,140
50,300	_	12,740	—			63,040
	(\$) 46,767 62,300 38,267 58,200 179,200 39,400	(\$)         (\$)           46,767         —           62,300         —           38,267         —           58,200         —           179,200         —           39,400         —	(s)         (s)         (s)           46,767         —         12,740           62,300         —         12,740           38,267         —         12,740           58,200         —         12,740           179,200         —         12,740           39,400         —         12,740	Fees earned (\$)         Share-based awards (\$)         Option-based awards(2) (\$)         plan compensation (\$)           46,767         —         12,740         —           62,300         —         12,740         —           38,267         —         12,740         —           58,200         —         12,740         —           179,200         —         12,740         —           39,400         —         12,740         —	Fees earned (\$)         Share-based awards (\$)         Option-based awards(2) (\$)         plan compensation (\$)         Pension value (\$)           46,767         —         12,740         —         —           62,300         —         12,740         —         —           38,267         —         12,740         —         —           58,200         —         12,740         —         —           179,200         —         12,740         —         —           39,400         —         12,740         —         —	Fees earned (s)         Share-based awards (s)         Option-based awards(2) (s)         plan compensation (s)         Pension value (s)         All other compensation (s)           46,767         —         12,740         —         —         1,500(3)           62,300         —         12,740         —         —         —           38,267         —         12,740         —         —         1,500(3)           58,200         —         12,740         —         —         —           179,200         —         12,740         —         —         —           39,400         —         12,740         —         —         —

(1) The services of Mr. Goyer are provided to the Company by Clinipharm (1987) Inc. ("Clinipharm"), a company controlled by Mr. Goyer, and all cash compensation for the services of Mr. Goyer is paid to this entity. Based on information received from Clinipharm, Mr. Goyer received from Clinipharm the amount of \$10,000 from December 1, 2008 to June 30, 2009. The fiscal year-end of Clinipharm is different from that of the Company and the amount to be received, if any, by Mr. Goyer for the period running from July 1, 2009 to November 30, 2009 is unknown. All options are granted to Mr. Goyer, personally.

(2) The value of the awards is comprised of one grant that occurred on March 28, 2009 (the "**March 2009 Grant**"). As part of the March 2009 Grant, each director was granted 10,000 options at an exercise price of \$1.84. Each option has a ten-year term and vests on the date of grant. The terms and conditions of those options are governed by the Share Option Plan.

The value of the option-based awards was calculated using the Black-Scholes-Merton model using the following assumptions:

- (i) Risk-free interest rate: 1.9%;
- (ii) Expected volatility in the market price of the Common Shares: 80.27%;
- (iii) Expected dividend yield: 0%; and
- (iv) Expected life: 6 years.
- Fair value per option: \$1.274

The value of the awards does not include the 5,000 options that were granted as part of the December 2008 Grant since these options were granted as compensation for the financial year 2008. These 5,000 options were not granted in the financial year 2008 as a result of the strategic review process that was ongoing during that financial year. These 5,000 options were granted at an exercise price of \$1.80, vested on the date of grant and have a ten-year term. The terms and conditions of those options are governed by the Share Option Plan.

(3) This amount was paid to each of Mr. Cloutier and Mr. Goyer, through Clinipharm in the latter case, for their *ad hoc* advice on certain clinical matters. Both Mr. Cloutier and Mr. Goyer were formerly on the scientific committee and used to receive an annual compensation of \$2,000 each to act as such. However, for the financial year ended on November 30, 2009, the Board of Directors determined that it was in the best interests of the Company to abandon this committee and to compensate Mr. Cloutier and Mr. Goyer if, and when, their services are required with attendance fees similar to those paid to members of committees.

#### **C. Incentive Plan Awards**

Outstanding Option-Based Awards and Share-Based Awards

The table below details the outstanding option-based awards and the share-based awards as at November 30, 2009 for each of the directors.

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		Option-Based Awards		Share-Based Awards		
Name	Number of securities underlying unexercised options (#)	Option exercice price (\$)	Option expiration date	Value of unexercised in-the-money options(1) (\$)	Number of shares or units of shares that have not vested (#)	Market or payout value of share- based awards that have not vested (\$)
Gilles Cloutier	5,000	5.40	2013.05.07			
	5,000	3.68	2014.05.03	_		
	5,000	1.75	2015.05.06	7,700		
	5,000	1.86	2016.03.30	7,150		
	5,000	8.29	2017.03.29			
	5,000	1.80	2018.12.18	7,450		
	10,000	1.84	2019.03.28	14,500		
A. Jean de Grandpré	5,000	8.65	2010.05.04		_	
rit beam de Grandpre	5,000	11.80	2011.05.10			
	5,000	10.55	2012.05.09	_		
	5,000	5.40	2012.05.05			
	5,000	3.68	2013.05.03			
	5,000	1.75	2015.05.06	7,700		
	5,000	1.86	2016.03.30	7,150		
	5,000	8.29	2017.03.29			
	5,000	1.80	2017.03.25	7,450		
	10,000	1.84	2019.03.28	14,500		
	F 000	1 75		7 700		
Robert Goyer	5,000	1.75	2015.05.06	7,700	—	
	5,000	1.86	2016.03.30	7,150		
	5,000	8.29	2017.03.29			
	5,000	1.80	2018.12.18	7,450		
	10,000	1.84	2019.03.28	14,500		
Gérald A. Lacoste	5,000	1.86	2016.03.30	7,150	_	_
	5,000	8.29	2017.03.29	—		
	5,000	1.80	2018.12.18	7,450		
	10,000	1.84	2019.03.28	14,500		
Paul Pommier	5,000	8.65	2010.05.04		_	
	5,000	11.80	2011.05.10	_		
	5,000	10.55	2012.05.09	_		
	5,000	5.40	2013.05.07	_		
	5,000	3.68	2014.05.03	_		
	5,000	1.75	2015.05.06	7,700		
	5,000	1.86	2016.03.30	7,150		
	5,000	8.29	2017.03.29	—		
	5,000	1.80	2018.12.18	7,450		
	10,000	1.84	2019.03.28	14,500		
Bernard Reculeau	5,000	1.86	2016.03.30	7,150		_
	5,000	8.29	2017.03.29	,		

