

U.S. SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 40-F

(Check One)

Registration statement pursuant to Section 12 of the Securities Exchange Act of 1934

or

Annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended November 30, 2019

Commission file number: 001-35203

**THERATECHNOLOGIES INC.**

(Exact name of registrant as specified in its charter)

**Québec, Canada**  
(Province or other jurisdiction  
of incorporation or  
organization)

**2834**  
(Primary  
Industrial  
Industrial  
Classification  
Code Number  
(if applicable))

**98-0618426**  
(I.R.S. Employer  
Identification Number)

**2015 Peel Street, 11th Floor  
Montreal, Québec, Canada H3A 1T8  
(514) 336-7800**

(Address and Telephone Number of Registrant's Principal Executive Offices)

**CT Corporation System  
28 Liberty Street, New York, New York 10005  
(212) 894-8940**

(Name, Address (Including Zip Code) and Telephone Number (Including Area Code) of Agent For Service in the United States)

Copies to:

**Jocelyn Lafond  
Theratechnologies Inc.  
2015 Peel Street, 11th Floor  
Montreal, Québec, H3A 1T8  
CANADA  
(438) 315-6607**

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title Of Each Class  
**Common Shares**

Trading Symbol  
**THTX**

Name Of Exchange On Which Registered  
**The NASDAQ Stock Market LLC**

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

For annual reports, indicate by check mark the information filed with this Form:

Annual Information Form

Audited Annual Financial Statements

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: **76,953,411**

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act.

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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## EXPLANATORY NOTE

Theratechnologies Inc. (“we”, “us”, “our”, the “Company” or the “Registrant”) is a Canadian issuer eligible to file its annual report pursuant to Section 13 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, on Form 40-F pursuant to the multi-jurisdictional disclosure system of the Exchange Act. We are a “foreign private issuer” as defined under Rule 3b-4 under the Exchange Act. Our equity securities are exempt from Sections 14(a), 14(b), 14(c), 14(f) and 16 of the Exchange Act pursuant to Rule 3a12-3.

### FORWARD LOOKING STATEMENTS

This annual report on Form 40-F, or Annual Report, and the documents incorporated herein by reference contain 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 include, but are not limited to, statements about:

- our expectations regarding the commercialization of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo®;
- our ability and capacity to grow the sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® successfully in the United States;
- our capacity to meet supply and demand for our products;
- the market acceptance of *EGRIFTA SV*™ in the United States;
- the continuation of our collaborations and other significant agreements with our existing commercial partners and third-party suppliers and our ability to establish and maintain additional collaboration agreements;
- our success in continuing to seek and in maintaining reimbursement for *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® by third-party payors in the United States;
- the success and pricing of other competing drugs or therapies that are or may become available;
- our ability to protect and maintain our intellectual property rights in *EGRIFTA*®, *EGRIFTA SV*™ and tesamorelin;
- our success in obtaining reimbursement for Trogarzo® in countries of the European Union;
- our ability and capacity to launch Trogarzo® in countries of the European Union;
- our capacity to develop a new formulation of tesamorelin;
- our capacity to conduct a phase III clinical trial using tesamorelin for the treatment of non-alcoholic steatohepatitis, or NASH, in the HIV-patient population and in the non-HIV population;
- our capacity to develop our oncology peptides and obtain positive results from our research and development activities using those peptides;
- our capacity to acquire or in-licence new products and/or compounds;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and
- our estimates regarding our capital requirements.

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:

- sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States will increase over time;
- our commercial practices in the United States, Canada and the countries of the European Union will not be found to be in violation of applicable laws;
- the long-term use of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® will not change their respective current safety profile;
- no recall or market withdrawal of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® will occur;
- no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States;
- the categorization of tesamorelin as a biologic will not have a material adverse effect on us;
- continuous supply of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® will be available;
- our relations with third-party suppliers of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® to meet market demand on a timely basis;

- no generic or biosimilar version of *EGRIFTA*® or *EGRIFTA SV*™ will be approved by the United States Food and Drug Administration, or FDA;
- our intellectual property will prevent companies from commercializing generic or biosimilar versions of *EGRIFTA*® and *EGRIFTA SV*™ in the United States;
- Trogarzo® will be added to the list of reimbursed drugs by countries of the European Union;
- the FDA will approve a new formulation of tesamorelin;
- we will obtain positive feedback from the FDA regarding our proposed phase III clinical trial to develop tesamorelin for the treatment of NASH in the HIV-patient population;
- we will succeed in conducting our phase III clinical trial to develop tesamorelin for the treatment of NASH in the HIV-patient population;
- our research and development activities using peptides derived from our oncology platform will yield positive results;
- the data obtained from our market research on the potential market for Trogarzo® in the United States and in the European Union are accurate;
- our European infrastructure is adequate to launch Trogarzo® in European countries; 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 statements and circumstances discussed in this Annual Report and the documents incorporated by reference may not occur, and you should not place undue reliance on these forward-looking statements. We discuss many of our risks in greater detail under the “Risk Factors” section of our annual information form attached hereto as Exhibit 99.1, but additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also adversely affect the forward-looking statements, our business, financial condition and prospects. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report. 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 Annual Report, and particularly our forward-looking statements, with these cautionary statements.

#### **NOTE TO UNITED STATES READERS**

We are permitted under the multi-jurisdictional disclosure system adapted by the United States Securities and Exchange Commission, or SEC, to prepare this annual report on Form 40-F, or Annual Report, in accordance with Canadian disclosure requirements, which differ from those of the United States.

The Company's financial statements, including those in the exhibits attached to this Annual Report, are prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, and the prior audit period is subject to Canadian auditing and auditor independence standards. IFRS differ in some significant respects from U.S. GAAP, and thus the Company's financial statements 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 Annual Report. 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.

#### **ANNUAL INFORMATION FORM**

The annual information form for the fiscal year ended November 30, 2019, is filed as Exhibit 99.1 to this Annual Report and is incorporated by reference herein.

#### **AUDITED ANNUAL FINANCIAL STATEMENTS**

The audited consolidated financial statements of the Company for the years ended November 30, 2019 and 2018, including the reports of the independent auditors thereon, are filed as Exhibit 99.2 to this Annual Report, and are incorporated by reference herein.

## MANAGEMENT'S DISCUSSION AND ANALYSIS

The Company's MD&A for the year ended November 30, 2019 is filed as Exhibit 99.3 to this Annual Report, and is incorporated by reference herein.

### TAX MATTERS

Purchasing, holding, or disposing of the Company's securities may have tax consequences under the laws of the United States and Canada that are not described in this Annual Report.

### CONTROLS AND PROCEDURES

#### *DISCLOSURE CONTROL AND PROCEDURES*

At the end of the period covered by this Annual Report for the fiscal year ended November 30, 2019, an evaluation was carried out by our President and Chief Executive Officer, or CEO, and by our Senior Vice President and Chief Financial Officer, or CFO, which are our principal executive officer and principal financial officer, respectively, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13(a)-15(e) of the Exchange Act). Based upon that evaluation, our CEO and CFO have concluded that our disclosure controls and procedures were effective.

#### *MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING AND AUDITOR'S ATTESTATION REPORT*

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

#### *CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING*

During the period covered by this Annual Report, no change occurred in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### AUDIT COMMITTEE

The Registrant has an audit committee, or Audit Committee, comprised of three independent directors, namely: Paul Pommier, its Chair, Gary Littlejohn and Gérald A. Lacoste.

The Audit Committee reviews the financial statements of the Registrant and performs other duties, as described in the Audit Committee's charter adopted by the board of directors and attached as Schedule "A" to the Annual Information Form of the Registrant for the year ended November 30, 2019 filed as Exhibit 99.1, as set forth in the Exhibit Index attached hereto.

All three members of the Audit Committee are independent and financially literate. The board of directors has determined that Paul Pommier is the financial expert of the Audit Committee. The SEC has indicated that the designation or identification of Mr. Pommier as an audit committee financial expert does not deem him an "expert" for any purpose, impose any duties, obligations or liability on Mr. Pommier that are greater than those imposed on members of the audit committee and board of directors who do not carry this designation or identification, or affect the duties, obligations or liability of any other member of the audit committee or board of directors.

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.

**Gary Littlejohn.** Mr. Littlejohn holds a B.A. (Honours Economics), a BCL and a MBA from McGill University. From 2008 to 2015, Mr. Littlejohn held the position of CEO and then of advisor to the Chairman and Board Member of the Arab National Investment Company, also known as ANB Invest, in Riyadh, a subsidiary of Arab National Bank. Previously, he was Managing Director of investment banking at Desjardins Securities in Montreal, a position he took after serving six years as Executive Vice-president at Ecopia Biosciences. Mr. Littlejohn also occupied various senior positions in investment banking at TD Securities, Midland Walwyn, BMO Nesbitt Burns and National Bank Financial.

**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 was 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 complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised in the Registrant's financial statements.

## AUDITORS FEES AND RELATED SERVICES

KPMG LLP have been acting as our auditors since 1993. In addition to performing the audit of our consolidated financial statements, KPMG LLP provided other services to us and they billed us the following fees in respect of each of our fiscal years ended November 30, 2019 and 2018:

### AUDITORS FEES

Fees	Fiscal Year Ended November 30, 2019 (CAD)	Fiscal Year Ended November 30, 2018 (CAD)
Audit Fees(1)	\$377,500	\$254,000
Audit-Related Fees(2)	\$43,750	\$43,750
Tax Fees(3)	\$158,092	\$90,620
<b>Total:</b>	<b>\$579,342</b>	<b>\$388,370</b>

- (1) Refers to the aggregate fees billed by our external auditors for audit services, including interim reviews, accounting consultations and work performed in connection with securities filings.
- (2) Refers to the aggregate fees billed for professional services rendered by our external auditors for translation.
- (3) Refers to the aggregate fees billed for professional services rendered by our external auditors for tax compliance, transfer pricing, tax advice and tax planning.

### AUDIT COMMITTEE PRE-APPROVAL POLICIES AND PROCEDURES

The Audit Committee charter sets out responsibilities regarding the provision of non-audit services by the Company's external auditors and requires the Audit Committee to pre-approve all permitted non-audit services to be provided by the Company's external auditors, which pre-approval may be delegated to any member of the Audit Committee. The Company also requires pre-approval of all audit services to be provided by its external auditors. All audit and non-audit services performed by the Company's external auditors for the fiscal year ended November 30, 2019, were pre-approved by the Audit Committee and none were approved on the basis of the *de minimis* exemption set forth in Rule 2-01(c)(7)(i)(C) of Regulation S-X.

## CODE OF ETHICS

The Company has adopted a code of ethics for all of its directors, officers and employees, or Code of Ethics. The Code of Ethics has been posted on the Company's website and is available at [www.theratech.com](http://www.theratech.com). On February 18, 2020, the Company adopted a policy based on the *Foreign Corrupt Practices Act of 1977*, as amended, or FCPA Policy. Such policy has also been posted on the Company's website and is also available at [www.theratech.com](http://www.theratech.com). The Company undertakes to provide to any person without charge, upon request, a copy of the Code of Ethics and of the FCPA Policy. In order to obtain such documents, a written request must be made to the Corporate Secretary of the Company at the following address: 2015 Peel Street, Suite 1100, Montreal, Québec, Canada, H3A 1T8.

## 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 Annual Report 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.

The Corporation does not follow Rule 5620(c), but instead follows its 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), the Corporation's directors approved a by-law amendment, which amendment was ratified by the Corporation's 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.

## OFF-BALANCE SHEET ARRANGEMENTS

The Corporation does not have any off-balance sheet arrangements.

## DISCLOSURE OF CONTRACTUAL OBLIGATIONS

The following table lists as of November 30, 2019 information with respect to the Corporation's known contractual obligations (stated in U.S. dollars).

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

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

### Credit facility:

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

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

Reference should be made to Note 12 (Intangible Assets) to the audited consolidated financial statements of the Registrant for the year ended November 30, 2019 for a description of all potential commercial milestones payable by the Registrant.

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## NOTICE PURSUANT TO REGULATION BTR

There were no notices required by Rule 104 of Regulation BTR during the fiscal year ended November 30, 2019, concerning any equity security subject to a blackout period under Rule 101 of Regulation BTR.

### UNDERTAKINGS

The Registrant undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the staff of the SEC, and to furnish promptly, when requested to do so by the staff of the SEC, information relating to the securities registered pursuant to Form 40-F, the securities in relation to which the obligation to file an annual report on Form 40-F arises, or transactions in said securities.

### CONSENT TO SERVICE OF PROCESS

The Registrant has previously filed with the SEC a written consent to service of process on Form F-X. Any change to the name or address of the agent for service of the Registrant shall be communicated promptly to the SEC by amendment to Form F-X referencing the file number of the Registrant.



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**SIGNATURES**

Pursuant to the requirements of the Exchange Act, the Registrant certifies that it meets all of the requirements for filing on Form 40-F and has duly caused this Annual Report to be signed on its behalf by the undersigned, thereto duly authorized.

