



## MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE-MONTH AND SIX-MONTH PERIODS ENDED MAY 31, 2012

The following Management's Discussion and Analysis, or MD&A, provides Management's point of view on the financial position and the results of operations of Theratechnologies Inc., on a consolidated basis, for the three- and six-month periods ended May 31, 2012, as compared to the three- and six-month periods ended May 31, 2011. This MD&A is dated July 11, 2012, was approved by our Audit Committee, and should be read in conjunction with our unaudited interim consolidated financial statements and the notes thereto as at May 31, 2012, as well as the MD&A and audited consolidated financial statements including the notes thereto as at November 30, 2011.

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

Unless otherwise indicated or unless the context requires otherwise, in this MD&A, all references to "Theratechnologies", the "Company", the "Corporation", "we", "us", "our" or similar terms refer to Theratechnologies Inc. and its consolidated subsidiaries. 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.

This MD&A contains information that we believe may affect our prospective financial condition, cash flows and results of operations. Readers are cautioned to consult the section, "Forward-Looking Information", below.

### Business Overview

Theratechnologies (TSX: TH) (NASDAQ: THER) is a specialty pharmaceutical company that discovers and develops innovative therapeutic peptide products, with an emphasis on growth-hormone releasing factor peptides.

### Commercial and Regulatory Activities

Our first product, *EGRIFTA*<sup>TM</sup> (tesamorelin for injection), was approved by the United States Food and Drug Administration, or FDA, in November 2010 and is, to date, the only approved therapy for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA*<sup>TM</sup> is currently being marketed in the United States by EMD Serono, Inc., or EMD Serono, pursuant to a collaboration and licensing agreement executed in October 2008.

EMD Serono began selling *EGRIFTA*<sup>TM</sup> in the United States in January 2011 and we receive royalties on their sales, which are paid quarterly in arrears based on the calendar year. Royalties received from EMD Serono in the first six months of fiscal 2011 and 2012 amounted to \$194,000 and \$1,562,000 respectively. According to IMS, a third-party supplier of sales information to the pharmaceutical industry, prescriptions in the April to June 2012 selling period were up significantly over the prior quarter. Royalties on these sales will be reported in our third quarter financial statements.

In December 2010, we granted an affiliate of sanofi-aventis, or Sanofi, exclusive commercialization rights to tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Latin America, Africa and the Middle East. Subsequent to this agreement, requests for regulatory approval were filed in Israel, Brazil, Argentina, Mexico, Colombia and Venezuela. In

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June 2012, we were informed by Sanofi that the National Health Surveillance Agency, or ANVISA, in Brazil has audited and identified technical deficiencies with the Montreal-based third-party manufacturing site for tesamorelin. The manufacturer has indicated that it is in a position to implement ANVISA's recommendations with regards to these deficiencies. However, this development may delay Brazil's regulatory decision.

In February 2011, we granted Ferrer Internacional S.A., or Ferrer, exclusive commercialization rights to tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries.

In June 2012, Ferrer withdrew its Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, for tesamorelin in the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy. Ferrer's decision to withdraw followed an oral explanation with the EMA's Committee for Medicinal Products for Human Use (CHMP). As higher IGF-1 (Insulin-like growth factor 1) levels were identified as a potential safety concern for long-term use of tesamorelin, the CHMP indicated that the lack of data on cardiovascular risk markers did not allow the committee to conclude on a positive benefit/risk balance.

Our New Drug Submission, or NDS, for tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy was filed in June 2011 with Health Canada. In February 2012, we granted Actelion Pharmaceuticals Canada Inc., or Actelion, exclusive commercialization rights to tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in Canada. Under the terms of the Agreement, we are responsible for the manufacture and supply of tesamorelin to Actelion and Actelion is responsible for conducting all regulatory and commercialization activities.

In June 2012, Health Canada issued a notice of non-compliance in relation to the NDS containing questions regarding the long-term safety of tesamorelin, the appropriate patient population and the proposed indication. We have been granted 90 days to respond to the questions. We now expect to receive Health Canada's final decision regarding the NDS during the first half of 2013.