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		Option-Based Awards		Share-Based Awards		
Name	Number of securities underlying unexercised options (#)	Option exercice price (\$)	Option expiration date	Value of unexercised in-the-money options(1) (\$)	Number of shares or units of shares that have not vested (#)	Market or payout value of share- based awards that have not vested (\$)
	5,000	1.80	2018.12.18	7,450		
	10,000	1.84	2019.03.28	14,500		
Jean-Denis Talon	5,000	11.80	2011.05.10	_	_	
	5,000	10.55	2012.05.09	_		
	5,000	5.40	2013.05.07	—		
	5,000	3.68	2014.05.03	_		
	5,000	1.75	2015.05.06	7,700		
	5,000	1.86	2016.03.30	7,150		
	5,000	8.29	2017.03.29	—		
	5,000	1.80	2018.12.18	7,450		
	10,000	1.84	2019.03.28	14,500		

(1) The value of unexercised in-the-money options at financial year end is the difference between the closing price of the Common Shares on November 30, 2009 (\$3.29) on the TSX and the respective exercise prices of the options.

## Incentive Plan Awards — Value vested or earned during the year

The table below shows the value vested or earned during the year under each incentive plan as at November 30, 2009 for each of the directors.

Name	Option-based awards Value vested during the year(1) (\$)	Share-based awards Value vested during the year (\$)	Non-equity incentive plan compensation Value earned during the year (\$)
Gilles Cloutier	—	—	—
A. Jean de Grandpré	_	_	_
Robert Goyer	—	—	—
Gérald A. Lacoste	_	_	_
Paul Pommier		—	—
Bernard Reculeau	_	_	_
Jean-Denis Talon		—	—

(1) The value is determined by assuming that the options vested during the financial year would have been exercised on the vesting date. The value corresponds to the difference between the closing price of the Common Shares on the TSX on the vesting date and the exercise price of the options on that date. Options granted to directors as part of the March 2009 Grant vested on their date of grant which was a day where the TSX was closed for business. No value was recorded for those options since their exercise price was equal to the closing price of the Common Shares on the day preceding the date of grant of the options.

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## **D.** Other Information

#### **Indebtedness of Directors**

As at the date of the Circular, none of the directors of the Company and proposed nominee for election as a director of the Company is indebted to the Company. During the financial year ended on November 30, 2009, none of the directors of the Company was indebted to the Company.

### Liability Insurance of Directors and Officers

The Company purchases liability insurance for its directors and officers in the performance of their duties. These insurance policies also cover the directors and officers of the Company's subsidiaries. During the fiscal year ended November 30, 2009, the policies provided maximum coverage of \$20,000,000 per claim, subject to a \$200,000 deductible per occurrence. Premiums paid by the Company for the policies amounted to \$109,000. The policies and the premiums do not distinguish between the insurance for the directors' liability and officers' liability, the coverage being the same for both groups.

STATEMENT OF EXECUTIVE COMPENSATION MANAGEMENT PROXY CIRCULAR Page 31 Theratechnologies Inc.

# ITEM III. CORPORATE GOVERNANCE DISCLOSURE

The Board of Directors of the Company considers good corporate governance to be important to the effective operations of the Company and to ensure that the Company is managed so as to optimize shareholder value. The Nominating and Corporate Governance Committee is responsible for examining the Company's needs in this regard and addressing all issues that may arise from its practices. This Committee ensures that the Company's corporate governance practices comply with *Regulation 58-101 respecting Disclosure of Corporate Governance Practices* (Québec) and oversees their disclosure according to guidelines described in *Policy Statement 58-201 to Corporate Governance Guidelines* (Québec) (hereinafter collectively referred to as the "**Regulation**").

# 1. Board of Directors

## A. Independence

A majority of the Company's directors are independent. Seven of the nine Board members meet the criteria for independence defined by the Regulation, as none of them have a direct or indirect material relationship with the Company.

Name	Independence	Material Relationship
Gilles Cloutier	Yes	None
A. Jean de Grandpré	Yes	None
Robert Goyer	Yes	None
Gérald A. Lacoste	Yes	None
Paul Pommier	Yes	None
Bernard Reculeau	Yes	None
Jean-Denis Talon	Yes	None
Luc Tanguay	No	Company Management
Yves Rosconi	No	Company Management

The Chairman of the Board of the Company is Paul Pommier, an independent director within the meaning of the Regulation.

## **B.** Meetings of the Board

The table below details the directors' attendances to the Board of Directors' meetings held in the fiscal year ended on November 30, 2009.

Number of Meetings	Attendance	Absence
7	7	0
7	7	0
7	7	0
7	7	0
7	7	0
7	7	0
7	7	0
7	7	0
7	7	0
	Number of Meetings           7	Number of Meetings         Attendance           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7           7         7

Corporate Governance Disclosure Management Proxy Circular PAGE 32 THERATECHNOLOGIES INC. A meeting of independent directors, at which non-independent directors and members of management are not in attendance, is planned as the last item of each Board meeting. Accordingly, at the conclusion of each Board meeting, the Chairman determines, along with the other independent directors, the relevance of meeting without non-independent directors and members of management. During the fiscal year ended November 30, 2009, independent directors held no meeting without non-independent directors and members of management.

## C. Other Board Memberships

As detailed in the following table, only one of the Company's directors is a board member of an other reporting issuer.

Name Luc Tanguav Reporting Issuer Ambrilia Biopharma Inc.

## 2. Mandate of the Board of Directors

The Board of Directors adopted the written mandate attached hereto as Appendix C which defines its role and duties.

Consistent with its mandate of identifying key business risks facing the Company and implementing systems to manage those risks, during the last financial year, the Board of Directors undertook to review the various risks faced by the Company. To that end, the Board of Directors delegated to the Audit Committee the responsibility of supervising the management team involved in this process. The process is two-pronged: first, it consists in identifying the most important risks and, second, it consists in reviewing and testing the measures in place to manage the identified risks or, alternatively, create measures if none is in place. During the last financial year, the first part of the review process was completed and, in the current financial year, the measures in place will be tested and, if need be, improved or created.