**THERATECHNOLOGIES INC.**

By: /s/ Luc Tanguay\_\_\_\_\_

Name: Luc Tanguay

Title: President and  
Chief Executive Officer

Date: February 25, 2020

## EXHIBIT INDEX

Exhibit	
99.1	<a href="#">Annual Information Form dated February 24, 2020 for the financial year ended November 30, 2019</a>
99.2	<a href="#">Audited Consolidated Annual Financial Statements for the years ended November 30, 2019 and 2018</a>
99.3	<a href="#">Management's Discussion and Analysis for the year ended November 30, 2019</a>
99.4	<a href="#">Certificate of CEO dated February 25, 2020 pursuant to Rule 13a-14(a) of the Exchange Act</a>
99.5	<a href="#">Certificate of CFO dated February 25, 2020 pursuant to Rule 13a-14(a) of the Exchange Act</a>
99.6	<a href="#">Certificate of CEO dated February 25, 2020 pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
99.7	<a href="#">Certificate of CFO dated February 25, 2020 pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
99.8	<a href="#">Master Services Agreement made as of July 15, 2019 by and between Asembia LLC and Theratechnologies Inc.</a>
99.9	<a href="#">Amendment No. 1 to Amended and Restated Statement of Work #1 made as of November 1, 2019 by and between RxC Acquisition Company d/b/a RxCrossroads by McKesson and Theratechnologies Inc.</a>
99.10	<a href="#">Amendment No. 1 to Amended and Restated Statement of Work #2 made as of November 1, 2019 by and between RxC Acquisition Company d/b/a RxCrossroads by McKesson and Theratechnologies Inc.</a>
99.11	<a href="#">Second Amendment to Amended and Restated Master Services Agreement made as of February 3, 2020 by and between inVentiv Commercial Services, LLC and Theratechnologies Inc.</a>
99.12	<a href="#">Amended and Restated License Agreement made as of February 3, 2020 by and between The General Hospital Corporation d/b/a Massachusetts General Hospital and Theratechnologies Inc.</a>
99.13	<a href="#">Consent of KPMG LLP</a>
101.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

**ANNUAL INFORMATION FORM**  
**Financial Year Ended November 30, 2019**



**February 24, 2020**

## **BASIS OF PRESENTATION**

In this Annual Information Form, or AIF:

- references to “Theratechnologies”, the “Company”, the “Corporation”, “we”, “our” and “us” or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis, unless otherwise indicated or unless the context requires otherwise;
- *EGRIFTA*<sup>®</sup> (tesamorelin for injection) and *EGRIFTA SV*<sup>™</sup> refer to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA* is our registered trademark in the United States and in Canada and it is used in those countries to commercialize tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.
- tesamorelin refers to the use of our tesamorelin compound for the potential treatment of non-alcoholic steatohepatitis, or NASH, in HIV-infected patients and for other diseases;
- Trogarzo<sup>®</sup> (Ibalizumab-uiyk) refers to the humanized monoclonal antibody ibalizumab for the treatment of multidrug-resistant HIV-1 infection; Trogarzo<sup>®</sup> is a registered trademark of TaiMed Biologics, Inc. and is under licence to us for use in the United States, Canada and the European Union.
- *THERA Patient Support*<sup>®</sup> is our registered trademark in the United States and it refers to our patients and physicians service desk providing support to these people in connection with our commercialized products.
- References to “\$” and “US\$” are to U.S. dollars and references to “CA\$” or “CAD” are to Canadian dollars;
- all information is provided as of February 24, 2020, except where otherwise stated.

## **FORWARD-LOOKING STATEMENTS**

This 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 expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the commercialization of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup>;
- our ability and capacity to grow the sales of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> successfully in the United States;
- our capacity to meet supply and demand for our products;
- the market acceptance of *EGRIFTA SV*<sup>™</sup> in the United States;
- the continuation of our collaborations and other significant agreements with our existing commercial partners and third-party suppliers and our ability to establish and maintain additional collaboration agreements;
- our success in continuing to seek and in maintaining reimbursement for *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> by third-party payors in the United States;

- the success and pricing of other competing drugs or therapies that are or may become available;
- our ability to protect and maintain our intellectual property rights in *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and tesamorelin;
- our success in obtaining reimbursement for Trogarzo<sup>®</sup> in countries of the European Union;
- our ability and capacity to launch Trogarzo<sup>®</sup> in countries of the European Union;
- our capacity to develop a new formulation of tesamorelin;
- our capacity to conduct a phase III clinical trial using tesamorelin for the treatment of NASH in the HIV-patient population and in the non-HIV population;
- our capacity to develop our oncology peptides and obtain positive results from our research and development activities using those peptides;
- our capacity to acquire or in-licence new products and/or compounds;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and
- our estimates regarding our capital requirements.

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:

- sales of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States will increase over time;
- our commercial practices in the United States, Canada and the countries of the European Union will not be found to be in violation of applicable laws;
- the long-term use of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> will not change their respective current safety profile;
- no recall or market withdrawal of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> will occur;
- no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States;
- the categorization of tesamorelin as a biologic will not have a material adverse effect on us;
- continuous supply of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> will be available;
- our relations with third-party suppliers of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> to meet market demand on a timely basis;
- no generic or biosimilar version of *EGRIFTA*<sup>®</sup> or *EGRIFTA SV*<sup>™</sup> will be approved by the United States Food and Drug Administration, or FDA;
- our intellectual property will prevent companies from commercializing generic or biosimilar versions of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> in the United States;
- Trogarzo<sup>®</sup> will be added to the list of reimbursed drugs by countries of the European Union;
- the FDA will approve a new formulation of tesamorelin;

- we will obtain positive feedback from the FDA regarding our proposed phase III clinical trial to develop tesamorelin for the treatment of NASH in the HIV-patient population;
- we will succeed in conducting our phase III clinical trial to develop tesamorelin for the treatment of NASH in the HIV-patient population;
- our research and development activities using peptides derived from our oncology platform will yield positive results;
- the data obtained from our market research on the potential market for Trogarzo® in the United States and in the European Union are accurate;
- our European infrastructure is adequate to launch Trogarzo® in key European countries; 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 statements 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 our risks in greater detail under “Item 3 - Risk Factors” (below) but additional risks and uncertainties, including those that we do not know about or that we currently believe are immaterial, may also adversely affect the forward-looking statements, our business, financial condition and prospects. 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.

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## SELECTED EVENTS IN FISCAL YEAR 2019 AND OUTLOOK

*The following summary highlights selected events that occurred in the fiscal year 2019 and our business objectives described elsewhere in this AIF for the fiscal year 2020. This summary does not contain all of the information about us and you should carefully read the entire AIF, including the section entitled “Risk Factors”.*

### Commercial Events

- *EGRIFTA SV™* became commercially available in the United States in November 2019;
- We listed our common shares on the U.S. NASDAQ stock market in October 2019;
- We terminated all of our distribution and licensing agreements with third parties regarding the distribution of *EGRIFTA®* and regained all of our worldwide distribution rights for this product from our commercial partners;
- We acquired a targeted oncology technology platform through the acquisition of Katana Biopharma Inc. in February 2019; and
- We appointed a general manager, Conor Walshe, to head our wholly owned subsidiary, Theratechnologies Europe Limited, based in Dublin, Ireland, and began recruiting and hiring employees to fill key positions.

### Regulatory Events

- In September 2019, the European Medicines Agency, or EMA, approved Trogarzo® for adults infected with multidrug-resistant HIV-1 for whom it is otherwise not possible to construct a suppressive antiviral regimen.

### Research and Development Events

- We received positive feedback from the FDA with respect to the development of our investigational peptide-conjugates, TH-1902 and TH-1904, and we aim to initiate one phase I clinical trial with TH-1902 by the end of 2020;
- *In vitro* and *in vivo* experiments demonstrated that TH-1902 improved efficacy and tolerability compared to docetaxel alone;
- In June 2019, we announced that we would pursue the development of tesamorelin for the treatment of NASH in people living with HIV.
- In April 2019, based on a study conducted by the Massachusetts General Hospital, or MGH,, we announced that tesamorelin reduced liver fat in HIV patients with non-alcoholic fatty liver disease.

### 2020 Business Objectives

- We intend to successfully continue growing our revenues in the United States from sales of *EGRIFTA®*, *EGRIFTA SV™* and Trogarzo®;
- We intend to successfully obtain reimbursement for Trogarzo® in key European countries;
- We intend to develop a new formulation of tesamorelin;



- We intend to initiate a phase III clinical trial using tesamorelin for the potential treatment of NASH in the HIV-patient population;
- We intend to pursue the development of our oncology platform and initiate a phase I clinical trial using TH-1902 in patients suffering from cancer by the end of 2020; and
- We intend to continue pursuing potential product acquisitions, in-licensing transactions complementary to our infrastructure, or other opportunities.

**1.1 NAME, ADDRESS AND INCORPORATION**

We were incorporated under Part IA of the *Companies Act* (Québec), or CAQ, on October 19, 1993 under the name Theratechnologies Inc. 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. 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. Finally, on June 21, 2011, we amended our articles to give the power to our directors to appoint a number of additional directors equal to 33.33% of the number of directors elected at the last shareholders meeting preceding any appointment.

On February 14, 2011, the CAQ was abrogated and replaced by the *Business Corporations Act* (Québec), or BCA, and companies governed by Part IA of the CAQ such as us became business corporations governed by the BCA. Accordingly, we did not have to file articles of continuation or amend our existing corporate articles. The BCA was applicable immediately without having to complete any formalities.

Our common shares are listed on the Toronto Stock Exchange, or TSX, under the symbol “TH” and on the U.S. NASDAQ stock market, or NASDAQ, under the symbol “THTX”. See Item 6.1 for a complete description of our authorized share capital.

Our head office and principal place of business are located at 2015 Peel Street, 11<sup>th</sup> Floor, Montreal, Québec, Canada H3A 1T8. Our phone number is (514) 336-7800. Our website is [www.theratech.com](http://www.theratech.com). The information contained on our website is not part of this AIF.

**1.2 SUBSIDIARIES**

As at February 24, 2020, Theratechnologies had the following five wholly owned subsidiaries:

- **Theratechnologies Europe Limited**, a company governed by the *Companies Act 2014* (Ireland). Theratechnologies Europe Limited is responsible to commercialize Trogarzo® in Europe;
- **Theratechnologies U.S., Inc.**, a company governed by the *Delaware General Corporation Law* (Delaware), provides the services of personnel to Theratechnologies Inc. for its activities in the United States;
- **Theratechnologies Intercontinental Inc.**<sup>1</sup>, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Intercontinental Inc., formerly Theratechnologies ME Inc., used to control the worldwide rights to commercialize *EGRIFTA*®, except in the United States, Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries, and Canada;
- **Theratechnologies Europe Inc.**<sup>1</sup>, a company governed by the *Business Corporations Act* (Québec). Theratechnologies Europe Inc., formerly 9176-5057 Québec Inc., used to control the rights to commercialize *EGRIFTA*® in Europe, Russia, South Korea, Taiwan, Thailand and certain central Asian countries; and
- **Pharma-G Inc.**<sup>1</sup>, a company governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.

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<sup>1</sup> We plan on winding-up those wholly owned subsidiaries into Theratechnologies Inc. in 2020.

## 2.1 OVERVIEW

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

Our vision is to grow our business to become a significant player in the pharma industry by making a difference in the lives of patients with special medical needs.

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

We currently commercialize three products: *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup>.

*EGRIFTA*<sup>®</sup> (tesamorelin for injection) was approved by the FDA in November 2010 and was launched in the United States in January 2011. *EGRIFTA*<sup>®</sup> was also approved by Health Canada in its 1 mg/vial presentation in March 2015 and was launched in Canada in June 2015. COFEPRIS, Mexico's health agency, also approved *EGRIFTA*<sup>®</sup> in its 1 mg/vial presentation in March 2016. *EGRIFTA*<sup>®</sup> is not commercialized in Mexico since it is not reimbursed. As of this date, we do not intend to commercialize *EGRIFTA*<sup>®</sup> in Mexico by ourselves.

*EGRIFTA*<sup>®</sup> is currently the only approved therapy in the United States for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and our organization has been commercializing this product in this country since May 1st, 2014.

In Canada, *EGRIFTA*<sup>®</sup> is also the only approved drug for the treatment of excess visceral adipose tissue, as assessed by waist circumference <sup>3</sup> 95 cm for men and <sup>3</sup> 94 cm for women, and confirmed by a visceral adipose tissue level of > 130 cm<sup>2</sup> by CT scan, in treatment-experienced adult HIV-infected patients. *EGRIFTA*<sup>®</sup> is marketed exclusively by us in this country but sales of *EGRIFTA*<sup>®</sup> are not material to our business.

*EGRIFTA SV*<sup>™</sup> is a new formulation of *EGRIFTA*<sup>®</sup> and was approved by the FDA in November 2018 and launched in the United States in November 2019. *EGRIFTA SV*<sup>™</sup> can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration.

Trogarzo<sup>®</sup> (ibalizumab-uiyk) injection was approved by the FDA in March 2018 and was made commercially available in the United States in April 2018. Trogarzo<sup>®</sup> was also approved by the EMA in September 2019 and is not yet commercially available in Europe, except through early access programs. Trogarzo<sup>®</sup> is under licence to us following our entering into an amended and restated distribution and marketing agreement, or TaiMed Agreement, with TaiMed Biologics, Inc., or TaiMed, pursuant to which we acquired the exclusive right to distribute and commercialize ibalizumab in Canada, in the United States, in Europe and in certain other countries.

In addition to the sale of our products, we are conducting research and development activities in the oncology field further to our acquisition of our oncology platform in February 2019. We are completing the pre-clinical work on two (2) peptide-conjugates, namely TH-1902 and TH-1904, which, amongst other things, are aimed at treating triple negative breast cancer and ovarian cancer. We plan on initiating a phase I clinical trial with TH-1902 by the end of 2020.

Research and development work is also being carried out to improve the current formulation of tesamorelin.

Finally, pending feedback from the FDA, we plan on beginning a phase III clinical trial using tesamorelin for the potential treatment of NASH in people living with HIV by the end of 2020 using a new formulation of tesamorelin currently under development.

## 2.2 THREE-YEAR HISTORY

### 2019

- *Preliminary Revenue Estimates for Fiscal 2019 and Revenue Guidance for Fiscal 2020.* On December 19, 2019, we issued preliminary consolidated revenue estimates of \$63.3 million for the fiscal year ended November 30, 2019 and consolidated revenue guidance ranging between \$83 and \$87 million for the fiscal year to end on November 30, 2020.
- *In Vitro and In Vivo Data on our Investigational Oncology Peptide-Conjugates Presented at Scientific Conference.* On December 13, 2019, we announced the results from *in vitro* and *in vivo* experiments using TH-1902, our proprietary peptide-conjugate, currently in pre-clinical development at the San Antonio Breast Cancer Symposium. Results showed that treatment using TH-1902, in combination with docetaxel, improved efficacy and has better tolerability over treatment with docetaxel alone. In addition, we also announced that we were aiming at initiating a phase I clinical trial using TH-1902 before the end of 2020.
- *Commercialization of EGRIFTA SV™ in the United States.* On November 25, 2019, we announced that EGRIFTA SV™ was commercially available in the United States.
- *Publication of NASH Study Results in The Lancet HIV Journal.* On October 11, 2019, we announced that results from a clinical trial conducted at the Massachusetts General Hospital on the effects of tesamorelin on non-alcoholic fatty liver disease, or NAFLD, in HIV-patients had been published in *The Lancet HIV Journal*.
- *Common Shares Listed on U.S. NASDAQ Stock Market.* On October 10, 2019, we announced that our common shares began trading on the U.S. NASDAQ stock market under the symbol “THTX”. The application to list on NASDAQ was filed on August 12, 2019.
- *Trogarzo® Approved by the EMA.* On September 26, 2019, we announced that the EMA approved Trogarzo® for commercialization in European Union countries.
- *Worldwide Distribution Rights of EGRIFTA® Regained.* On August 8, 2019, we announced the termination of all of our distribution and licensing agreements with our international commercial partners regarding their rights to distribute EGRIFTA® and, as a result, we regained all worldwide distribution rights to EGRIFTA®.
- *Change to our Board of Directors.* On August 7, 2019, we announced that Mr. Jean-Denis Talon retired from our board of directors after 18 years of directorship.
- *Tesamorelin to be Developed for the Treatment of NASH in HIV Patient Population.* On June 17, 2019, we announced that we would pursue the development of tesamorelin for the potential treatment of NASH

in people living with HIV. Our intent is to use a new formulation of tesamorelin currently under development.