#### Research and Development (R&D) Activities

##### *TH1173*

In October 2011, we announced the discovery of a new GRF peptide, known as TH1173, which may prove to be suitable for the treatment of a broader range of medical indications than tesamorelin. We are also testing alternative, more patient-friendly methods of administration such as nasal, transdermal and subcutaneous. We conducted pre-clinical feasibility studies to explore TH1173's potential using new modes of administration in the first quarter and these studies are ongoing. In May 2012, we initiated a preclinical safety program for TH1173, with a view to beginning clinical testing by early 2013.

##### *EGRIFTA™*

In the six-month period ended May 31, 2012, our R&D activities also included work on post-approval commitments made to the FDA in relation to the marketing approval granted to *EGRIFTA™*. These included the development of a single-vial formulation of *EGRIFTA™* and preparations with respect to a Phase 4 clinical trial to assess whether *EGRIFTA™* has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat.

#### Other Events

On February 24, 2012, the Superior Court of Quebec certified the class action suit against Theratechnologies, a director, and a former executive officer, alleging that the Company did not comply with its continuous disclosure obligations. We are of the view that the allegations against us are entirely without merit and we will take all appropriate actions to vigorously defend its position.

We are seeking leave to appeal this decision. The hearing date regarding leave to appeal, which was scheduled for June 5, 2012 and was subsequently postponed, has yet to be re-established.

### **Revenues**

Our revenues are mainly sales of *EGRIFTA*<sup>™</sup> to EMD Serono for re-sale, royalties received from EMD Serono on U.S. sales to customers, and the amortization of the initial payment received upon the closing of the agreement with EMD Serono.

Revenues generated from sale of goods amounted to \$856,000 in the three-month period ended May 31, 2012 and \$2,135,000 in the six months ended May 31, 2012, compared to \$2,005,000 and \$3,803,000 in the comparable periods of 2011. The higher sales in the prior-year reflect the build-up of stocks needed by EMD Serono for the *EGRIFTA*<sup>™</sup> launch in the U.S. market. Revenues from sale of goods are now more closely tied to sales to patients but they can also vary significantly as a function of EMD Serono's procurement policies.

Royalties, which are almost entirely derived from the sales of *EGRIFTA*<sup>™</sup>, are up significantly over the comparable periods in 2011 when the product launch was in its early stages. Royalties are paid quarterly in arrears based on the calendar year. In the three- and six-month periods ended May 31, 2012, we received royalty revenue from EMD Serono of \$726,000 and \$1,562,000 respectively in relation to the three-month selling period from January 1, 2012 to March 31, 2012 and the six-month selling period from October 1, 2011 to March 31, 2012, compared to \$190,000 and \$194,000 for the comparable periods in 2011.

Our revenues also include the amortization of the initial payment of \$27,097,000 received upon the closing of the agreement with EMD Serono. For the three- and six-month periods ended May 31, 2012, amounts of \$1,069,000 and \$2,139,000 were recognized as revenue related to this transaction, compared to \$1,284,000 and \$2,995,000 in the comparable periods of 2011. The decrease in the amortization amount for the current year reflects a change in the service period attributed to the initial payment. The initial payment will be fully amortized by year end 2013.

Reflecting the variations in product sales, royalties and amortization of the initial payment described above, consolidated revenues for the three- and six-month periods ended May 31, 2012 amounted to \$2,656,000 and \$5,846,000 compared to \$3,483,000 and \$7,001,000 in the comparable periods of 2011.

### **Cost of Sales**

For the three- and six-month periods ended May 31, 2012, the cost of sales of *EGRIFTA*<sup>™</sup> amounted to \$692,000 and \$2,029,000 compared to \$2,562,000 and \$5,157,000 in the comparable periods of 2011. Sale of goods revenue exceeded cost of sales for the first time since *EGRIFTA*<sup>™</sup> was launched in the first quarter of 2011. Prior to the latest three-month period, the cost of sales exceeded revenue due to an accounting requirement that we expense certain historical inventory costs as well as the current costs related to validating back-up suppliers for raw materials and finished goods. The old inventory is now essentially depleted; however, quarter-over-quarter variations in gross margins will continue to be experienced due to the costs associated with validating additional suppliers. Cost of sales is detailed in note 4 "cost of sales" of our unaudited consolidated financial statements for the three- and six-month periods ended May 31, 2012 and May 31, 2011.