## 3. Position Descriptions

The Board of Directors has developed written position descriptions for the Chairman of the Board and the Chairs of the Board's Committees. A position description was also developed for the President and Chief Executive Officer.

## 4. Orientation and Continuing Education

The Orientation and Continuing Education Policy for newly appointed directors is attached hereto as Appendix D.

In the last financial year, the members of the Audit Committee attended a seminar organized by the Company's auditors, KPMG LLP, on the upcoming IFRS accounting rules. In addition, throughout the last financial year, the Company provided its directors with reading material covering topics in various fields, including biotechnology, corporate governance and executive compensation.

In the current financial year, directors will be invited to attend a seminar on Bill 63, the *Business Corporations Act* (Québec), the new act intended to replace the *Companies Act* (Québec).

Corporate Governance Disclosure Management Proxy Circular Page 33 Theratechnologies Inc.

## 5. Ethical Business Conduct

The Board of Directors has not adopted a written ethical business code of conduct for the Company's directors, executive officers and employees. However, it has a series of internal policies substantially covering the same issues as those found in a business code of conduct (confidentiality, harassment and whistleblowing). In addition, it encourages and promotes ethical business conduct that upholds integrity and fault prevention.

In the event a director or an executive officer has a material interest in any transaction or agreement, the matter may initially be reviewed by the Nominating and Corporate Governance Committee to determine the scope of the interest and its impact on management's decision-making. The Committee will report its findings to the Board of Directors, which will take appropriate action to ensure independent exercise of judgement. In the event a director has a material interest in any transaction or agreement, such director must disclose, without delay, this conflict of interest and follow the rules provided by the General By-Laws of the Company.

## 6. Nomination of Directors

The Nominating and Corporate Governance Committee is responsible for proposing new candidates for Board nominations. This Committee is exclusively composed of independent directors. A copy of the Committee's Charter is attached hereto as Appendix E.

## 7. <u>Compensation</u>

## A. Independence

The Compensation Committee is responsible for examining matters relating to compensation of directors and executive officers on behalf of the Board of Directors. The Compensation Committee is comprised exclusively of independent directors. A detailed description of the procedure used by the Compensation Committee to establish compensation is provided under Item II of the Circular.

## **B.** Meetings of the Compensation Committee

The table below details members' attendance to the Compensation Committee's meetings held in the financial year ended November 30, 2009.

Name	Number of Meetings	Attendance	Absence
A. Jean de Grandpré	2	2	0
Paul Pommier	2	2	0
Bernard Reculeau	2	2	0
Jean-Denis Talon	2	2	0

At each meeting of the Compensation Committee, its members meet without members of management.

## 8. Audit Committee

#### A. Independence

The Company has an audit committee comprised of three independent directors, namely Paul Pommier, who is the Chair, Gérald A. Lacoste and Jean-Denis Talon. Reference is made to section 4.2 of the Company's annual information form dated February 23, 2010 for a description of the Audit Committee.

Corporate Governance Disclosure Management Proxy Circular PAGE 34 THERATECHNOLOGIES INC. Each member of the Audit Committee has acquired in-depth financial expertise giving each the ability to read and understand a set of financial statements which presents the breadth and level of complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised in the Company's financial statements.

## **B.** Meetings of the Audit Committee

The table below details members' attendance to the Audit Committee's meetings held in the financial year ended on November 30, 2009.

Name	Number of Meetings	Attendance	Absence
Gérald A. Lacoste	5	5	0
Paul Pommier	5	5	0
Jean-Denis Talon	5	5	0

A meeting of the members, at which members of management are not in attendance, is planned as the last item of each Audit Committee meeting when members of management are asked to attend Audit Committee meetings. Accordingly, at the conclusion of each Audit Committee meeting, the Chairman determines, along with the members, the relevance of meeting without members of management. During the last financial year ended November 30, 2009, members held one (1) meeting without members of management.

## 9. Other Committees

## A. Financing Committee

In addition to the Audit Committee, the Nominating and Corporate Governance Committee and the Compensation Committee, the Board of Directors created a Financing Committee composed of two independent directors and two directors who are executive officers of the Company. The Financing Committee's mandate is to study and analyze financing matters. No meeting of the Financing Committee was held in the financial year ended November 30, 2009.

## **B. Strategic Committee**

In August 2007, the Board of Directors created a Strategic Review Committee comprised of four (4) independent directors, namely Paul Pommier, who is the Chair, Gilles Cloutier, A. Jean de Grandpré and Gérald A. Lacoste. The mandate of the Strategic Review Committee consisted in reviewing potential strategic alternatives to enhance shareholder value such as the entering into of a co-promotion or a partnership agreement with regards to tesamorelin, the finding of a possible partner, acquiror or target business with a view to complete a merger, a sale or an acquisition. As a result of the announcement in October 2008 of the collaboration and licensing agreement entered into between the Company and EMD Serono, Inc., the mandate of the Strategic Review Committee was changed by the Board of Directors in December 2008 to assist executive officers and recommend to the Board of Directors a business strategy to further the growth of the Company.

The Strategic Review Committee currently has the following role and responsibilities:

- to evaluate and review the various business alternatives of the Company for enhancing shareholder value (the "Strategic Alternatives");
- to make recommendations to the Board of Directors with respect to the Strategic Alternatives and to undertake a process it considers appropriate in order to provide such recommendations;

Corporate Governance Disclosure Management Proxy Circular PAGE 35 THERATECHNOLOGIES INC.

- if one of the Strategic Alternatives is approved by the Board of Directors, to maintain, on behalf of the Board of Directors, a review of its implementation; and
- to perform any action deemed necessary or advisable to comply with its duties and obligations under applicable laws.

The table below details the members' attendance to the Strategic Committee's meetings held in the financial year ended on November 30, 2009.