- *Appointment of New Director.* On March 29, 2019, we announced the appointment of Ms. Sheila Frame as a new independent member to our board of directors.
- *EMA Issues Good Manufacturing Practice Certificates to WuXi.* On March 20, 2019, we announced that the EMA issued good manufacturing practice certificates to WuXi Apptec for its manufacturing sites of Trogarzo® in Wuxi City, China, and in Shanghai, China.
- *FDA Authorizes Study for a New Mode of Administration of Trogarzo®.* On March 4, 2019, we announced that we were informed by TaiMed that the FDA authorized a study protocol to evaluate an intravenous slow-push formulation of Trogarzo®.
- *Acquisition of Oncology Platform.* On February 25, 2019, we announced the acquisition of all of the issued and outstanding common shares of Katana BioPharma Inc., or Katana. Katana had exclusive worldwide rights through a licence agreement entered into with Transfer Plus L.P. to the development and commercialization of a targeted oncology technology platform. The technology platform uses peptides as a vehicle to deliver existing cytotoxic agents to sortilin receptors which are overexpressed in cancer cells.
- *Appointment of General Manager for our European Subsidiary.* On February 11, 2019, we announced the appointment of Mr. Conor Walshe as the general manager of our wholly owned subsidiary Theratechnologies Europe Limited (formerly Theratechnologies International Limited).
- *Appointment of New Chief Commercial Officer.* On December 3, 2019, we announced the appointment of Mr. Jovan Antunovic as our new Chief Commercial Officer further to the retirement of Ms. Lyne Fortin.

## 2018

- *FDA Approves F4 Formulation for EGRIFTA®.* On November 5, 2018, we announced that the FDA approved the supplemental new drug application, or sNDA, filed for the new single vial formulation, or F4 Formulation, of EGRIFTA®. The sNDA was filed in July 2018. The F4 Formulation is four times more concentrated than the 1mg/vial formulation currently being commercialized, thereby reducing the volume of injection, and is also stable at room temperature.
- *Trogarzo® Included in Treatment Issued by DHHS.* On October 29, 2018, we announced that Trogarzo® had been included in the most recent version of the treatment guidelines issued by the United States Department of Health and Human Services, or DHHS.
- *New Board Member at Theratechnologies.* On October 15, 2018, we announced that Mr. Gary Littlejohn was appointed as a new independent member to our board of directors.
- *Filing of MAA for Trogarzo® with EMA.* On August 28, 2018, we announced the filing of a marketing authorization application, or MAA, with the EMA to seek marketing approval of Trogarzo® in the European Union. Prior to filing the MAA, we obtained a decision from the EMA allowing us to defer the conduct of a pediatric investigation plan for Trogarzo® after the filing of the MAA. Prior to filing the MAA, we also obtained a decision from the Committee for Medicinal Products for Human Use, or CHMP, of the EMA that the MAA was eligible to be processed through the accelerated assessment procedure. The MAA is currently under review through the accelerated assessment procedure with a timeframe of

150 review days, which does not include the time required to answer questions which might be asked by the EMA. We received questions from the EMA on December 14, 2018 and submitted our answers on January 25, 2019. We expect a decision from the EMA in the second half of 2019.

- *Trogarzo® Included in Treatment Guidelines Issued by IAS.* On July 25, 2018, we announced that Trogarzo® was included in the most recent version of the treatment guidelines issued by the International Antiviral Society-USA Panel, or IAS. These guidelines state, among other things, that Trogarzo® may be useful as a fully active agent for patients with multi class-resistant virus. The full guidelines are available in the *Journal of the American Medical Association*, 2018; 320(4): 379-396.
- *US\$57.5 Million Notes Offering.* On May 30, 2018, we announced that we had entered into an underwriting agreement with a syndicate of underwriters pursuant to which those underwriters agreed to purchase US\$50 million aggregate principal amount of 5.75% convertible unsecured senior notes due June 30, 2023, or Notes, at a price of US\$1,000 per Note, or Offering. We also granted the underwriters an option to purchase up to an additional US\$7,500,000 aggregate principal amount of Notes. The closing of the Offering of the Notes occurred on June 19, 2018, and resulted in gross proceeds to us of US\$57,500,000.
- *Repayment of Long-Term Obligation to EMD Serono.* On May 30, 2018, we announced the entering into of an amendment to a termination and transfer agreement, or the EMD Serono Termination Agreement, with EMD Serono Inc., or EMD Serono, to repay our long-term obligations, then totaling US\$28.2 million in consideration of one lump sum payment of US\$23.8 million. The payment of US\$23.8 million was sourced from the Offering.
- *EGRIFTA® to be Studied in NAFLD-NASH Independent Study.* On May 11, 2018, we announced that the National Institutes of Health, or NIH, in the United States awarded a grant to the Massachusetts General Hospital to conduct a study using EGRIFTA® in non-HIV patients suffering from Non-Alcoholic Liver Disease and Non-Alcoholic Steatosis Hepatosis, or NAFLD-NASH.
- *Release by FDA From Post-Approval Studies for EGRIFTA®.* On May 1, 2018, we announced that the FDA released us from the conduct of a long-term observational safety study and a phase IV clinical trial to assess whether EGRIFTA® increased the incidence or progression of diabetic retinopathy in diabetic HIV-infected patients with lipodystrophy and excess abdominal fat. These two studies were mandated by the FDA upon the approval of EGRIFTA® in November 2010;
- *Ibalizumab Approved by FDA.* On March 6, 2018, we announced that the FDA approved ibalizumab for the treatment of human immunodeficiency virus type 1, or HIV-1, infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. Ibalizumab is commercialized in the United States under the tradename “Trogarzo” and was made commercially available on April 30, 2018.

## 2017

- *Ibalizumab Efficacy and Safety Results Presented at IDWeek 2017.* On October 4, 2017, we announced that an oral presentation regarding the 48-week efficacy and safety results for ibalizumab in patients infected with MDR HIV-1 would be presented. The 27 patients who completed the 24-week treatment period using ibalizumab during the phase III trial in the United States entered the expanded access program study where they continued to receive ibalizumab at 800 mg every two 2 weeks for up to 48 weeks. The viral suppression observed at week 24 was sustained through week 48; median viral load reduction from baseline was 2.5 log<sub>10</sub> at weeks 24 and 48. In the expanded access program study, 15 patients having an undetectable viral load at week 24 maintained suppression to week 48. In the

expanded access program, ibalizumab plus optimized background regimen was well tolerated. The most common adverse reactions noted with respect to the use of ibalizumab in the expanded access program were diarrhea, dizziness, nausea and rash.

- *FDA Inspection of Ibalizumab Manufacturing Facility.* On August 2, 2017, we announced that we had been notified by our partner, TaiMed, that the FDA completed the pre-licence inspection of WuXi AppTec Biopharmaceuticals Co., Ltd.'s facility, or WuXi, where ibalizumab is manufactured. The inspection was carried out from July 17, 2017 until August 2, 2017. We were informed by TaiMed that the FDA completed the inspection with no critical findings, although a series of observations were made requiring corrections by WuXi.
- *Results Presented at 9<sup>th</sup> IAS Conference on HIV Science.* On July 24, 2017, we announced that results on HIV susceptibility to ibalizumab and new findings for *EGRIFTA*<sup>®</sup> would be presented during poster sessions at the 9<sup>th</sup> IAS Conference on HIV Science in Paris, France. The data for ibalizumab showed no significant difference in susceptibility (measured by maximum percent inhibition or ICHALF MAX Fold Change) in patients HIV isolated that were either sensitive or resistant to other antiretroviral agents. With respect to *EGRIFTA*<sup>®</sup>, in a retrospective analysis of datasets from two, multicenter, randomized placebo-controlled trials using *EGRIFTA*<sup>®</sup> among HIV-infected adults with lipodystrophy, fat in trunk muscles decreased and trunk muscle area increased over 26 weeks in patients with excess visceral adipose tissue who showed a clinical response to *EGRIFTA*<sup>®</sup>.
- *Priority Review for Ibalizumab.* On June 30, 2017, we announced that we had been notified by our partner, TaiMed, that the FDA had accepted for review the BLA filed by TaiMed for ibalizumab as a treatment for MDR HIV-1 and that the FDA had granted priority review status for this BLA.
- *New Board Member at Theratechnologies.* On May 16, 2017, we announced that Ms. Dale Weil was elected as a new independent member to our board of directors.
- *BLA Filed for Ibalizumab.* On May 3, 2017, we announced that our partner, TaiMed, had completed the filing of the BLA to the FDA for ibalizumab seeking the treatment of MDR HIV-1.
- *European Commercialization Rights Acquired by Us.* On March 6, 2017, we announced that we had reached an agreement with TaiMed for the acquisition of the commercial rights to ibalizumab in the European Union countries as well as for Albania, Iceland, Israel Liechtenstein, Norway, Russia, Switzerland and Turkey. These territories are in addition to the territories of Canada and the United States of America for which we have the exclusive commercialization rights to ibalizumab as well.
- *Holding of Investment Community Meeting.* On March 1<sup>st</sup>, 2017, we announced that we had hosted a webcast meeting for the investment community, the purpose of which was to provide the investment community with our corporate strategy for the years to come and an updated guidance for the fiscal year 2017.
- *Additional Secondary Efficacy and Safety Endpoint Results for Ibalizumab.* On February 14, 2017, we announced that additional secondary efficacy and safety endpoint results from the 24-week ibalizumab phase III trial were presented at a late-breaker session at the 2017 Conference on Retroviruses and Opportunistic Infections. The new data showed that patients with MDR-HIV-1 infection experienced a mean increase in CD4<sup>+</sup> T cell of 48 cells/ $\mu$ L after 24 weeks of treatment with ibalizumab plus an optimized background regimen. These data supplemented previously reported findings, where 83% of patients achieved a <sup>3</sup> 0.5 log<sub>10</sub> decrease in viral load from baseline seven days after the single loading dose of 2000 mg of ibalizumab (primary endpoint) and a mean reduction in viral load of 1.6 log<sub>10</sub> over the 24 week treatment period with more than 48% of patients experiencing a viral load reduction of more than 2.0

log<sub>10</sub>. Patients enrolled in this phase III trial experienced a significant decrease in viral load after receiving a single loading dose of ibalizumab 2,000 mg intravenously in addition to their failing antiretroviral therapy (or no therapy). Viral load decreases were maintained during the 24-week trial. At the end of the treatment period, the proportion of study participants with undetectable viral load (HIV-1 <50 copies/mL) was 43% (mean viral load reduction of 3.1 log<sub>10</sub>) and 50% of patients had a viral load lower than 200 copies/ml. The safety results in this phase III trial were consistent with the ones previously observed in the phase IIb trial. Other than for one case of immune reconstitution inflammatory syndrome, an inflammatory response in HIV-infected patients that may be triggered after changing to more active antiretroviral therapy, no serious adverse events were considered to be related to ibalizumab. Most treatment-emergent adverse events reported were mild to moderate in severity. No notable trends in laboratory abnormalities were observed. Additionally, no anti-ibalizumab antibodies were detected in blood samples from patients.

### 2.3 OUR 2020 STRATEGY AND OBJECTIVES

Our strategy for value creation in 2020 is focused on: increasing sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States; developing a new formulation of tesamorelin which could be used for the treatment of lipodystrophy and for the potential treatment of NAFLD/NASH in patients living with HIV; beginning a phase III clinical trial for the potential treatment of NAFLD/NASH in patients living with HIV; and initiating a phase I clinical trial with our investigational peptide-conjugate TH-1902.

We will also continue to seek reimbursement for Trogarzo® in key European countries. Finally, we will continue to assess the market for potential product acquisitions or in-licensing transactions that would be complementary to our infrastructure.

Below is a table detailing our approved products and our pipeline.

Product	Indication (Potential Indication)	Phase of Development					Commercial and Development Status	
		Preclinical	Phase 1	Phase 2	Phase 3	Commercial		
HIV	TROGARZO®	MDR HIV-1	Commercialized in U.S.					On the market
	TROGARZO®	MDR HIV-1	Approved in E.U.					Seeking reimbursement
	TROGARZO® IV Slow Push	(MDR HIV-1)	Safety and pharmacokinetics (bioequivalence study)					In clinical study
	EGRIFTA®	HIV-associated lipodystrophy	Commercialized in U.S. and Canada					On the market
	EGRIFTA SV™	HIV-associated lipodystrophy	Commercialized in U.S.					On the market
	EGRIFTA F8	(NASH-HIV)	Bioequivalence study initiated					FDA meeting requested
Oncology	TH-1902	(Triple Negative Breast Cancer (TNBC))	Preclinical					Toxicity Program and Manufacturing Scale-up
	TH-1904	(Ovarian Cancer)	Preclinical					Toxicity Program and Manufacturing Scale-up



**Our Approved Products*****EGRIFTA® (tesamorelin for injection)***

*EGRIFTA®* (tesamorelin for injection) 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).

*EGRIFTA®* 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®*, 1 ml is retrieved from each vial into one syringe to prepare a single 2 ml patient self-administered subcutaneous injection. *EGRIFTA®* is injected under the skin into the abdomen once a day.

*EGRIFTA SV™* was approved by the FDA in November 2018 and was launched in the United States in November 2019. *EGRIFTA SV™* is a new formulation of *EGRIFTA®*. *EGRIFTA SV™* comes in a single vial, has a higher concentration, can be stored at room temperature and results in a smaller volume of administration.