### **R&D Activities**

Research and development, or R&D, expenses, net of tax credits, for the three- and six-month periods ended May 31, 2012 amounted to \$1,410,000 and \$2,723,000 compared to \$3,072,000 and \$6,065,000 in the comparable periods of 2011, decreases of 54% and 55% respectively. The significant reduction in R&D expenses is largely attributable to restructuring and the adoption of a more focused business plan. R&D expenses in the six months ended May 31, 2012 were associated with helping our commercial partners to pursue regulatory approvals in their respective

jurisdictions, the Phase 4 clinical trial, pursuing the development of TH1173 and the new formulation of *EGRIFTA*<sup>™</sup>.

### **Selling and Market Development Expenses**

Selling and market development expenses for the three- and six-month periods ended May 31, 2012 amounted to \$256,000 and \$517,000 compared to \$569,000 and \$1,046,000 in the comparable periods of 2011, decreases of 55% and 50% respectively. With licensing agreements now in place in major markets, the ongoing selling and market development expenses are reduced to the costs of managing our relationships with our commercial partners.

### **General and Administrative Expenses**

General and administrative expenses for the three- and six-month periods ended May 31, 2012 amounted to \$1,795,000 and \$3,838,000 compared to \$3,695,000 and \$6,910,000 in the comparable periods of 2011, decreases of 51% and 44% respectively. The expenses in the 2012 periods were considerably lower as a result of the restructuring. In addition, the expenses in 2011 included the cost of the proposed financing, costs related to the change in leadership of the Company, many of which were entirely expensed in the first three months of the 2011 fiscal year, as well as all of the annual compensation paid to the directors in deferred stock units, which was also expensed in the first three months of 2011. In 2012, deferred stock units granted as compensation to our directors are being expensed on a quarterly basis.

### **Restructuring Costs**

In December 2011, we restructured the business to concentrate the Company's efforts on *EGRIFTA*<sup>™</sup> and on developing TH1173, giving rise to restructuring costs of \$6,058,000 in the three months ended February 29, 2012. An additional \$115,000 of restructuring costs was incurred in the three months ended May 31, 2012. The largest restructuring cost is an onerous lease provision of \$4,055,000, which is based on the Company now occupying approximately fifty percent of its leased premises. Other restructuring costs include employee termination benefits of \$1,249,000, costs associated with terminating the COPD clinical program of \$1,072,000 and professional fees of \$278,000.

### **Net Finance Income**

Finance income for the three- and six-month periods ended May 31, 2012 was \$241,000 and \$518,000 compared to \$455,000 and \$827,000 in the comparable periods of 2011. Interest revenues in 2012 were lower than 2011 due to the gradual decline in the portfolio size as investments are liquidated to fund operations.

Finance costs for the three months ended May 31, 2012 were \$51,000. In the six months ended May 31, 2012 there was a gain of \$16,000 due to positive foreign exchange fluctuations. In the comparable periods of 2011, finance costs were \$12,000 and \$589,000. Finance costs for the first three months of 2011 include a foreign exchange loss of \$550,000 incurred upon receipt of a US\$25,000,000 milestone payment from EMD Serono. The milestone payment had originally been converted into the functional currency of the Company at the more favorable exchange rate in effect at the November 30, 2010 fiscal year end for an exchange gain of \$635,000 at that time.

### **Net Results**

Taking into account the revenues and expenses described above, we recorded a net loss of \$1,417,000 in the three months ended May 31, 2012 compared to \$5,941,000 in the comparable period of 2011. For the six-month period ended May 31, 2012 the net loss was \$8,901,000 (including \$6,173,000 of restructuring costs) compared to \$11,873,000 in the comparable period of 2011. On a per share basis, the net loss for three months ended May 31, 2012 was \$0.02 compared to \$0.10 in the comparable period of 2011. Net loss per share for the six months ended May 31, 2012 was \$0.15 (including the per share impact of the restructuring costs) compared to \$0.20 in the comparable period of 2011.

## Financial Position

At May 31, 2012, liquidities, which include cash and bonds, amounted to \$24,000,000 and tax credits and grants receivable amounted to \$517,000, for a total of \$24,517,000.

Use of cash from operating activities for the three- and six-month periods ended May 31, 2012 was \$4,440,000 and \$12,369,000 compared to \$7,957,000 and \$15,721,000 in the comparable periods of 2011. The current-year amounts include the cash impact of the December restructuring.

For the three months ended May 31, 2012, cash used in operating activities, before changes in operating assets and liabilities amounted to \$1,245,000, and change in deferred revenue amounted to \$1,072,000 for a total of \$2,317,000.