Name	Number of Meetings	Attendance	Absence
Gilles Cloutier	5	4	1
A. Jean de Grandpré	5	5	0
Gérald A. Lacoste	5	5	0
Paul Pommier	5	5	0

A meeting of the members, at which members of management are not in attendance, is planned as the last item of each Strategic Committee meeting when members of management are asked to attend Strategic Committee meetings. Accordingly, at the conclusion of each Strategic Committee meeting, the Chairman determines, along with the members, the relevance of meeting without members of management. During the last financial year ended November 30, 2009, members held two (2) meetings without members of management.

## 10. Assessment

While there is no formal process for assessing directors on an ongoing basis, the directors are free to discuss specific situations from time to time amongst themselves and/or with the Chairman of the Board and, if deemed necessary, steps are taken to remedy a situation.

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# ITEM IV. OTHER INFORMATION

## 1. Additional Documentation

The Company is a reporting issuer in all Canadian provinces and is required to file its financial statements and Circular with each Canadian Securities Commission. Each year, the Company also files an Annual Information Form with such commissions. The financial information of the Company is provided in the Company's comparative financial statements and Management's Discussion & Analysis for its fiscal year ended November 30, 2009. Copies of the Company's financial statements, management proxy circular and Annual Information Form may be obtained on request to the Secretary of the Company at the following address: 2310 Alfred-Nobel Blvd, Montreal, Québec, H4S 2B4 or by consulting the SEDAR Website at www.sedar.com. The Company may require the payment of a reasonable fee if the request is made by someone other than a security holder of the Company, unless the Company is in the course of a distribution of its securities pursuant to a short-form prospectus, in which case these documents will be provided free of charge.

## 2. Approval by the Board Of Directors

The content and the sending of this Circular have been approved by the Board of Directors of the Company on February 22, 2010.

Montreal, Québec, February 23, 2010.

Jocelyn Lafond Corporate Secretary

Corporate Governance Disclosure Management Proxy Circular PAGE 37 THERATECHNOLOGIES INC.

### APPENDIX A

## **RESOLUTION OF THE SHAREHOLDERS OF THERATECHNOLOGIES INC. (THE "COMPANY")**

## RESOLUTION 2010-1 SHAREHOLDER RIGHTS PLAN

# **BE IT RESOLVED:**

- 1. That the shareholder rights plan adopted by the Board of Directors of the Company on February 10, 2010 be and is hereby approved;
- 2. That any director or officer of the Company be and is hereby authorized to execute and deliver such documents and instruments and to take such other actions as such director or officer may deem necessary or advisable to give effect to this resolution in his entire discretion, his determination being conclusively evidenced by the execution and delivery of such documents or instruments and the taking of such actions.

Appendix A — Resolution 2010-1 Management Proxy Circular

#### APPENDIX B

## **COMPENSATION COMMITTEE CHARTER**

## I. <u>Mandate</u>

The Compensation Committee (the "Committee") is responsible for assisting the Company's Board of Directors (the "Board") in overseeing the following:

- A. compensation of Senior Management;
- B. assessment of Senior Management;
- C. compensation of Directors;
- D. stock option grants;
- E. overall increase in total compensation.

# II. Obligations and Duties

The Committee carries out the duties usually entrusted to a compensation committee and any other duty assigned from time to time by the Board. Specifically, the Committee is charged with the following obligations and duties:

- A. Compensation of Senior Management
  - 1. Develop a compensation policy for the Company's Senior Management, notably the Senior Management compensation structure, annual salary adjustments as well as the creation and administration of short and long term incentive plans, stock options, indirect advantages and benefits proposed by the President and Chief Executive Officer.
  - 2. Review and establish all forms of compensation to Senior Management.
  - 3. Oversee, as required, employment contracts and terminations of Senior Management, notably severance pay.
  - 4. Oversee the Company's annual report on Senior Management compensation part of the Company's continuous disclosure requirements under applicable laws and regulations.
- B. Assessment of Senior Management
  - 1. Develop a written position description for the President and Chief Executive Officer.
  - 2. Establish general objectives annually for the President and Chief Executive Officer of the Company and for other members of senior management.

Appendix B — Compensation Committee Charter Management Proxy Circular

- 3. Examine and review annually the President and Chief Executive Officer's performance against specific performance criteria pre-established by the Committee.
- 4. Examine, in collaboration with the President and Chief Executive Officer, the annual performance assessment of other senior managers.
- C. Compensation of Directors
  - 1. Recommend to the Board approval of the Director's Compensation Policy.
  - 2. Examine the compensation of Directors in relation to the risks and duties of their position.
- D. Stock Option Grants
  - 1. Oversee, review as needed and recommend Board approval of the Company Share Option Plan.
  - 2. The Committee may delegate, at its discretion, the plan's administration to members of the Company's Management and employees.
  - 3. Examine, oversee and recommend Board approval of stock option grants, specifically:
    - a. the people to whom options are granted;
    - b. the number of options granted;
    - c. the exercise price of the options;
    - d. the exercise period of the options; and
    - e. all other conditions relating to options granted.
  - 4. Overall Increase in Total Compensation

Approve annually the Company's increase in overall compensation.

#### III. External Advisors

In discharging its duties and responsibilities, the Committee is empowered to retain external legal counsel or other external advisors, as appropriate. The Company shall provide the necessary funds to secure the services of such advisors.

## IV. Composition of the Committee

The Committee is composed of any number of Directors, but no less than three, as may be determined by the Board from time to time by resolution. Each member of the Committee shall be independent from the Company, as determined by the Board, in accordance with applicable laws, rules and regulations.

Appendix B — Compensation Committee Charter Management Proxy Circular

## V. Term of the Mandate

Committee members are appointed by Board resolution to carry out their mandate extending from the date of the appointment to the next annual general meeting of shareholders, or until successors are so appointed.

## VI. Vacancy

The Board may fill vacancies at any time by resolution. Subject to the constitution of the quorum, the Committee's members can continue to act even if there is one or many vacancies on the Committee.

## VII. <u>Chairman</u>

The Board appoints the Committee Chairman who will call and chair the meetings.