***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.

In HIV-infected patients, lipodystrophy may be caused by the viral infection itself, the use of antiretroviral therapy (not class-specific), or both. 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 and markers of disease severity, including higher pre-antiretroviral treatment viral load. Other factors include age, genetics, and gender.

***Tesamorelin***

Tesamorelin is the active peptide comprising *EGRIFTA®* and *EGRIFTA SV™*. 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.

## *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.

### **Trogarzo® (ibalizumab-uiyk) Injection**

Trogarzo® is a CD-4 directed post-attachment HIV-1 inhibitor. Trogarzo® was approved by the FDA on March 6, 2018 and was made commercially available to patients in the United States on April 30, 2018. In the United States, Trogarzo® is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. Since its approval, Trogarzo® was included in the treatment guidelines issued by the IAS and the treatment guidelines issued by the DHHS. In addition, effective January 1, 2019, in order to facilitate the reimbursement of Trogarzo® for physicians, the Centers for Medicare and Medicaid Services assigned a specific J-Code to Trogarzo®: J-1746.

Trogarzo® is available in the United States as a single dose, 2 mg/vial containing 200 mg of ibalizumab-uiyk. Trogarzo® is administered intravenously after diluting the appropriate number of vials in 250 ml of 0.9% Sodium Chloride Injection, USP. Patients receive a single loading dose of 2,000 mg followed by a maintenance dose of 800 mg every two weeks.

Trogarzo® was also approved by the EMA on September 26, 2019. In Europe, Trogarzo® is indicated for the treatment of adults infected with multi-drug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen.

Trogarzo® is currently not commercially available in Europe, except through early access programs in a few countries, as we work on obtaining reimbursement in key European countries. We anticipate launching Trogarzo® sequentially in countries where the product will be reimbursed.

Trogarzo® was developed by TaiMed and is under licence to us. See “TaiMed Agreement” below.

## *Mechanism of Action*

Unlike other antiretroviral agents, Trogarzo® binds primarily to the second extracellular domain of the CD4 receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents the HIV virus from infecting CD4<sup>+</sup> immune cells while preserving normal immunological function. Trogarzo® is active

across all major HIV clades and irrespective of tropism. No drug-drug interactions and no cross-resistance with other antiretroviral therapies, or ART, were noted during the clinical trials.

## 2.5 **COMMERCIALIZATION ACTIVITIES**

### ***EGRIFTA® and EGRIFTA SV™ - United States***

#### *General*

Since May 1, 2014, we are responsible for the commercialization of *EGRIFTA®* (tesamorelin for injection) in the United States after regaining our commercialization rights to *EGRIFTA®* pursuant to the EMD Serono Termination Agreement.

*EGRIFTA SV™* was made commercially available in the United States in November 2019. Since the launch of *EGRIFTA SV™*, physicians and patients are encouraged to use this new formulation.

#### *Manufacturing*

We do not own or operate commercial scale manufacturing facilities for the production of *EGRIFTA®* and *EGRIFTA SV™*, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party service providers, Bachem Americas, Inc., or Bachem, and Jubilant HollisterStier, General Partnership, or Jubilant, for all of our required raw materials, drug substance and finished product for commercial sale and clinical trials, if any, and we have entered into supply agreements with those two third-party service providers.

We currently manufacture *EGRIFTA®* in a 1 mg/vial formulation and *EGRIFTA SV™* in a 2 mg/vial formulation. Two vials of *EGRIFTA®* are required to administer the recommended dose of 2 mg; whereas *EGRIFTA SV™* only requires one vial to administer a bioequivalent dose of 1.4 mg. Given its higher concentration, *EGRIFTA SV™* results in a lower volume of administration.

#### *Active Pharmaceutical Ingredient*

We have an agreement with Bachem, an American subsidiary of Swiss-based Bachem AG, providing for the manufacture and supply of the active pharmaceutical ingredient of tesamorelin, or API, for *EGRIFTA®* and *EGRIFTA SV™* for commercial sale in the United States and in Canada (*EGRIFTA®* only) as well as for clinical programs. Bachem is our only validated supplier of raw materials. The price of tesamorelin manufactured by Bachem has been set under our agreement and is not subject to volatility. See “Item 9 - Material Contracts” below.

#### *Finished Product*

We have an agreement with Jubilant providing for the manufacture and supply of the finished form of *EGRIFTA®* and *EGRIFTA SV™* for commercial sale in the United States and in Canada (*EGRIFTA®* only) and for tesamorelin in connection with clinical programs. Under our agreement, Jubilant must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions. See “Item 9 - Material Contracts” below.

#### *Injection Tool Kit*

In connection with the sale of *EGRIFTA®* and *EGRIFTA SV™*, we decided to provide patients with the necessary devices to administer *EGRIFTA®* and *EGRIFTA SV™*. These devices are comprised of syringes, needles and water for injection. We have entered into supply agreements with third parties for the supply of syringes, hypodermic

needles and sterile water for injection. The packaging of those devices is done through third-party service providers.

### *Distribution*

In connection with the commercialization of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> in the United States, we have entered into various agreements with third-party service providers to distribute our products to patients. The distribution of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> is tightly controlled and is only available through certain selected pharmacies. Below is a summary of our agreements entered into with our third-party service providers forming part of the supply chain of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>.

#### *Logistic Service Provider and Distributor*

On November 1<sup>st</sup>, 2017, we entered into an amended and restated master services agreement with Rx Acquisition Company, LLC, or RxCrossroads, along with two amended and restated statements of work, or RxCrossroads Agreements. Under the terms of the RxCrossroads Agreements, RxCrossroads acts as our exclusive third-party logistic service provider for all of our products in the United States and as such, provides us with warehousing and logistical support services, including inventory control, account management, customers support, product return management and fulfillment of orders.

Under the RxCrossroads Agreements, RxCrossroads also acts as our exclusive third-party distributor of our products in the United States. In such role, RxCrossroads purchases products from us and takes title thereto. RxCrossroads' purchases of our products are triggered by its expectations of market demand for them over a certain period of time. RxCrossroads fulfills orders received from authorized wholesalers and, with respect to *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>, delivers it directly to that authorized wholesaler's client, namely a specialty pharmacy forming part of our network of specialty pharmacies. See "Item 9 - Material Contracts" below.

#### *Wholesalers*

Our supply chain of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> in the United States is comprised of a limited number of wholesalers through which specialty pharmacies we have contracted with can order *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>. These wholesalers accept purchase orders from those specialty pharmacies, purchase *EGRIFTA*<sup>®</sup> or *EGRIFTA SV*<sup>™</sup> from RxCrossroads and resell any of those two products to these specialty pharmacies. Our wholesalers do not handle the physical delivery of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>. The shipping and delivery of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> to those specialty pharmacies is handled by RxCrossroads. To date, we have agreements in place with the following wholesalers for *EGRIFTA*<sup>®</sup>: H.D. Smith, LLC., Cardinal Health, McKesson Corporation, Morris & Dickson Co., LLC, and Cesar Castillo, Inc. We are currently amending some of those agreements to include *EGRIFTA SV*<sup>™</sup>. For a description of these agreements, see "Item 9 - Material Contracts" below.

#### *Specialty Pharmacies*

We have entered into agreements with various specialty pharmacies across the United States providing them with the right to order *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> from our authorized wholesalers and distribute *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> to patients in the United States through their networks of local pharmacies.

In addition, a limited number of those specialty pharmacies are allowed to purchase *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> directly from RxCrossroads for redistribution within their own retail specialty pharmacy stores.

## ***EGRIFTA® - Canada***

### *General*

*EGRIFTA®* was approved for commercialization in Canada on April 30, 2014 in its 2 mg/vial presentation and, on March 30, 2015, in its 1 mg/vial presentation. No filing has been made in Canada to seek the approval of *EGRIFTA SV™*.

We have been commercializing *EGRIFTA®* in Canada since June 2015 using our internal team.

*EGRIFTA®* is not reimbursed in any of the provinces of Canada. However, *EGRIFTA®* is available in Canada to cash-paying patients and those with certain types of private insurance plans.

The supply chain and commercialization process of *EGRIFTA®* in Canada is described below.

### *Manufacturing*

The manufacturing components of *EGRIFTA®* for commercialization in Canada are made by Bachem and Jubilant under the same agreements as those of the United States. The sterile water for injection is purchased off-the-shelf from a distributor. Since sterile water for injection is easily available in Canada, no formal agreement has been entered into with a third-party supplier.

On March 30, 2015, we entered into a packaging agreement with a third party supplier. Under this agreement, such supplier is responsible to label the vials of *EGRIFTA®* and place them in boxes ready for shipping and to package syringes, needles, sterile water for injection and patients inserts in the boxes ready for shipping. The agreement was scheduled to terminate on March 30, 2018 and has since been renewed for one-year terms. This agreement renews automatically for one-year terms unless a party gives the other party written notice of its intent not to renew the agreement. Such written notice must be given to the other party at least 90 days prior to the expiration of the agreement. To date, we have not issued nor received any such notice.

### *Distribution*

The distribution of *EGRIFTA®* in Canada is made through McKesson Specialized Distribution Inc., or McKesson Distribution, an affiliate of McKesson Canada Corporation, or McKesson Canada. McKesson Distribution purchases *EGRIFTA®* from us, resells and distributes it to Canadian pharmacies which form part of its network. McKesson Canada provides us with various other services related to the commercialization of *EGRIFTA®* in Canada.

### ***EGRIFTA® - Other Territories***

*EGRIFTA®* is approved in Mexico but is not commercialized in such country since it is not reimbursed. In 2019, we have terminated all of our distribution and licensing agreements with third parties granting those third parties the exclusive right to commercialize *EGRIFTA®* in various territories of the world, including Latin America, Africa, the Middle East, the European Union countries and South Korea. As a result, we currently own all of the worldwide rights to *EGRIFTA®*. The termination of those agreements was part of our strategy to ensure that we would have all of the worldwide rights to commercialize *EGRIFTA®* if we develop tesamorelin for the potential treatment of NASH in the HIV-patient population.

## Trogarzo®

### *General*

On March 18, 2016, we entered into a distribution and marketing agreement with TaiMed and, on March 6, 2017, we amended and restated the TaiMed Agreement, as further amended on November 6, 2018. Pursuant to the terms of the TaiMed Agreement, we have the exclusive rights to commercialize Trogarzo® in the United States, in Canada, in the European Union countries as well as in Albania, Iceland, Israel, Liechtenstein, Norway, Russia, Switzerland and Turkey, or, collectively, European Territory.

Effective November 5, 2019, we re-amended the TaiMed Agreement to set forth some of the obligations of the parties in connection with the payment of expenses and the delivery terms of Trogarzo® in the European Territory.

Under the TaiMed Agreement, TaiMed is responsible for all development activities regarding ibalizumab. TaiMed is also responsible to manufacture and supply Trogarzo® to us for each territory/country covered by the TaiMed Agreement. Since TaiMed has no manufacturing facility, TaiMed has subcontracted the manufacture of Trogarzo® to WuXi Apptec Biologics, Inc., or WuXi. However, TaiMed has indicated to us that it began the construction of its own manufacturing facility with the aim of manufacturing Trogarzo®.

The TaiMed Agreement will expire on a country-by-country basis 12 years after marketing approval for ibalizumab has been obtained in each country, unless earlier terminated. The TaiMed Agreement contains customary representations and warranties, indemnification provisions and other provisions customarily found in agreements of this nature. In the last fiscal year, we met the minimum sales requirement under the TaiMed Agreement and there exists no more minimum sales requirement under the TaiMed Agreement.

### *North American Territory – Terms and Conditions*

In Canada, we are responsible, but under no obligation, to seek the approval of Trogarzo® from Health Canada. No filing seeking the approval of Trogarzo® has been made in Canada and no decision has been taken yet regarding a filing in Canada.

In the United States, Trogarzo® was approved by the FDA on March 6, 2018.

We are responsible for all regulatory activities, regulatory filings and communications with Health Canada, if any, and with the FDA, in addition to all commercialization activities in the North American Territory.

The transfer price for sales of Trogarzo® in Canada and in the United States has been determined at 52% of its net selling price.

Under the terms of the TaiMed Agreement, we agreed to make the following payments to TaiMed in consideration of the rights granted to us in the North American Territory:

- a cash payment of US\$1,000,000, which cash payment was made on the execution of the TaiMed Agreement in March 2016; and
- a payment of US\$4,000,000 through the issuance of common shares and such payment was made after the first commercial sale of Trogarzo® in the United States.

The US\$4,000,000 payment was made on May 15, 2018, and resulted in the issuance of 1,463,505 common shares to TaiMed.

Furthermore, we agreed to make the following one-time milestone payments to TaiMed based on the net sales of Trogarzo® in the North American Territory:

- US\$7,000,000 in two annual equal installments once net sales reached an aggregate amount of US\$20,000,000 over four consecutive Theratechnologies's financial quarters. The first installment of US\$3,500,000 was paid in July 2019;
- US\$10,000,000 once annual net sales will have reached US\$200,000,000 in any of our financial year;
- US\$40,000,000 once annual net sales will have reached US\$500,000,000 in any of our financial year; and
- US\$100,000,000 once annual net sales will have reached US\$1,000,000,000 in any of our financial year.

We also agreed to pay TaiMed a development milestone of US\$3,000,000 upon the first commercial sale in the North American Territory of a bi-weekly intramuscular, subcutaneous or intravenous-push (either fast or slow) injection formulation. This milestone will be payable in two annual equal installments of US\$1,500,000 each, with the first one being paid 30 days after the first sale of such new formulation in the North American Territory, while the second one will be paid 12 months thereafter.

We also agreed to pay TaiMed an additional development milestone as a result of the potential conduct by TaiMed of a phase III trial using Trogarzo® with a once every four-week intramuscular, subcutaneous or intravenous-push (either fast or slow) injection formulation. This development milestone would be equal to 50% of all costs associated with the development and approval of such new formulation, subject, however, to a maximum of US\$50,000,000. We need to agree with TaiMed on the amount of the milestone after taking into consideration the size of the market for this new formulation of Trogarzo® and the market exclusivity related thereto. The TaiMed Agreement contains a provision dealing with a disagreement between the parties on the determination of the amount of this development milestone. This development milestone would be paid quarterly, based on a percentage of net sales then generated by the sale of Trogarzo® using this new formulation, and would include a payment of interest on the principal.