## Quarterly Financial Information

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

(In thousands of Canadian dollars, except per share amounts)

	2012				2011			2010
	Q2	Q1	Q4	Q3	Q2	Q1	Q4	Q3
Sale of goods	\$856	\$1,279	\$2,670	\$1,878	\$2,005	\$1,798	-	-
Upfront and milestone payments	\$1,069	\$1,070	\$1,069	\$1,070	\$1,284	\$1,711	\$26,711	\$1,711
Royalties and license fees	\$731	\$841	\$671	\$569	\$194	\$9	\$6	\$6
<b>Revenue</b>	<b>\$2,656</b>	<b>\$3,190</b>	<b>\$4,410</b>	<b>\$3,517</b>	<b>\$3,483</b>	<b>\$3,518</b>	<b>\$26,717</b>	<b>\$1,717</b>
<b>Net (loss) profit</b>	<b>\$(1,417)</b>	<b>\$(7,484)</b>	<b>\$(1,687)</b>	<b>\$(4,170)</b>	<b>\$(5,941)</b>	<b>\$(5,932)</b>	<b>\$21,299</b>	<b>\$(3,357)</b>
<b>Basic and diluted (loss) earnings per share</b>	<b>\$(0.02)</b>	<b>\$(0.12)</b>	<b>\$(0.03)</b>	<b>\$(0.07)</b>	<b>\$(0.10)</b>	<b>\$(0.10)</b>	<b>\$0.35</b>	<b>\$(0.06)</b>

Quarterly sale of goods amounts vary in accordance with the inventory management policies of EMD Serono.

Royalty revenues tend to track patient prescriptions, with some variations due to provision policies of EMD Serono and inventory fluctuations in the supply chain.

The net losses in the first and second quarters of 2012 include the December 2011 restructuring costs of \$6,058,000 and \$115,000 respectively.

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*<sup>TM</sup> by the FDA.

## Upcoming changes in accounting standards:

### (a) Amendments to existing standards:

#### *Annual improvements to IFRS:*

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

#### (i) IFRS 7:

##### *Amendment to IFRS 7, Financial Instruments: Disclosures:*

Multiple clarifications related to the disclosure of financial instruments and in particular in regards to transfers of financial assets.

#### (ii) IAS 1:

##### *Amendment to IAS 1, Presentation of Financial Statements:*

Entities may present the analysis of the components of other comprehensive income either in the statement of changes in equity or within the notes to the financial statements.

#### (iii) IAS 24:

##### *Amendment to IAS 24, Related Party Disclosures:*

There are limited differences in the definition of what constitutes a related party; however, the amendment requires more detailed disclosures regarding commitments.

#### (iv) IAS 34:

##### *Amendment to IAS 34, Interim Financial Reporting:*

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

The adoption of these amendments to existing standards had no impact on the consolidated financial statements.

### (b) New or revised standards and interpretations issued but not yet adopted:

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

#### (i) IFRS 9 Financial instruments:

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

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

(ii) IFRS 10 Consolidated Financial Statements:

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

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

(iii) IFRS 13 Fair Value Measurement:

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

Provides new guidance on fair value measurement and disclosure requirements.

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

#### **Outstanding Share Data**

On July 10, 2012, the number of shares issued and outstanding was 61,010,603 while outstanding options granted under the stock option plan were 1,998,628.

#### **Contractual Obligations**

In connection with its approval of *EGRIFTA*<sup>TM</sup>, the FDA has required the following three post-approval commitments:

- 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 using *EGRIFTA*<sup>TM</sup>.

The Company has developed a new presentation of *EGRIFTA*<sup>TM</sup> which complies with the first of the FDA's post-approval requirements. It is required to be available by November 2013.

The long-term observational safety study is to evaluate the safety of long-term administration of *EGRIFTA*<sup>TM</sup> and the protocol for this study, which has been submitted to the FDA by EMD Serono, has yet to be finalized. We have agreed to share the cost of this study equally with EMD Serono. We estimate that our share of the cost could amount to an average of \$1,300,000 per year, over a fifteen-year period.