## VIII. Secretary

Unless decided otherwise by resolution of the Board, the Secretary of the Company shall act as Committee Secretary. The Secretary must attend Committee meetings and prepare the minutes. He/she must provide notification of meetings as directed by the Committee Chairman. The Secretary is the guardian of the Committee's records, books and archives.

## IX. Meeting Proceedings

The Committee establishes its own procedures as to how meetings are called and conducted. Unless it is otherwise decided, the Committee shall meet privately and independently from Management at each regularly scheduled meeting. In the absence of the regularly appointed Chairman, the meeting shall be chaired by another Committee member selected among attending participants and appointed accordingly. In the absence of the regularly appointed Secretary, Committee members shall designate someone to carry out this duty.

## X. Quorum and Vote

Unless the Board otherwise specifies by resolution, two Committee members shall constitute an appropriate quorum for deliberation of items on the agenda. During meetings, decisions are reached by a majority of votes from Committee members, unless the quorum is of two members, in which case decisions are made by consensus of opinion.

## XI. <u>Records</u>

The Committee keeps records that are deemed necessary for its deliberations and reports to the Board on its activities and recommendations on a regular basis.

## XII. Effective Date

This charter was adopted by the Directors at its May 3, 2004 Board meeting. It was amended by the Directors during the February 8, 2006 Board meeting.

#### APPENDIX C

### MANDATE OF THE BOARD OF DIRECTORS

# I. <u>Role</u>

The Company's Board of Directors (the "**Board**") is ultimately responsible for the stewardship of the Company and executes its mandate directly or after considering recommendations from its related committees and Management.

Management is responsible for the Company's day-to-day activities and is charged with realizing strategic activities approved by the Board within the scope of its authorized business activities, capitalization plan and company directives. Management must report regularly to the Board on matters relating to short-term results and long-term development activities.

## II. Obligations and Responsibilities

The Board carries out the functions, performs duties and assumes the responsibilities entrusted by the laws and regulations. The Board may delegate some of its responsibilities to Board committees and Management within the scope of the Company's General By-laws, the laws and the regulations. Therefore, day-to-day management of the Company's activities is entrusted to Senior Management, which reports directly to the Board. One of the key functions of the Board is to appoint the senior management team.

The functions and duties of Board members include, without limitation, the following functions and duties:

- A. Appointment, assessment, succession planning of Senior Management
  - 1. Select and appoint the President and Chief Executive Officer of the Company.
  - 2. Oversee the appointment of other members of Senior Management.
  - 3. Ensure that the Company has a succession plan for the President and Chief Executive Officer.
  - 4. Monitor the performance of the President and Chief Executive Officer and others Executive Officers, with respect to pre-established objectives.
- B. Compensation of Directors
  - 1. Establish the compensation of Directors.
- C. Strategic Direction and Planning
  - 1. Adopt the Company's strategic planning process.
  - 2. Approve the Company's strategic plan and review Senior Management's performance in implementing the plan.

Appendix C — Mandate of the Board of Directors Management Proxy Circular

- 3. Review the strategic plan annually, taking into account opportunities and risks, and monitoring the Company's performance against the plan.
- 4. Review and approve the Company's annual plans towards financing the strategic plan.
- 5. Review and approve the Company's annual operating budget.
- 6. Identify key business risks facing the Company and the implementation of appropriate systems to manage these risks.
- 7. Discuss with Management how the strategic environment is changing and the key strategic issues.

### D. Corporate Behaviour and Governance

- 1. Develop an approach to corporate governance, including the determination of principles and guidelines for the Company.
- 2. Obtain reasonable assurance of the integrity of the President and Chief Executive Officer and other senior members of Management, and that they uphold principles of integrity within the ranks of the Company.
- 3. Oversee the implementation of a Company disclosure policies and procedures.
- 4. Monitor the integrity of the Company's internal controls and disclosure systems.
- 5. Be available to receive feedback from stakeholders, which must be provided in writing, at the Company's head office, bearing the mention "Confidendial".
- E. Personal Behaviours
  - 1. Keep up-to-date with the regular programs and employees of the Company.
  - 2. Upon request, join a committee and actively participate at its meetings.
  - 3. Be accessible, at least by telephone, to personnel and other Company Directors, as required.
  - 4. Keep confidential information discussed during meetings.
  - 5. Attend regular and special Board meetings.
  - 6. Get to know other members of the Board and promote collegial decision-making.

## III. External Advisors

In discharging its duties and responsibilities, the Board is empowered to retain external legal counsel or other external advisors, as appropriate. The Company shall provide the necessary funds to secure the services of such advisors.

 $\begin{array}{l} \mbox{Appendix } C \longrightarrow \mbox{Mandate of the Board of Directors} \\ \mbox{Management } Proxy \ \mbox{Circular} \end{array}$ 

# IV. Composition of the Board

The Board consists of such number of Directors as the Board may determine from time to time by resolution. The Board must assure itself that it is composed of Directors that are sufficiently familiar with the business of the Company, and the risks it faces, to ensure active and effective participation in the deliberations of the Board. Directors should have diverse backgrounds and personal characteristics and traits as well as competencies and expertise that add value to the Company. Finally, a majority of the Directors must be independent for the purposes of National Policy 58-201 Corporate Governance Guidelines.

## V. Board Meeting Procedures

The Board follows the procedure established in the Company's General By-Laws.

## VI. <u>Records</u>

The Company's Secretary keeps the records required by law and any other relevant document.

## VII. Effective Date

This written mandate was adopted by the Directors at its February 8, 2006 Board meeting.

Appendix C — Mandate of the Board of Directors Management Proxy Circular

#### APPENDIX D

### DIRECTOR ORIENTATION AND CONTINUING EDUCATION POLICY

The Board must first ensure that every new nominee as Director possesses the necessary skill, expertise, availability and knowledge to properly fulfil its mandate. Once a Director is effectively elected, the Chairman of the Board, the President and Chief Executive Officer and Secretary provide him with the specific information required for a well-informed contribution.