#### *Distribution*

We began the distribution of Trogarzo® at the end of April 2018.

##### *Logistic Service Provider and Distributor*

RxCrossroads acts as our exclusive third-party logistic service provider and exclusive third-party distributor in the United States under the RxCrossroads Agreements.

##### *Specialty Pharmacies*

We have entered into agreements with specialty pharmacies and infusion therapy providers that had a large U.S. network capable of handling drug products whose administration is made intravenously. These specialty pharmacies have the capacity to deliver Trogarzo® to patients, physicians or infusion centers. Each of those specialty pharmacies purchase Trogarzo® from RxCrossroads and deliver it to infusion centers, physicians or patients for home-infusion. Patients are administered Trogarzo® at infusion centers, at physicians' offices or at home with the assistance of nurses.

To provide these services to patients, we entered into agreements with Accredo Health Group, Inc., or Accredo, Option Care Enterprises, Inc., or Option Care, Priority Healthcare Distribution, Inc., or Curascript, and Walgreen Co., or Walgreen. For a description of these agreements, see "Item 9 -Material Contracts" below.

Accredo and Option Care are specialty pharmacies that provide home-infusion services. Curascript is a specialty pharmacy that can deliver Trogarzo® to physicians and Walgreen is a specialty pharmacy.

#### *European Territory – Terms and Conditions*

In the European Territory, Trogarzo® was approved by the EMA on September 26, 2019. We are responsible for all regulatory activities, including regulatory filings and communications with the EMA, in addition to all commercialization activities.

The transfer price for sales occurring in a country forming part of the European Territory is set at (i) 52% of the net selling price of Trogarzo® in such country on annual net sales in such country up to, or equal to, US\$50,000,000 and (ii) an amount equal to 57% of the net selling price of Trogarzo® in such country on the portion of annual net sales of Trogarzo® in the European Territory that exceeds annual net sales of Trogarzo® in the European Territory of US\$50,000,000.

Under the terms of the TaiMed Agreement, we agreed to issue to TaiMed 906,077 common shares in consideration of the rights granted to us in the European Territory. The common shares were issued on March 17, 2017.

Furthermore, we agreed to make the following one-time milestone payments to TaiMed based on the net sales of Trogarzo® in the European Territory:

- US\$10,000,000 to be paid in two annual equal installments upon the date of the first commercial sale of Trogarzo® in the European Territory. The first installment of US\$5,000,000 is payable twelve (12) months after the first commercial sale of Trogarzo® in the European Territory, whereas the second installment of US\$5,000,000 is payable twelve (12) months after first achieving aggregate net sales of US\$50,000,000 in the European Territory over four (4) consecutive Theratechnologies' financial quarters;
- US\$10,000,000 upon achieving aggregate net sales of Trogarzo® of US\$150,000,000 over four consecutive financial quarters (based on our fiscal year);
- US\$20,000,000 upon achieving aggregate net sales of Trogarzo® of US\$500,000,000 over four consecutive financial quarters (based on our fiscal year); and
- US\$50,000,000 upon achieving aggregate net sales of Trogarzo® of US\$1,000,000,000 over four consecutive financial quarters (based on our fiscal year).

#### *Distribution*

We will be responsible for the importation of Trogarzo® into the European Territory and its distribution will be made through third parties. Trogarzo® will be supplied to us by TaiMed in brite stock form. We will be responsible for quality testing and release of the Product to the market and for its packaging and labeling. We intend to follow the North American Territory distribution model in the European Territory in that we will sell Trogarzo® to one distributor that will resell it to end-users. We are currently finalizing the negotiations of commercial agreements with our proposed third-party suppliers in relation to the distribution of Trogarzo® in the European Territory.

#### **Marketing and Sales of Our Products**

##### *North American Territory*

Our marketing and sales activities in the United States for *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® are conducted from our head office in Montreal, Québec, Canada. We have also retained the services of Syneos Health, or Syneos, to assist us with sales activities in the United States. Syneos is a recognized provider of



commercial, clinical and consulting services around the globe. We have renewed our agreement with Syneos and we entered into an amendment to our amended and restated master service agreement in this respect as of February 3, 2020, or Syneos Agreement, pursuant to which Syneos will continue providing us with various services in connection with the commercialization of *EGRIFTA*<sup>®</sup>, *EGRIFTA SVTM* and Trogarzo<sup>®</sup> in the United States. In addition, we sometimes retain Syneos and other third parties for certain marketing activities.

The services currently provided by Syneos comprise a sales force team fully dedicated to *EGRIFTA*<sup>®</sup>, *EGRIFTA SVTM* and Trogarzo<sup>®</sup>, a medical science liaison team solely assigned to our medical activities, a managed market team solely dedicated to the reimbursement of our products with both public and private payors.

The Syneos Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions. The Syneos Agreement is scheduled to expire on November 30, 2021, unless earlier terminated.

Last year, we have contracted with Asembia, LLC, or Asembia, for the provision of services related to a call center. The call center, *THERA Patient Support*<sup>®</sup>, guides physicians and patients through the process of initiating treatment under reimbursement. This process, which can be complex and time-consuming, begins with a referral and concludes with the final reimbursement decision. *THERA Patient Support*<sup>®</sup> also helps patients adhering to their treatment and answering questions about our products. See “Item 9 – Material Contracts” below

In Canada, the commercialization of *EGRIFTA*<sup>®</sup> is conducted internally. Trogarzo<sup>®</sup> is not approved in Canada since no filing has been made with Health Canada to seek its approval.

In addition, McKesson Canada provides the services of a call center, *EGRIFTA Support*<sup>®</sup>, which guides physicians and patients through the process of initiating treatment with *EGRIFTA*<sup>®</sup>, which answers questions patients may have regarding *EGRIFTA*<sup>®</sup> and which helps patients with the reimbursement process with their private insurance providers.

#### *European Territory*

##### *EGRIFTA*<sup>®</sup> and *EGRIFTA SVTM*

*EGRIFTA*<sup>®</sup> and *EGRIFTA SVTM* are not approved in Europe.

##### *Trogarzo*<sup>®</sup>

Thera International has focused its efforts on obtaining reimbursement for Trogarzo<sup>®</sup> in key European countries and it is anticipated that Trogarzo<sup>®</sup> will be launched sequentially as public reimbursement is obtained in individual countries.

Thera International has also retained the services of Syneos who provide medical science liaison personnel for Italy, France and Germany.

## **2.6 RESEARCH AND DEVELOPMENT ACTIVITIES**

### ***EGRIFTA*<sup>®</sup> and Tesamorelin**

#### *F8 Formulation*

We are currently working on the development of a new formulation of *EGRIFTA*<sup>®</sup>, or F8 Formulation. The F8 Formulation would be eight times more concentrated than the current *EGRIFTA*<sup>®</sup> formulation and twice as

concentrated as the *EGRIFTA SV*<sup>TM</sup> formulation. The F8 Formulation would have a number of advantages for the patients over the previous *EGRIFTA*<sup>®</sup> formulations: (1) it would be presented in a multidose vial that would be reconstituted once per week; (2) it would be stable at room temperature, even once reconstituted; and (3) the volume of administration is expected to be smaller, approximately 0.2 ml. We initiated the conduct of a bioequivalence study to further the development of this new formulation. If the development of the F8 Formulation is successful and if approved by regulatory authorities, the F8 Formulation could be used for the treatment of HIV-associated lipodystrophy in territories where *EGRIFTA*<sup>®</sup> has already been approved.

#### *Tesamorelin for NASH in HIV-Patient Population*

On June 17, 2019, we announced that we would move forward with the development of tesamorelin for the potential treatment of NASH in patients living with HIV using the F8 Formulation. This decision was made following the results of the study conducted by Dr. Steven Grinspoon of the Massachusetts General Hospital, or MGH, evaluating the safety and efficacy of tesamorelin in the treatment of HIV-infected patients suffering from NAFLD - NASH. The study sought to determine the effects of tesamorelin on liver fat, inflammation, fibrosis, and hepatocellular damage seen in conjunction with NASH.

The 12-month randomized, double-blind, placebo-controlled clinical trial enrolled a total of 61 men and women with HIV infection and hepatic fat fraction <sup>35%</sup>, assessed by magnetic resonance spectroscopy; 31 patients were randomized in the tesamorelin group while 30 patients were enrolled in the placebo group. At baseline, patients enrolled in the study had hepatic fat levels of 13.8%. In total, 43% of patients had fibrosis as assessed by liver biopsies.

The results of the study showed a statistically significant difference in the progression of fibrosis for patients in the tesamorelin arm. In the tesamorelin group, only 10.5% of patients experienced progression of liver fibrosis compared to 37.5% in patients receiving a placebo (p=0.04). Previously released data showed that in patients on tesamorelin, liver fat decreased by 32% while it increased by 5% in placebo patients, from baseline, (p=0.02), amounting to a 37% relative reduction in liver fat. Furthermore, 35% of patients in the tesamorelin group returned to liver fat values below 5% in comparison to only 4% of patients on placebo (p=0.007).

Exploratory analyses showed that the higher the baseline NASH score was, the more change was seen among the tesamorelin-treated individuals (r=-0.48, P=0.04), whereas a similar relationship was not observed in the placebo group (r=-0.14, P=0.52).

The results of the study were published in October 2019 in *The Lancet HIV Journal*.

NAFLD includes nonalcoholic fatty liver, or NAFL, NASH and NASH cirrhosis. NAFLD is the leading cause of liver diseases in the Western world (Central Europe and United States). As the global epidemic of obesity fuels NAFLD prevalence, NASH has become one of the most common liver disorders. In the absence of approved therapies, NASH remains widely untreated, and has become a critical public health concern with high unmet medical needs.

Without therapeutic intervention, NASH can cause the development of fibrosis, which is the accumulation of non-functional scar tissue, as the body tries to heal itself.

Because this build-up leads to tissue remodeling, development of fibrosis leads to progressive loss of liver function which may ultimately progress to life-threatening conditions such as cirrhosis, liver cancer and ultimately liver failure, a stage where patients have no other choice than undergoing a liver transplantation.

In addition to its deleterious effects on the liver, NASH multiplies the risk of a patient developing cardiovascular problems (myocardial infarction, stroke and peripheral vascular accident).

This contributes to higher mortality rates in NASH patients, and cardiovascular disease is the leading cause of death in NASH patients.

HIV-infected patients are at higher risk of NAFLD than the general population as a result of multiple cofactors, including lifelong use of antiretrovirals, HIV itself, host factors and highly prevalent metabolic comorbidities. The reported prevalence of NAFLD ranges from 13% to 65% in HIV-monoinfected patients. Moreover, NASH and significant liver fibrosis may be at least twice as frequent in HIV-monoinfected patients as in the general population.

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

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

We have filed a demand for a Type C meeting with the FDA to discuss the opportunity for Theratechnologies to develop tesamorelin for the treatment of NASH with liver fibrosis in the HIV population. We expect a response from the FDA in the second quarter of 2020.

We have also filed a request for a CHMP Scientific Advice with the EMA in order to assess the development of tesamorelin for the treatment of NASH with liver fibrosis in the HIV population. We expect a decision from the CHMP in the first half of 2020.

Based on the feedback received from either of these regulatory agencies, assuming it is positive, we will then complete our protocol for our intended phase III clinical trial related to the development of tesamorelin for the treatment of NASH with liver fibrosis in the HIV population.

## **Oncology Platform**

### *Acquisition of Oncology Platform*

On February 25, 2019, we acquired all of the issued and outstanding common shares of Katana Biopharma Inc., or Katana, a company who had the exclusive worldwide rights, through a licence agreement, or Licence Agreement, with Transfert Plus, LP, or Transfert Plus, to a technology platform using peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells. Katana was subsequently wound-up into Theratechnologies in May 2019.

The maximum purchase price, or Purchase Price, for all of the issued and outstanding common shares of Katana was set at CAD 7,980,000 and was payable as to a maximum of CAD 2,600,000 in cash and through the issuance of common shares on the closing date, or Up-Front Payment, subject to an upward adjustment aggregating CAD 1,080,000 upon obtaining a subsidy, or Subsidy, from a Québec-based governmental agency to pursue the research and development work on the oncology platform, and at later dates through the issuance of common

shares based on the attainment of two development milestones. The first development milestone of CAD 2,000,000, or Second Installment, is payable on the date that a phase I clinical trial is initiated using one of the peptides developed through the oncology platform and the second development milestone of up to CAD 3,000,000, or Third Installment, is payable upon our decision to pursue the development of the peptide studied in the phase I clinical trial if the results of such study warrant the pursuit of its development.

On the closing date, we paid to Katana's shareholders the Up-Front Payment as to CAD 2,592,800 in cash and issued 900 common shares having an aggregate value of CAD 7,200. The Subsidy was subsequently obtained and, in October 2019, we paid an amount of CAD 500,000 in cash to the former Katana's shareholders.

The balance of the payment resulting from the receipt of the Subsidy (CAD 580,000) will be paid through the issuance of common shares simultaneously to the payment of the Third Installment.

#### *Description of Licence Agreement*

Under the License Agreement, Katana (now Theratechnologies) obtained the exclusive worldwide rights to develop, make, have made, use, sell, offer to sell, distribute, commercialize and import the technology related to the technology platform that uses peptides as a vehicle to deliver existing cytotoxic agents to sortilin receptors which are overexpressed on cancer cells.

Annual maintenance fees amount to CAD 25,000 for the first five (5) years and CAD 100,000 thereafter, until royalties become payable beginning with the first commercial sale of a product developed using the licensed technology.

The royalties payable under the License Agreement vary between 1% and 2.5% on net sales of a product based on the licensed technology. If we enter into a sublicense agreement, we must then pay amounts varying between 5% and 15% of revenues received from such sublicense agreement. The percentage varies based on the timing of the entering into of such a sublicense agreement.

We must also pay Transfert Plus the following milestone payments upon the occurrence of the following development milestones for the first product developed in the field of oncology:

- (i) first milestone payment: CAD 50,000 upon the successful enrolment of the first patient in the first phase I clinical trial;
- (ii) second milestone payment: CAD 100,000 upon the successful enrolment of the first patient in the first phase II clinical trial;
- (iii) third milestone payment: CAD 200,000 upon the successful enrolment of the first patient in the first phase III clinical trial.

Also, we must pay CAD 200,000 for each product upon receiving the first approval for such product by a regulatory authority. The approval shall entitle the holder thereof to commercialize the product in the territory in which the approval was obtained.