The Phase 4 clinical trial is to assess whether *EGRIFTA*<sup>TM</sup> has an impact on diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. EMD Serono is responsible for executing the trial and is to be reimbursed by the Company for the direct costs involved. The FDA-approved protocol for the trial calls for patients to inject themselves daily with either *EGRIFTA*<sup>TM</sup> or placebo over a three-year treatment period. While the Company is committed to supporting the trial, management believes that the protocol conditions will be difficult to meet. We estimate that the trial, if completed, could cost approximately \$20,000,000 over a four- to five-year period.

The Company has entered into long-term procurement agreements with third-party suppliers in connection with the commercialization of *EGRIFTA*<sup>TM</sup>. As at May 31, 2012, the Company had

outstanding purchase orders under these agreements amounting to \$2,124,000 for the manufacture of *EGRIFTA*<sup>™</sup> to be delivered in fiscal years 2012 and 2013.

There were no other material changes in contractual obligations during the three months ended May 31, 2012, other than in the ordinary course of business.

### **Economic and Industry Factors**

Economic and industry factors were substantially unchanged from those reported in our 2011 MD&A.

### **Forward-Looking Information**

This MD&A contains certain statements that are considered "forward-looking information" within the meaning of applicable securities legislation, which statements may contain words such as "will", "may", "could", "should", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. This forward-looking information includes, but is not limited to, information regarding the potential regulatory approval of tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in various territories outside of the United States, the timing regarding the obtaining of decisions from various regulatory authorities relating to the pending marketing applications for tesamorelin in various jurisdictions outside of the United States and regarding clinical testing of TH1173 and the development of TH1173 suitable for the treatment of a broad range of medical indications.

Forward-looking information is based upon a number of assumptions and is subject to a number of risks and uncertainties, many of which are beyond our control that could cause actual results to differ materially from those that are disclosed in or implied by such forward-looking information. These assumptions made in preparing the forward-looking information include, but are not limited to, the assumption that tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy will receive approvals in the territories where we have marketing applications for tesamorelin pending, the withdrawal of the MAA with the EMA will have no consequence on the decisions of other regulatory authorities regarding the pending marketing authorizations and the decisions of our commercial partners to pursue the approval of tesamorelin for the treatment of excess abdominal fat in HIV-infected patients with lipodystrophy in various jurisdictions, the safety and efficacy data gathered through the development of tesamorelin will be accepted by the regulatory authorities where marketing applications for tesamorelin are pending, no additional clinical studies will be required by regulatory authorities to obtain regulatory approval of tesamorelin, if approved, *EGRIFTA*<sup>™</sup> will be accepted by the marketplace and will be on the list of reimbursed drugs by third-party payers in the jurisdictions where approval will be obtained, our relations with our commercial partners and our third-party suppliers of *EGRIFTA*<sup>™</sup> will be conflict-free and such third-party suppliers will have enough capacity to manufacture and supply *EGRIFTA*<sup>™</sup> to meet its demand and will manufacture on a timely-basis, the Montreal-based manufacturer of tesamorelin will be able to implement successfully ANVISA's recommendations, the results from the ongoing studies with TH1173 will be positive and we will have the financial capacity to develop TH1173 within the timeline described herein. These risks and uncertainties include, but are not limited to, the risk that tesamorelin is not approved in the jurisdictions where marketing applications are pending, the risk that, even if approved, revenue and royalties we expect to generate from sales of *EGRIFTA*<sup>™</sup> are not high enough to sustain our business, the risk that conflicts occur with our commercial partners jeopardizing the commercialization of *EGRIFTA*<sup>™</sup>, the risk that ANVISA's recommendations are not implemented successfully, the risk that the supply of *EGRIFTA*<sup>™</sup> to our commercial partners is delayed or suspended as a result of problems with our suppliers, the risk that *EGRIFTA*<sup>™</sup> is withdrawn from the market as a result of defects or recalls, the risk that our intellectual property is not adequately protected, the risk that delays occur in obtaining the final decisions of regulatory authorities in certain jurisdictions, the risk that the ongoing development work on TH1173 is delayed or do not yield positive results causing us to halt the development of TH1173 and the risk that we do not have the financial capacity to pursue the development of TH1173.



We refer potential investors to the "Risk Factors" section of our Annual Information Form (AIF) dated February 27, 2012. The AIF is available at <http://www.sedar.com/> and at <http://www.sec.gov/> under our public filings. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking information. Forward-looking information reflects current expectations regarding future events and speaks only as of the date of this MD&A and represents our expectations as of that date.

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