#### I. <u>Purpose</u>

The purpose of this Director Orientation and Continuing Education Policy (the "**Policy**") is to set forth the Company's process of orientation for newly appointed Company Directors to familiarize them with the role of the Company's Board of Directors, its committees, its directors, and the nature and operation of the Company's business activities. The Policy also indicates the elements of continuing education of the Board of Directors to ensure the Company Directors maintain the skill and knowledge necessary to fulfill their obligations as directors.

## II. Orientation of New Directors

Newly appointed Directors first meet with the Chairman of the Board to discuss the functioning of the Board of Directors. Then, they meet with the President and Chief Executive Officer to discuss the nature and operation of the Company's business activities. As required, meetings may be set up with other Senior Managers to further clarify some of the Company's business activities. Finally, the Secretary provides new directors with the following documents:

- A. Copies of Board meeting minutes and written resolutions since the beginning of the fiscal year (which may include those of the preceding fiscal year, depending of the date of appointment), including a copy of the minutes of the last annual meeting;
- B. A schedule of Board Meetings for the year;
- C. The disclosure policies et procedures and the "Undertaking" form (for signature);
- D. The policy on insider trading in force at Theratechnologies (with mention to register as an insider with the Canadian securities agency through SEDI.ca and to prepare an initial insider report within ten (10) days following appointment);
- E. Theratechnologies' Share Option Plan;
- F. The latest annual report and accompanying information on Theratechnologies (fact sheet, latest press releases, latest annual information form and corporate presentation);
- G. The Director Disclosure Form (to complete and return within afforded time);
- H. The General By-Laws, the Board's written mandate, the Audit Committee Charter, Compensation Committee Charter, Nominating and Corporate Governance Charter; and
- I. The Directors and Senior Management coverage and compensation.

Appendix D — Director Orientation and Continuing Education Policy Management Proxy Circular

# III. Continuing Education

The following actions are taken to ensure the continuing education of Directors:

- A. Management provides Directors, from time to time, with pertinent articles and books relating to the Company's business, its competitors, corporate governance and regulatory issues;
- B. Key Company executives make regular presentations to the Board on business activities;
- C. Certain consultants present to the Board on matters relevant to their role and duties. Consultants such as insurance brokers presenting on risks faced by the Company or consultants presenting a long-term strategy for the Company;
- D. The Secretary offers Directors continuing education in the form of presentations on new legal and regulatory requirements that impact the Board.

### IV. <u>Review</u>

This Policy is reviewed and modified when the Board of Directors considers it necessary and desirable.

#### APPENDIX E

# NOMINATING AND CORPORATE GOVERNANCE COMMITTEE CHARTER

# I. <u>Mandate</u>

The Nominating and Corporate Governance Committee (the "**Committee**") is responsible for assisting the Company's Board of Directors (the "**Board**") in overseeing the following:

- A. Recruit candidates for the Board;
- B. Review the size of the Board;
- C. Composition of the Board;
- D. Function of the Board;
- E. Orientation and education of Board members; and
- F. Governance.

### II. Obligations and Duties

The Committee carries out the duties usually entrusted to a Nominating and Corporate Governance Committee and any other duty assigned from time to time by the Board. Specifically, the Committee is charged with the following obligations and duties:

- A. Recruit Candidates for the Board
  - 1. Identify potential candidates as members of the Company's Board of Directors. In so doing, the Committee will consider:
    - a. independence of candidates under the terms of National Policy 58-201 on corporate governance;
    - b. the competencies, skills and personal characteristics sought in candidates. The Committee will determine what it considers necessary by assessing competencies, skills and personal characteristics of the candidates in relation to: (1) those generally required by the Board; (2) those already present in other Board members; and (3) those which are a welcome addition; and
    - c. the availability of candidates.
  - 2. All Board members may submit to the Committee potential candidates for membership, and the Committee shall review such candidates in light of above described competencies and skills desirable for the Board.
  - 3. The Committee shall proceed as follows for the recruitment of candidates:

Appendix E— Nominating and Corporate Governance Committee Charter Management Proxy Circular

- a. as it is determined by the Committee and the Board of Directors that Board vacancies must be filled or new members are desirable, the Chairman of the Board of Directors shall make contact with candidates that have been identified by the Committee per the above described criteria;
- b. upon a positive evaluation by the Chairman of the Board of Directors and positive reaction from the candidate, at least two (2) members of the Board shall meet with the candidate; and
- c. upon a positive evaluation by the two (2) Board members and the continuing interest of the candidate, the Committee shall make a recommendation to the Board of Directors, providing all pertinent background information for analysis and discussion by the Directors.
- B. Board Size

The Board must be composed of 3 to 20 directors, as per the Company's articles of incorporation and by law. As provided under the terms of the Company General By-Laws, the Board shall exercise its power to establish by resolution the exact number of directors. In this regard, the duties of the Committee are as follows:

- 1. Examine the size of the Board annually in view of assessing its effectiveness.
- 2. Consider modifications to the number of constituting members and issue its recommendations to the Board.
- C. Composition of the Board
  - 1. Ensure that the Board is composed of Directors that are sufficiently familiar with the business of the Company, and the risks it faces, to ensure active and effective participation in the deliberations of the Board.
  - 2. Ensure that Directors have diverse backgrounds and personal characteristics and traits as well as competencies and expertise that add value to the Company.
  - 3. Ensure that a majority of the directors are independent directors for the purposes of National Policy 58-201 Corporate Governance Guidelines.
- D. Board Functioning
  - 1. Examine the Board's functions and issue recommendations as to its obligations and role. Among others, the Committee must regularly review the Board's written mandate.
  - 2. Determine and review, as needed, the roles and mandates of Board committees and issue recommendations.
- E. Orientation and Continuing Education of Board Members

Develop an orientation and continuing education policy for Directors.

Appendix E— Nominating and Corporate Governance Committee Charter Management Proxy Circular

THERATECHNOLOGIES INC.