We must also pay Transfert Plus the same milestone payments upon the occurrence of any of those development milestones for the first product developed outside the field of oncology.

#### *Research and Development Activities*

To date, we are studying two proprietary compounds derived from our oncology platform, TH-1902 (conjugated with docetaxel) and TH-1904 (conjugated with doxorubicin), for the potential treatment of various types of cancer, including breast cancer, ovarian cancer and lung cancer.

Sortilin, or SORT1, is a newly identified receptor that plays a role in carrying large molecules across the cell membrane. It was discovered that SORT1 is overexpressed in ovarian, triple-negative breast, skin, lung, colorectal and pancreatic cancers, among others. SORT1 plays a significant role in protein internalization, sorting and trafficking via the endocytosis mechanism making it an attractive target for drug development.

Peptides derived from our oncology platform target SORT1 positive cancer cells by linking commercially available anticancer drugs, like docetaxel, doxorubicin or tyrosine kinase inhibitors, to SORT1.

We believe that the conjugation of already commercialized anti-cancer agents, with already proven efficacy, to our peptides to specifically target cancer cells could potentially improve the efficacy and safety of those anti-cancer agents.

Results from *in vitro* and *in vivo* experiments demonstrated that TH-1902 (when combined with docetaxel) improves efficacy and tolerability compared to docetaxel alone. We presented the following conclusions on the use of TH-1902 for the potential treatment of triple negative breast cancer, or TNBC, at the San Antonio Breast Cancer Symposium:

- Stronger and sustained inhibition of TNBC tumor growth in mice treated with TH-1902 when using equimolar doses of TH-1902 and docetaxel;
- Efficacy improved significantly over full dose of docetaxel, even with conjugate administered at a quarter of the dose of docetaxel;
- Very low level of free docetaxel found in the blood when conjugated to TH-1902;
- No significant side effects, weight loss or neutropenia observed *in vivo*;
- Absence of neutropenia after six consecutive treatments with TH-1902 while neutrophil counts decreased after only one treatment with non-conjugated docetaxel.

TH-1904 is also another investigational peptide aimed at carrying anti-cancer agents to SORT1 positive cancer cells.

*In vitro* and *in vivo* experiments using TH-1904 demonstrated results similar to the ones obtained with TH-1902 and confirmed that our new technology is a platform that could lead to a number of compounds that could help in the fight against cancer.

Based on feedback received from the FDA, we plan on completing the pre-clinical program for TH-1902 and on initiating a phase I clinical trial by the end of 2020 in TNBC or other types of cancer, including ovarian cancer, breast cancer or colon cancer. We will also pursue the development of TH-1904 as soon as pre-clinical work and manufacturing scale-up are completed.

#### *Slow-Push Formulation of Trogarzo®*

TaiMed has begun the recruitment of patients to test a new method of administering the intravenous formulation of Trogarzo®. The study consists of assessing the safety and pharmacokinetic levels of Trogarzo® when administered directly, without dilution as it is presently administered, in the vein of the patient over a 30 second period. This new approach of administering Trogarzo® should make it easier and faster for a clinic to administer the treatment as well as making it faster for the patient to receive the treatment.

## 2.7 COMPETITION

### ***EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>**

We are not aware of other GRF products indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy being commercialized. However, we are aware that we face indirect competition for *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup> from other drugs, such as human growth-hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin that may be prescribed by physicians. To our knowledge, 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 or Health Canada. Other approaches to reduce excess abdominal fat include coping mechanisms such as lifestyle modification (diet and exercise), switching antiretroviral therapy, or liposuction.

### **Trogarzo<sup>®</sup>**

We monitor other ARTs, both already on the market and still under clinical development, that may potentially be used to treat MDR HIV-1. Dolutegravir and darunavir, for instance, are the most commonly used in regimens for the treatment of MDR HIV-1. Other agents currently under clinical development programs include long acting-ARTs, such as Pro-140, and broadly neutralizing antibodies. None of these agents have the same mechanism of action as Trogarzo<sup>®</sup>. We are aware that the company manufacturing fostemsavir, an attachment inhibitor, has filed a new drug application with the FDA and a marketing authorization application with the EMA seeking its approval for the treatment of MDR HIV-1 infection.

## 2.8 GOVERNMENT REGULATION

### **Overview**

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

Governmental authorities in the United States, European Union, Canada, 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>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> and any other compound that we may develop. 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 requirements at any time during the product development process, approval process or commercialization process, may subject an applicant to administrative or judicial sanctions. Sanctions could include, but are not limited to, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters or other enforcement letters, product recalls, import/export delays, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, and government reimbursement, restitution, disgorgement or civil or criminal penalties.

The text below explains some of the most important features of government regulations that we must follow in connection with the commercialization of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States and in the European Union.

Government regulations in Canada are similar, albeit not identical to those in the United States.

## ***Sales and Marketing Regulation – United States***

We are subject to various United States requirements relating to the sales and marketing of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States. The FDA regulates all advertising and promotional activities for prescription drug products under its jurisdiction both prior to and after approval. *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> may be promoted only for their approved indications and in accordance with the provisions of their approved label. Any promotional claims regarding an approved drug must be accurate, not misleading and contain a fair balance of risk and benefit information. The FDA, as well as other government authorities, actively enforces the laws and regulations prohibiting the promotion of inaccurate, misleading or inadequately balanced product claims and the promotion of product for unapproved (i.e. off-label) uses. If we are found to have improperly promoted a prescription drug, we may be subject to significant sanctions. Failure to comply with applicable FDA requirements may subject us to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

The FDA does not regulate the practice of medicine by physicians in their choice of treatment.

The marketing of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> 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 or reward, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions, it is possible that we might be challenged under anti-kickback or similar laws. Sanctions under these laws include civil monetary penalties, exclusion from U.S. federal and state healthcare programs (i.e., those programs will not provide reimbursement or payment coverage for *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and/or Trogarzo<sup>®</sup>), and criminal penalties, including imprisonment; further, an alleged violation of the anti-kickback statute could be used as a basis for a federal or state false claims law challenge. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to certain third-party payors (including Medicare and Medicaid) claims for reimbursement for drugs or services that are false or fraudulent. Generally, claims for drugs prescribed for off-label uses may be considered to be “false claims”. Sanctions under false claims laws include significant civil monetary penalties. In addition, there is ability for private individuals to bring similar actions.

In addition, several states require that companies implement compliance programs or comply with industry ethics codes, adopt marketing spending limits, and report to state governments any gifts, compensation, and other remuneration provided to certain healthcare professionals. Regulations implementing certain provisions of federal health care legislation require record-keeping and disclosure to the federal government of certain transfers of value to U.S.-licensed physicians and certain teaching hospitals, otherwise known as the “Sunshine Act”. Any activities relating to the sale and marketing of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> may be subject to scrutiny under these laws. Failure to make these required reports or comply with these laws can result in civil monetary penalties and/or other sanctions. If the government were to allege or convict us of violating these laws, our business could be harmed.

## ***Sales and Marketing Regulation – European Union***

In addition to regulations in the United States, we are subject to a variety of European Union regulatory requirements. These requirements govern human clinical trials, marketing approval, and post marketing regulation for drugs. The European Union regulatory approval process includes all of the risks associated with FDA approval set forth above, as well as additional country-specific regulations. Whether or not we obtain FDA approval for a product, we must obtain approval of a product under the European Union regulatory system before we can commence clinical trials or marketing of the product in the European Union. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions and the approval process may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product

licensing, pricing, and reimbursement vary greatly amongst the European Union member states, or EU Member States.

Under the European Union regulatory system, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of an opinion by the EMA. A centralized marketing authorization is valid for all EU Member States and three of the four European Free Trade Association States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between EU Member States. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all EU Member States in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other EU Member States are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of EU Member States by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of an EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of another EU Member State.

Trogarzo® was approved by the EMA through the centralized marketing authorization procedure.

Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application by the EMA Committee for Medicinal Products for Human Use, or CHMP, is, in principle, 210 days from receipt of a valid application for marketing authorization. This time period excludes any clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP and if the applicant requests a re-examination of the CHMP opinion. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be a major public health interest particularly from the point of view of therapeutic innovation. The accelerated evaluation shortens the period to 150 days from 210. Regardless of the assessment procedure, the opinion of the CHMP will be provided to the European Commission which will make the final decision on the application for centralized marketing authorization of a medicinal product.

The holder of a European Union marketing authorization for a medicinal product must also comply with European Union pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. These rules can impose on central marketing authorization holders for medicinal products the obligation to conduct a labor-intensive collection of data regarding the risks and benefits of marketed products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies.

The sales and distribution of medicinal products into and within the European Union is subject to compliance with the applicable European Union laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU Member States.

In the European Union, the advertising and promotion of drug products are subject to EU Member States' laws governing promotion of medicinal products, interactions with physician, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. The laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the European Union. The applicable laws at European Union level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. These laws may further limit



or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. Violation of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Failure by us or by any of our third party partners, including suppliers, manufacturers and distributors to comply with European Union laws and the related national laws of individual EU Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of marketing authorization, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or refusal to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

### ***Good Manufacturing Practices***

Drug products must be manufactured and packaged in accordance, among other things, with current good manufacturing practices, or GMPs, and both Bachem and Jubilant, the contract manufacturers of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>, as well as WuXi, the manufacturer of Trogarzo<sup>®</sup>, must adhere to GMPs in connection with the manufacture and packaging of these products. If a company wants to make certain changes in its manufacturing equipment, location or process, regulatory review and approval may be required. The FDA often conducts audits of manufacturing sites to ensure that manufacturers comply with quality-related requirements and GMPs. If, as a result of these inspections, it is determined that a manufacturer's equipment, facilities or processes do not comply with the regulations and conditions of product approval, the FDA may issue an FD-483 list of observations or seek civil, criminal or administrative sanctions and/or remedies against the manufacturer, including seeking corrective action, or requiring suspension of manufacturing operations, which would delay the product and sale of our products.

Similarly to the U.S., in the European Union, both marketing authorization holders and manufacturers of medicinal products must comply with European Union GMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union. The manufacturing process for medicinal products in the European Union is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations.

### ***Good Clinical Practices***

The FDA promulgates regulations and standards, commonly referred to as good clinical practices, or GCPs, 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. Our research and development activities are subject to GCPs. The FDA enforces GCPs through periodic inspections of trial sponsors, principal

investigators and trial sites. If study sites fail to comply with applicable GCPs or other applicable requirements, such as informed consent or Institutional Review Board oversight, the clinical data generated in clinical trials may be deemed unreliable and the FDA may require a sponsor to redo its studies or even stop a study. Where patient safety is at risk, the FDA could impose a clinical hold.

Similarly, in the European Union, the conduct of clinical trials is governed by Directive 2001/20/EC which imposes obligations and procedures that are similar to those in the United States. The European Union Good Clinical Practice rules and European Union Good Laboratory Practice obligations must also be respected during conduct of the trials. Clinical trials must be approved by the competent regulatory authorities and the competent Ethics Committees in the EU Member States in which the clinical trials take place. All entities conducting clinical trials in the European Union will be required to comply with the requirements of the new EU Clinical Trials Regulation, which may enter into force in 2019. The new EU Clinical Trials Regulation, which will replace the EU Clinical Trials Directive, introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the European Union, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products, and an increased obligation on sponsors to publish clinical trial results.

## **2.9 PHARMACEUTICAL PRICING AND REIMBURSEMENT**

In the United States and in other countries, sales of *EGRIFTA*®, *EGRIFTA SV*<sup>TM</sup> and Trogarzo® will depend in large part on the availability of reimbursement from third-party payors. These payors include both government (such as Federal Medicare and State Medicaid, AIDS Drug Assistance Programs and special needs plans in the United States) and private managed care organizations as well as pharmacy benefit managers.

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 may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of *EGRIFTA*®, *EGRIFTA SV*<sup>TM</sup> and Trogarzo®. *EGRIFTA*®, *EGRIFTA SV*<sup>TM</sup> and/or Trogarzo® 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, or our commercial partners, to sell *EGRIFTA*®, *EGRIFTA SV*<sup>TM</sup> and/or Trogarzo® on a competitive and profitable basis.

### **United States**

The U.S. Congress, state legislatures, and federal and state agencies from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our drug products profitably. For example, in March 2010, the *Patient Protection and Affordable Care Act*, and the associated reconciliation bill, which we refer to collectively as the *Health Care Reform Law* was enacted, and was 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 (inclusive of price increases) 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 all Medicaid drug rebates. On January 21, 2016, the Centers for Medicare and Medicaid Services finalized a rule detailing reforms to the rebate and reimbursement systems for Medicaid prescription drugs. This final rule was intended to save taxpayers billions and ultimately improve beneficiary access to prescription drugs. The final rule allowed manufacturers to recalculate the baseline “average manufacturer price” and includes US territories in the calculation of “average manufacturer price” and “best price” effective April 1st, 2017. Further, 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 to modify our business practices with healthcare practitioners, and also may increase our regulatory burdens and operating costs.

The U.S. Medicare program provides payment for many pharmaceuticals under the Medicare Part D program. 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 standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. 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.

Under Part D, 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 Part D applies only to drug benefits for Medicare beneficiaries, state Medicaid programs and private payors may follow Medicare coverage policy limitations in setting their own payment rates. Any reduction in payment that results under Part D may influence decision-making and negotiations for payments from non-governmental payors. Payors are, however, forbidden to negotiate both commercial and Part D agreements together. Negotiations must be kept separate.

The cost of pharmaceuticals continues to generate substantial governmental and third-party private payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, particularly towards specialty pharmacy, 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.

The Health Care Reform Law may be repealed and may or may not be replaced with a different law or health care payment system.

## **European Union**

In the European Union, sales of Trogarzo® will depend in part on the availability and level of reimbursement from third-party payors. Third-party payors 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 EU Member State and are given different weight depending on the EU Member States' attitudes towards providing public healthcare and the government's willingness to pay for these new drugs. We 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 the European Union, the requirements governing drug pricing vary widely from country to country. In many EU Member States, 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 EU Member States and in other EU Member States, the evaluation of what a fair price would be based on the condition that is being treated and the innovative quality of the new drug.

The sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or Price Transparency Directive. The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in EU Member States are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual EU Member States. Neither does it have any direct consequence for pricing or levels of reimbursement in individual EU Member States. The national authorities of the individual EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Individual EU Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other EU Member States adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms. Further, an increasing number of EU Member States use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States. These countries include France, Germany and Sweden. The HTA process in the EU Member States is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA will often influence the pricing and reimbursement status for specific medicinal products within individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product varies between the EU Member States.

## **2.10 CHANGES TO REGULATION – UNITED STATES**

The BPCI Act requires that marketing applications for “biological products” needs to be submitted as a biologic licence application, or BLA. When enacted, the BPCI Act provided for a ten (10) year transition period, ending March 23, 2020, for biological products to file BLAs instead of new drug applications under Section 505 of the U.S. Food Drug and Cosmetic Act, or FDCA. In the BPCI Act, the definition of “biological product” was defined to include a “protein (except any chemically synthesized polypeptide)”.

On December 20, 2019, the Further Consolidated Appropriations Act, 2020 (Public Law No. 166-94) became law. This appropriations bill amended the definition of “biological product” by striking the language “(except any chemically synthesized polypeptide)”. By removing the parenthetical, FDA now includes tesamorelin acetate (*EGRIFTA*® and *EGRIFTA SV*™) as a biological product.

FDA has given companies until February 19, 2020 to comment on the recent changes. We have filed a letter with the FDA seeking a reversal of the decision of the FDA to include tesamorelin acetate as a biologic product. If tesamorelin acetate remains a “biological product”, we would potentially lose the three-year market exclusivity

period provided under Section 505(c) (3) (D) (iv) of the FDCA resulting from the conduct of clinical trials using tesamorelin for the treatment of NASH in people living with HIV.

Trogarzo® benefits from a 12-year market exclusivity period in the United States, calculated from March 6, 2018 and from ten (10) years of market exclusivity in the European Territory.

In Canada, the Food and Drug Regulations provide an eight-year market exclusivity period to a Notice of Compliance (NOC) holder who markets an innovative drug in Canada (including a biological drug).

In Europe, when a marketing authorisation for a product is issued by the EMA, the approved product (including a biological product) benefits from 10 years of market exclusivity.

## **2.11 INTELLECTUAL PROPERTY**

As further described below, *EGRIFTA*® is protected by patents in both Canada and the United States whereas Trogarzo® benefits from twelve (12) years of market exclusivity in the United States and ten (10) years of market exclusivity in the European Territory.

### ***Our Patent Portfolio***

#### *EGRIFTA*® and tesamorelin

Our current patent portfolio is comprised of the following material patents for *EGRIFTA*®, *EGRIFTA SV*<sup>TM</sup> (tesamorelin):

- In the United States, we own U.S. patent 5,861,379 covering the composition of matter of tesamorelin, which is scheduled to expire in May 2020 after having obtained a patent term extension certificate from the USPTO for such patent. In addition, we own three issued United States patents relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which are scheduled to expire in 2023, as well as a patent relating to the use of tesamorelin in the treatment of mild cognitive impairment that is scheduled to expire in 2025. Furthermore, we have a patent set to expire in 2027 that relates to the use of tesamorelin in the improvement of muscle function in subjects suffering from severe wasting. Finally, we have a patent on the F8 scheduled to expire in 2033.
- We have also filed patent applications covering the formulation of *EGRIFTA SV*<sup>TM</sup> in the United States and in Canada which, if granted, would expire in 2039. Furthermore, we have filed two U.S. provisional patent applications covering the treatment of NASH using tesamorelin. We plan to file a PCT application claiming priority from these provisional applications in 2020. If granted, patents stemming from this PCT application would expire in 2040.
- In Canada, we own a patent relating to the use of tesamorelin in the treatment of metabolic conditions associated with fat accumulation and/or hypercholesterolemia, including HIV-associated lipodystrophy, which is scheduled to expire in October 2024, as well as a patent relating to the use of tesamorelin in the treatment of mild cognitive impairment that is scheduled to expire in May 2023.
- In Mexico, we own one patent related to the use of tesamorelin in the treatment of HIV-associated lipodystrophy which is scheduled to expire in October 2025.

Through the License Agreement, we have obtained the rights to different patent families involving applications filed in various countries of the world. These patent families relate to peptides and conjugates integrated to our oncology platform as well as the use thereof. A first patent was recently issued in Canada under number CA 3,006,313. This patent will expire in November 2036. In addition, we own a patent application filed in December 2019 that relates to formulations made with such peptides and conjugates.

### **Regulatory Exclusivity**

The regulatory regimes of certain countries and territories such as the United States, Canada and Europe provide market exclusivity for a pharmaceutical product once approved. Data protection provides a person with protection against third parties who may wish to commercialize a product similar to an approved product.

In the United States, the *Drug Price Competition and Patent Term Restoration Act of 1984*, or *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 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 generally prevents the FDA from approving, in certain circumstances, any abbreviated new drug application, or ANDA, for a generic drug or any 505(b)(2) NDA that references the pioneer drug product. The market exclusivity for *EGRIFTA*® in the United States has expired.

In the United States, distinct from exclusivity for drug products, biological products, such as toxins and serums, may be eligible for non-patent exclusivity. Specifically, the *Biologics Price Competition and Innovation Act of 2009*, or the BPCI Act, amended the Public Health Service Act to provide an abbreviated licensure pathway for biological products, or 351(k) application, shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. In turn, the BPCI provides a 4-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted. In addition, FDA may grant a 12-year exclusivity period from the date of first licensure of the reference product, during which approval of a 351(k) application referencing that product may not be made effective. For the first biological product determined to be interchangeable with the reference product for any condition of use, the agency may provide a period of market exclusivity, during which a second or subsequent biological product may not be determined interchangeable with that reference product. However, unlike the process for drug products, FDA will not grant exclusivity for supplements or changes to the reference biological product. Like drug products, biologic products can receive seven (7) years of market exclusivity for an orphan indication. Finally, FDA may issue an exclusivity period for certain biological products for which pediatric studies are conducted in accordance with a written request.

### **Our Trademark Portfolio**

*EGRIFTA*® is our registered trademark in the United States and in Canada and it is used in those countries to commercialize tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

*EGRIFTA SV*™ is our trademark and it is used in the United States to commercialize a new formulation of tesamorelin for the treatment of HIV-associated lipodystrophy.

Trogarzo® is a registered trademark of TaiMed in the United States and in Europe and it is under licence to us pursuant to the TaiMed Agreement.

*THERA Patient Support*<sup>®</sup> is our registered trademark in the United States and it is used to designate our call center that assists healthcare professionals and patients in processing referrals, following-up on treatment adherence and answering questions from both healthcare professionals and patients regarding *EGRIFTA*<sup>®</sup> and Trogarzo<sup>®</sup>.

*EGRIFTA Support*<sup>®</sup> is our registered trademark in Canada and it is used to designate our call center that assists healthcare professionals and patients in processing referrals and answering questions from both healthcare professionals and patients regarding *EGRIFTA*<sup>®</sup>.

### ***Other Intellectual Property Portfolio***

Our portfolio of intellectual property contains additional trademarks, pending trademark registrations and domain names associated with our trademarks and pending trademark applications.

### ***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 whose addresses include our trademark names; and
- maintain our intellectual property rights by paying government fees as may be necessary to ensure such rights remain in force.

## **2.12 EMPLOYEES**

As at November 30, 2019, we had 37 employees in Canada and five (5) employees in Ireland. All of our employees are engaged in administration, finance, medical affairs, regulatory, marketing and sales and research and development functions. None of our employees are unionized. We believe the relations with our employees are good.

Through Syneos, as at November 30, 2019, we had an additional 67 persons dedicated to the commercialization of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States and three (3) persons dedicated to medical affairs in the European Territory.

## **2.13 FACILITIES**

Our head office is located at 2015 Peel Street, 11<sup>th</sup> Floor, in the City of Montreal, Québec, Canada where we lease a 15,000 square-foot office space. We conduct our European activities from premises located at 2 Hume Street, 4<sup>th</sup> Floor, Dublin 2, Ireland, where we lease a 1,765 square-foot office space.

We also conduct some of our research and development activities at laboratories leased from the Université du Québec à Montréal, in Montreal, Canada

#### **2.14 ENVIRONMENT**

To our knowledge, environmental issues do not have a material financial or operational impact on our capital expenditures, income or competitive position within the normal course of our operating activities.



## ITEM 3 RISK FACTORS

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

### 3.1 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

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

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

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

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

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

There can be no assurance that sales of our products to customers in the United States and in the European Territory will increase in the future or that we will generate sales at a profitable level. If sales of our products

decrease, our revenue would be adversely affected which, in turn, could materially adversely affect our business, financial condition and operating results.

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

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

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

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

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

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

We do not own or operate manufacturing facilities for the production of *EGRIFTA*®, *EGRIFTA SV*™ and tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Bachem and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for sales of *EGRIFTA*® and *EGRIFTA SV*™. Our agreement with Bachem will expire in May 2020 and our agreement with Jubilant will expire in December 2020. Although we are in discussions with Bachem and Jubilant to extend the term of these agreements, our inventory of drug product is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with them. Also, we have not qualified these alternative manufacturers to date and no assurance can be given that such manufacturers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more.

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

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

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

We do not employ sales, medical service liaison and reimbursement personnel in the United States and in the European Territory in connection with the commercialization of our products in these territories. We rely on Syneos to provide us with all of the services related to the commercialization of our products, namely sales personnel, medical science liaison personnel, reimbursement specialists and other individuals whose roles and functions pertain to the commercialization of our products. Although we are aware that there exists other third-party services providers that could provide the same services as Syneos, we have not entered into any agreements with them nor conducted any audit on them. If we need to find another third-party service provider for some or all of the services provided by Syneos, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

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

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

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

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

We may be subject to a decrease in sales of our products in the United States or in the European Territory or we may face reimbursement challenges if Syneos:

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

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

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

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

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

Sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® to patients benefitting from U.S. funded reimbursement programs represent the most important part of all sales of our products. *EGRIFTA SV*™ is currently not as covered

as *EGRIFTA*® and Trogarzo® in the United States since it was recently launched. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

In the European Territory, sales of Trogarzo® will be highly dependent on obtaining reimbursement. As discussed under “Pharmaceutical Pricing and Reimbursement” above, the process of seeking reimbursement for a new drug is complex and varies from one EU Member State to another. In many EU Member States, pricing plays an important role in the evaluation of prescription drugs for reimbursement. There can be no assurance that Trogarzo® will be reimbursed by all or any EU Member State.

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

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

Sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® will depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including:

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

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

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

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have substantially greater financial, technical and personnel resources than us. We believe there is currently no approved drug product competing directly with our approved products. However, with respect to *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>, we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching ARTs or liposuction. With respect to Trogarzo<sup>®</sup>, we are aware that dolutegravir and darunavir are being used in regimens to treat MDR HIV-1 and that attachment inhibitors, long-acting ARTs and broadly working antibody products are under development. We are also aware that the manufacturer of fostemsavir has filed a new drug application with the FDA and a marketing authorization application with the EMA.

### **3.2 RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES**

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

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

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

In connection with the development of a new treatment or a new drug, such as the development of tesamorelin for the potential treatment of NASH in patients living with HIV and the development of our proprietary peptides resulting from our oncology platform, we must conduct clinical trials. Clinical trials require the enrolment of patients and we may have difficulties enrolling patients for those clinical trials. These difficulties may arise as a result of design protocol, the size of the patient population, the eligibility criteria to participate in the clinical trials, the availability of competing therapies, the patient referral practices of physicians and the availability of clinical trial sites. Difficulty in enrolling patients in connection with the conduct of clinical trials could result in their cancellation or delays in completing them. Once patients are enrolled in a clinical trial, the occurrence of any adverse drug effects or side effects observed during the trial could also result in the clinical trial being cancelled. The cancellation of clinical trials for the foregoing reasons could lead to our forfeiting the development of the product candidate tested in those clinical trials and have a material adverse effect on our long-term growth and revenue prospect.

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

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

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

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

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

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

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

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

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

For example, EMD Serono has listed a patent held by one of its affiliates in the Orange Book under the *Hatch-Waxman Act* with respect to *EGRIFTA*® and *EGRIFTA SV*™ in HIV-associated lipodystrophy. With the termination of the EMD Serono Agreement, EMD Serono could assert that such patent would be infringed by our continued sale of *EGRIFTA*® and *EGRIFTA SV*™ in the United States for the treatment of lipodystrophy. To counter that risk, we have obtained a non-exclusive licence from EMD Serono's affiliate under the EMD Serono Termination Agreement in order to continue selling *EGRIFTA*® and *EGRIFTA SV*™ in the United States. The termination of that licence could prevent us from selling *EGRIFTA*® and *EGRIFTA SV*™ in the United States for the treatment of lipodystrophy if we were found to infringe the patent listed by one of EMD Serono's affiliates in the Orange Book and this could have a material adverse effect on our business, financial condition and operating results.

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

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

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

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



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

### 3.4 **REGULATORY RISKS**

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

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

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

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

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

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

- the FFDCA and similar laws regulating advertisement and labeling; and
- European Union's, EU Member States' and U.S. States' law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of our products in the United States, which could harm the commercial sales of our products and materially affect our business, financial condition and results of operations. We cannot guarantee that we will be able to mitigate all operational risks. In addition, we cannot

guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup>, Trogarzo<sup>®</sup> or their respective manufacturing processes, withdrawal of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> or Trogarzo<sup>®</sup> from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material adverse effect on our product sales, business and results of operations.

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

### 3.5 LITIGATION RISKS

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

We rely on third-party service providers for sales, marketing, distribution and manufacturing activities related to *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States. Under our agreements with our third-party service providers, we have assumed certain obligations, undertakings and covenants which, if breached by us and not remedied within the agreed upon periods, could expose us to claims for damages and/or termination of these agreements. If we are unable to meet our obligations under any of our agreements with TaiMed as well as with third-party service providers which results in termination of such agreements, this will materially adversely affect our business, financial condition and operating results since we rely on single third-party service providers, each of whom performing key services for the success of our business plan.

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

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

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

expend significant financial and managerial resources and would have a material adverse effect on our reputation and our financial condition.