### F. Governance

- 1. Follow corporate governance developments and, as required, advise the Board of appropriate actions.
- 2. Examine appropriate actions to promote ethical business conduct, issue relevant recommendations to the Board and oversee their implementation.
- 3. Examine conflict of interest issues that may be brought to the attention of the Board and offer solutions.

#### III. External Advisors

In discharging its duties and responsibilities, the Committee is empowered to retain external legal counsel or other external advisors, as appropriate. The Company shall provide the necessary funds to secure the services of such advisors.

#### IV. Composition of the Committee

The Committee is composed of any number of Directors, but no less than three, as may be determined by the Board from time to time by resolution. Each member of the Committee shall be independent from the Company, as determined by the Board in accordance with applicable laws, rules and regulations.

#### V. Term of the Mandate

Committee members are appointed by Board resolution to carry out their mandate extending from the date of the appointment to the next Annual General Meeting of Shareholders, or until successors are so appointed.

#### VI. <u>Vacancy</u>

The Board may fill vacancies at any time by resolution. Subject to the constitution of the quorum, the Committee's members can continue to act even if there is one or many vacancies on the Committee.

#### VII. <u>Chairman</u>

The Board appoints the Committee Chairman who will call and chair the meetings.

### VIII. Secretary

Unless decided otherwise by resolution of the Board, the Secretary of the Company shall act as Committee Secretary. The Secretary must attend Committee meetings and prepare the minutes. He must provide notification of meetings as directed by the Committee Chairman. The Secretary is the guardian of the Committee's records, books and archives.

### IX. Meeting Proceedings

The Committee establishes its own procedures as to how meetings are called and conducted. Unless it is otherwise decided, the Committee shall meet privately and independently from Management at each regularly scheduled meeting. In the absence of the regularly appointed Chairman, the meeting shall be chaired by another Committee member selected among attending participants and appointed accordingly.

Appendix E— Nominating and Corporate Governance Committee Charter Management Proxy Circular

THERATECHNOLOGIES INC.

In the absence of the regularly appointed Secretary, Committee members shall designate someone to carry out this duty.

### X. Quorum and Vote

Unless the Board otherwise specifies by resolution, two Committee members shall constitute an appropriate quorum for deliberation of items on the agenda. During meetings, decisions are reached by a majority of votes from Committee members, unless the quorum is of two members, in which case decisions are made by consensus of opinion.

### XI. <u>Records</u>

The Committee keeps records that are deemed necessary for its deliberations and reports to the Board on its activities and recommendations on a regular basis.

#### XII. Effective Date

This charter was adopted by the Directors during the February 8, 2006 Board meeting.

Appendix E— Nominating and Corporate Governance Committee Charter Management Proxy Circular

THERATECHNOLOGIES INC.

#### MATERIAL CHANGE REPORT

#### Regulation 51-102 Respecting Continuous Disclosure Obligations Form 51-102F3

#### 1. <u>NAME AND ADDRESS OF COMPANY</u>:

THERATECHNOLOGIES INC. 2310 Alfred-Nobel Boulevard Montreal, Québec Canada H4S 2B4

### 2. DATE OF MATERIAL CHANGE:

December 6, 2010

### 3. <u>NEWS RELEASE</u>:

A news release was issued concerning this material change on December 6, 2010 on "Marketwire". A copy of the news release is available at SEDAR website at www.sedar.com.

### 4. <u>SUMMARY OF MATERIAL CHANGE</u>:

On December 6, 2010, Theratechnologies Inc. (the "Company") announced the execution of a distribution and licensing agreement (the "Agreement") with Sanofi-Aventis ("Sanofi") for the commercialization rights to *EGRIFTA*<sup>TM</sup> (tesamorelin for injection) in Latin America, Africa and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

### 5. FULL DESCRIPTION OF MATERIAL CHANGE:

On December 6, 2010, the Company announced the execution of the Agreement with Sanofi for the commercialization rights to *EGRIFTA*<sup>TM</sup> (tesamorelin for injection) in Latin America, Africa and the Middle East for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

Under the terms of the Agreement, the Company will be responsible to supply *EGRIFTA*<sup>TM</sup> to Sanofi. Sanofi will buy *EGRIFTA*<sup>TM</sup> from the Company at an undisclosed selling price. The Company has kept all future development rights to *EGRIFTA*<sup>TM</sup> and will be responsible for conducting additional research and development for any additional programs. Sanofi will be responsible to conduct all regulatory activities in the aforementioned territories in connection with *EGRIFTA*<sup>TM</sup> for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy, including seeking the approval of *EGRIFTA*<sup>TM</sup> in the different countries. The Company granted Sanofi an option to commercialize *EGRIFTA*<sup>TM</sup> in the aforementioned territories for other uses.

#### 6. <u>RELIANCE ON SUBSECTION 7.1(2) OF REGULATION 51-102:</u>

Not applicable.

### 7. <u>OMITTED INFORMATION</u>:

Not applicable.

## 8. <u>SENIOR OFFICER</u>:

For further information, contact Jocelyn Lafond, Vice President, Legal Affairs, and Corporate Secretary of Theratechnologies Inc., at (514) 336-4804, ext. 288.

## 9. <u>DATE OF REPORT</u>:

December 16, 2010.

#### MATERIAL CHANGE REPORT Regulation 51-102 Respecting Continuous Disclosure Obligations Form 51-102F3

### 1. NAME AND ADDRESS OF COMPANY:

THERATECHNOLOGIES INC. 2310 Alfred-Nobel Boulevard Montreal, Québec Canada H4S 2B4

### 2. DATE OF MATERIAL CHANGE:

February 3, 2011

### 3. <u>NEWS RELEASE:</u>

A news release describing this material change was issued on February 3, 2011 on "Marketwire". A copy of the news release is available on the SEDAR website at www.sedar.com.

### 4. <u>SUMMARY OF MATERIAL CHANGE:</u>

On February 3, 2011, Theratechnologies Inc. (the "Company") announced the execution of a distribution and licensing agreement (the "Agreement") with Ferrer Internacional S.A. ("Ferrer") for the commercialization rights to tesamorelin in Europe, Russia, South Korea, Taiwan and certain central Asian countries for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

## 5. <u>FULL DESCRIPTION OF MATERIAL CHANGE:</u>

On February 3, 2011, the Company announced the execution of the Agreement with Ferrer for the commercialization rights to tesamorelin in Europe, Russia, South Korea, Taiwan and certain central Asian countries for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy.

Under the terms of the Agreement, Ferrer will be responsible for conducting all regulatory and commercialization activities in connection with tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories subject to the Agreement. Theratechnologies will be responsible for the manufacture and supply of tesamorelin to Ferrer. Ferrer will purchase tesamorelin at a transfer price equal to the higher of a significant percentage of the net selling price and a predetermined floor price. Theratechnologies has the option to co-promote tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy in the territories. Theratechnologies has kept all development rights to tesamorelin for other indications and will be responsible for conducting research and development for any additional programs. Ferrer has the option to enter into a codevelopment and commercialization agreement using tesamorelin relating to any such new indications. The terms and conditions of such a co-development and commercialization agreement will be negotiated based on any additional program chosen for development.

## 6. <u>RELIANCE ON SUBSECTION 7.1(2) OR (3) OF NATIONAL INSTRUMENT 51-102:</u>

Not applicable.

## 7. <u>OMITTED INFORMATION:</u>

Not applicable.

## 8. EXECUTIVE OFFICER:

For further information, contact Jocelyn Lafond, Vice President, Legal Affairs, and Corporate Secretary of the Company at (514) 336-4804, ext. 288.

## 9. <u>DATE OF REPORT:</u>

February 10, 2011

#### MATERIAL CHANGE REPORT Regulation 51-102 Respecting Continuous Disclosure Obligations Form 51-102F3

#### 1. NAME AND ADDRESS OF COMPANY:

THERATECHNOLOGIES INC. 2310 Alfred-Nobel Boulevard Montreal, Québec Canada H4S 2B4

### 2. DATE OF MATERIAL CHANGE:

February 22, 2011

### 3. NEWS RELEASE:

A news release describing this material change was issued on February 22, 2011 on "Marketwire". A copy of the news release is available on the SEDAR website at www.sedar.com.

### 4. SUMMARY OF MATERIAL CHANGE:

On February 22, 2011, Theratechnologies Inc. (the "Company") announced a new clinical program for muscle wasting in Chronic Obstructive Pulmonary Disease (COPD) using the Company's lead compound, tesamorelin, a human growth hormone releasing factor ("GRF") analogue.

### 5. FULL DESCRIPTION OF MATERIAL CHANGE:

On February 22, 2011, the Company announced a new clinical program for muscle wasting in COPD using the Company's lead compound, tesamorelin, a GRF analogue.

Based on tesamorelin's anabolic properties, the Company has chosen to pursue the development of its lead compound in muscle wasting in patients with COPD as its second indication. COPD is characterized by progressive airflow obstruction due to chronic bronchitis or emphysema leading in certain cases to muscle wasting, a decrease of muscle mass and deterioration in functionality. Previously, the Company completed a Phase 2 trial in stable ambulatory COPD patients which demonstrated a statistically significant increase in lean body mass. The Company intends to commence a second Phase 2 clinical study in the second half of 2011 to test different dosages of tesamorelin with a new formulation.

The Phase 2 clinical study will evaluate the use of tesamorelin in a randomized, placebo controlled study with approximately 200 COPD patients, in Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage II and III, with muscle wasting.

Patients will be randomized to receive either one of two different dosages of tesamorelin or placebo each day for six months. Theratechnologies intends to randomize its first patient in the second half of 2011. The primary endpoint will be an increase in lean body mass. Other efficacy endpoints will be measured, such as a six-minute walking distance test, exercise endurance time, and quality of life (daily activities). Safety assessments will include monitoring of adverse events and laboratory evaluations. If the Phase 2 study is successful, two Phase 3 studies (one pivotal and one confirmatory) are to be conducted in parallel. This clinical trial program is estimated to take approximately four years and will use a new and more concentrated formulation of tesamorelin. The new formulation will require a smaller volume of injection and is expected to be stable at room temperature.

### 6. RELIANCE ON SUBSECTION 7.1(2) OR (3) OF NATIONAL INSTRUMENT 51-102:

Not applicable.

### 7. OMITTED INFORMATION:

Not applicable.

### 8. EXECUTIVE OFFICER:

For further information, contact Jocelyn Lafond, Vice President, Legal Affairs, and Corporate Secretary of the Company at (514) 336-4804, ext. 288.

### 9. DATE OF REPORT:

February 22, 2011

The Board of Directors Theratechnologies Inc.

We consent to the use of our report dated February 8, 2011 with respect to the consolidated statements of financial position of the Company as at November 30, 2010 and 2009 and December 1, 2008, and the consolidated statements of comprehensive income, changes in equity and cash flows for the years ended November 30, 2010 and 2009 included and incorporated by reference in the prospectus, which is part of the registration statement on Form F-10 and to the reference to our firm under the headings "Summary Consolidated Financial Data", "Selected Consolidated Financial Data" and "Interest of Experts" in the prospectus, which is part of the registration statement on Form F-10.

/s/ KPMG LLP

Chartered Accountants

Montreal, Canada February 22, 2011

### [Letterhead of Fasken Martineau Dumoulin LLP]

February 22, 2011

Theratechnologies Inc. 2310 Alfred-Nobel Boulevard Montréal, Québec, Canada H4S 2B4

Re: Registration Statement on Form F-10 of Theratechnologies Inc.

Ladies and Gentlemen:

We hereby consent to the reference to our firm under the heading "Legal Matters" in the short form base prospectus filed as part of this Registration Statement on Form F-10. By giving this consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended, or the rules and regulations promulgated thereunder.

Yours truly,

/s/ Fasken Martineau Dumoulin LLP

# [Letterhead of Goodwin Procter LLP] February 22, 2011

Theratechnologies Inc. 2310 Alfred-Nobel Boulevard Montréal, Québec, Canada H4S 2B4

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Yours truly,

/s/ Goodwin Procter LLP