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

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

### **3.6 GEO-POLITICAL RISKS**

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

International business relationships in the United States, Europe, China, Taiwan and elsewhere subject us to additional risks, including:

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

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

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

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

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

### **3.7 OTHER RISKS RELATED TO OUR BUSINESS**

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

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

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

In connection with the conduct of activities in Europe, we have to comply with the European Union General Data Protection Regulation, or GDPR. The GDPR introduced data protection requirements in the European Union relating to the consent of individuals to whom the personnel data relates, the information provided to the individuals, the security we must retain, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR has increased the responsibility of all parties collecting personal data. As we build our infrastructure in Europe, we will have to put in place mechanisms to ensure compliance with the GDPR. However, our efforts to comply

with the GDPR may not be successful and could increase our costs of doing business. In addition, data protection authorities of the various EU Member States may interpret the GDPR differently adding a layer of complexity in implementing adequate compliance measures.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. Unauthorized access to data files held in our information technology systems or those of third parties could result in inappropriate use, change or disclosure of sensitive and/or personal data of our customers, employees, suppliers and patients. Any such access, disclosure or other loss of information could subject us to litigation, regulatory fines, penalties or reputational damages, any of which could have a material adverse effect on our competitive position, reputation, business, financial condition and operating results.

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

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

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States. In addition, there is no guarantee that we will be able to successfully launch and commercialize Trogarzo<sup>®</sup> in the European Territory. If revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, financial condition and operating results could be materially adversely affected and we may never sustain profitability.

***We may not be able to generate sufficient cash from our operating activities to service our debt obligations.***

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

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

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

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to develop our marketing and commercial capabilities, to meet our compliance obligations with various rules and regulations to which we are subject, to conduct our research and development activities, and to in-license or acquire new molecules or approved products. However, our business performance may prevent us from generating enough cash-flow to meet our obligations and the market conditions may also prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional capital by way of public or private offerings in the future. In such a case, we

would have to use other means of financing, such as entering into private financing or credit agreements, the terms and conditions of which may not be favorable to us. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our common shares.

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified manufacturing, managerial and scientific personnel. We have entered into employment agreements with our executive officers and provided them with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers will remain employed by us for any significant period of time, or at all. In addition, we have a limited workforce to pursue our business plan and the loss of any of our key employees could materially adversely affect our business. Our third-party service provider, Syneos, has hired sales representatives and other qualified individuals to assist us with the commercialization of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States. Syneos has also hired medical science liaison personnel in the European Territory. Although these individuals are not our employees, the loss of any of those individuals and the inability of Syneos to attract and retain these individuals could have a material adverse effect on the commercialization of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup>, and, accordingly, our business, financial condition and operating results. In addition, it could adversely affect the market price of our common shares.

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

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

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

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

The preparation of our consolidated financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date

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

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

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

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

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

### **3.8 RISKS RELATED TO OUR COMMON SHARES**

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

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

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

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

- the level of sales of EGRIFTA® and EGRIFTA SV™ in the United States;
- the level of sales of Trogarzo® in the United States;



- the level of sales of Trogarzo® in the European Territory;
- supply issues with *EGRIFTA*®, *EGRIFTA SV*™ or Trogarzo®;
- default under the terms of our Notes;
- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates;
- the outcome of any litigation;
- payment of fines or penalties for violations of laws;
- foreign currency fluctuations;
- the timing of achievement and the receipt of milestone or royalty payments from future third parties; and
- failure to enter into new or the expiration or termination of current agreements with third parties.

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

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

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

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

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

***Our shareholder rights plan and certain Canadian laws could delay or deter a change of control.***

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

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


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

**ITEM 4 DIRECTORS AND EXECUTIVE OFFICERS**

**4.1 DIRECTORS**

The table below sets forth the following information about our directors as of February 24, 2020: his/her name, age, province/state of residence, principal occupation, the year each director first became a director of the Corporation, his/her status as an independent director, his/her biography, his/her areas of expertise, his/her memberships on the committees of the Board of Directors, whether he/she acts as director for other public companies or entities involved in the pharmaceutical industry, and the number of common shares (the only voting securities of the Corporation), DSUs, options and Notes beneficially held or controlled.

Each elected director remains in office until the next annual meeting of shareholders, unless he/she resigns or his/her position becomes vacant following his/her death, destitution or for any other reason before the next annual meeting of shareholders.

 <p><b>Sheila M. Frame</b> Age: 58 Skillman, New Jersey, USA</p> <p><b>Independent</b></p> <p><b>Director since:</b> March 29, 2019</p> <p><b>Areas of Expertise:</b> - Pharmaceutical Industry - Sales and Marketing Strategy - Government Relations - Leadership</p> <p><b>Other Directorship:</b> None</p>	<b>Principal Occupation</b>		Vice President and Head of Biopharmaceuticals, North America Sandoz Inc.	
	<p>Ms. Frame is currently Vice President and Head Biopharmaceuticals, North America at Sandoz Inc. (a division of Novartis) in the United States. Previously, she successively held the positions of Worldwide General Manager, Immunoscience, Worldwide Commercial Lead, Opdivo® new indications and Biomarker diagnostics, Worldwide Commercial Lead Yervoy® from the US and Vice President, specialty business at Bristol-Myers Squibb in Canada. She was also called upon to occupy several senior roles at UCB Inc. and at AstraZeneca in Canada, the US and the Nordics.</p> <p>Ms. Frame completed the requirements for the Chartered Corporate Director program with the Director’s college in 2006. She also completed a Masters of Business Administration at Concordia University in Montreal and she holds a Bachelor of Arts from York University in Toronto.</p>			
	<b>Securities Held or Controlled</b>			
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
	-	4,229	-	-
	<b>Committees of the Board of Directors</b>			
None				



**Gérald A. Lacoste**  
 Age: 76  
 Rivière-Rouge,  
 Québec, Canada

**Independent**

**Director since:**  
 February 8, 2006

**Areas of Expertise:**  
 - Securities and  
 Market Regulations  
 - Corporate  
 Governance  
 - Mergers &  
 Acquisitions

**Other Directorship:**  
 None

<b>Principal Occupation</b>		Corporate Director	
Gérald A. Lacoste is a retired 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 <i>Autorité des marchés financiers</i> ) and was also President and Chief Executive Officer of the Montreal 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 has been a member of the North American Free Trade Agreement arbitration panel and is currently a corporate director.			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
100,000	21,936	56,146	45,000
<b>Committees of the Board of Directors</b>			
Chair of Nominating and Corporate Governance Committee Member of Audit Committee			



**Gary Littlejohn**  
 Age: 64  
 Lac-Tremblant-Nord,  
 Québec, Canada

**Independent**

**Director since:**  
 October 15, 2018

**Areas of Expertise:**

- Capital Markets
- Corporate governance
- Corporate Finance
- Risk Management

**Other Directorship:**

None

<b>Principal Occupation</b>		Corporate Director	
<p>From 2008 to 2015, Mr. Littlejohn held the position of CEO and then of advisor to the Chairman and Board Member of the Arab National Investment Company, also known as ANB Invest, in Riyadh, a subsidiary of Arab National Bank. Previously, he was Managing Director of investment banking at Desjardins Securities in Montreal, a position he took after serving six years as Executive Vice-president at Ecopia Biosciences. Mr. Littlejohn also occupied various senior positions in investment banking at TD Securities, Midland Walwyn, BMO Nesbitt Burns and National Bank Financial. Most recently, he held the position of Interim CEO at Helix BioPharma. Mr. Littlejohn also served on the Board of several corporations including Helix BioPharma, ANB Invest, Aegera Pharmaceuticals, Ecopia Biosciences and The Montreal Exchange. Mr. Littlejohn holds a B.A. (Honours Economics), a BCL and a MBA from McGill University. He also completed the Director Education Program provided by the Canadian Institute of Corporate Directors in 2015. He is a retired lawyer of the Quebec Bar.</p>			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
11,080	Nil	8,900	Nil
<b>Committees of the Board of Directors</b>			
<p>Chair of Compensation Committee            Member of Audit Committee</p>			



**Dale MacCandlish Weil**

Age: 64  
 Baie d'Urfé,  
 Québec, Canada

**Independent**

**Director since:**  
 May 16, 2017

**Areas of Expertise:**

- Healthcare Industry
- Commercialization of products
- Management
- Strategic Planning

**Other Directorship:**

None

<b>Principal Occupation</b>		Corporate Director	
<p>Ms. Dale MacCandlish Weil has more than 35 years of experience in the commercialization, marketing, sale of consumer products and B2B services. From May 2018 to January 2020, Ms. Weil has been Managing Director of the Montreal Institute for Palliative Care (a branch of the West Island Palliative Care Residence) and, in January 2020, she became executive director of the West Island Palliative Care Residence and of the Montreal Institute for Palliative Care. She spent the prior 18 years of her career in management positions related to health care services such as distribution, pharmaceutical and retail pharmacy services. She worked with McKesson Canada Corporation, or McKesson, since August 1999 where she occupied the position of Vice President and Senior Vice President for various divisions of McKesson. She acted in an advisory role to the President from May 2015 to February 2018. Prior to May 2015, she acted as Senior Vice President Retail Management Services with McKesson from July 2014 to May 2015 and, from November 2011 to June 2014, she acted as Senior Vice President, Integrated Health Care Solutions, Strategy and Business Development with McKesson. Ms. Weil holds a Master in Business Administration from McGill University and has obtained her certification as a certified director after successfully completing the ICD Directors Education Program.</p>			
<b>Securities Held or Controlled</b>			
<b>Common Shares</b>	<b>DSU</b>	<b>Options</b>	<b>Notes</b>
<b>(#)</b>	<b>(#)</b>	<b>(#)</b>	<b>(US\$)</b>
16,700	5,531	31,146	2,000
<b>Committees of the Board of Directors</b>			
Member of Nominating and Corporate Governance Committee			



**Paul Pommier**  
 Age: 77  
 Laval, Québec,  
 Canada

**Independent**

**Director since:**  
 January 6, 1997

**Areas of Expertise:**

- Corporate Finance
- Securities
- Mergers & Acquisitions

**Other Directorship:**  
 None

<b>Principal Occupation</b>		Corporate Director	
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.			
<b>Securities Held or Controlled</b>			
<b>Common Shares</b>	<b>DSU</b>	<b>Options</b>	<b>Notes</b>
<b>(#)</b>	<b>(#)</b>	<b>(#)</b>	<b>(US\$)</b>
390,100	122,208	56,146	Nil
<b>Committees of the Board of Directors</b>			
Chair of the Audit Committee Member of Compensation Committee			



**Dawn Svoronos**  
 Age: 66  
 Hudson,  
 Québec, Canada

**Independent  
 Director since:**  
 April 8, 2013

**Areas of Expertise:**  
 - Pharmaceutical  
 Industry-  
 Commercialization  
 of Drug Products

**Other Directorship:**  
 Xenon Pharmaceuticals Inc.;  
 PTC Therapeutics, Inc.;  
 Global Blood Therapeutics, Inc.

<b>Principal Occupation</b>		Corporate Director – Chair of the Board of the Corporation	
Ms. Dawn Svoronos worked in the commercial side of the business for the multinational pharmaceutical company Merck & Co. Inc., for 23 years, retiring in 2011. From 2009 to 2011, Ms. Svoronos was President of the Europe/Canada region for Merck and from 2006 to 2009 was President of Merck in Canada. Previously held positions with Merck include Vice-President of Asia Pacific and Vice-President of Global Marketing for the Arthritis, Analgesics and Osteoporosis franchise. Ms. Svoronos is a member of the board of directors of three other public companies: PTC Therapeutics, Inc. in New Jersey, U.S.A., Xenon Pharmaceuticals Inc. in British Columbia, Canada, and Global Blood Therapeutics, Inc. in San Francisco, California.			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
200,000	855	96,146	Nil
<b>Committees of the Board of Directors</b>			
Member of Nominating and Corporate Governance Committee Member of Compensation Committee			





**Luc Tanguay (1)**  
Age: 61  
Magog, Québec, Canada

**Non-independent**

**Director since:**  
December 6, 1993

**Areas of Expertise:**

- Corporate Finance
- Securities
- Mergers & Acquisitions
- Management

**Other Directorship:**  
None

<b>Principal Occupation</b>		President and Chief Executive Officer of the Corporation	
<p>Mr. Luc Tanguay has been active in the biotechnology industry for over 20 years and has been a member of our senior management since 1996. A member of the board of directors since 1993, he became President and Chief Executive Officer of the Corporation in October 2012. Prior to his appointment as President and Chief Executive Officer, Mr. Tanguay held the position of Senior Vice President and Chief Financial Officer. Since his appointment as President and Chief Executive Officer, the Corporation's evolution changed immensely. From a pure research and development company, the Corporation became fully integrated with commercial activities in the United States, Canada and Europe and resumed research and development activities. Mr. Tanguay was instrumental in negotiating with EMD Serono in order to regain all commercialization rights to <i>EGRIFTA</i>® in the United States and in setting up the infrastructure required to commercialize such product in such territory and in Canada. Mr. Tanguay was also at the center of the strategy to acquire the North American and European rights to Trogarzo® and to set-up the infrastructure to commercialize this product in the United States and in Europe. As President and Chief Executive Officer, he also led the Corporation to resume research and development activities through the acquisition of Katana Biopharma. Prior to joining us, Mr. Tanguay had a career in investment banking at National Bank Financial Inc. Mr. Tanguay obtained his M. Sc. Finance from the University of Sherbrooke and holds the title of Certified Financial Analyst.</p>			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
254,000	27,572	959,448	100,000

(1) Mr. 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), or CCAA. 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, the TSX decided 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 the TSX. The common shares remain suspended from trading. On April 8, 2011, Ambrilia announced that it would seek permission to terminate the protection granted by the Superior Court pursuant to the CCAA and, upon permission of the Court, it would file for bankruptcy pursuant to the Bankruptcy Act. On April 12, 2011, Ambrilia went bankrupt.

## 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, 2019, the Audit Committee was composed of three members: Paul Pommier, its Chair, Gary Littlejohn 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.

**Gary Littlejohn.** Mr. Littlejohn holds a B.A. (Honours Economics), a BCL and an MBA from McGill University. From 2008 to 2015, Mr. Littlejohn held the position of CEO and then of advisor to the Chairman and Board


Member of the Arab National Investment Company, also known as ANB Invest, in Riyadh, a subsidiary of Arab National Bank. Previously, he was Managing Director of investment banking at Desjardins Securities in Montreal, a position he took after serving six years as Executive Vice President at Ecopia Biosciences. Mr. Littlejohn also occupied various senior positions in investment banking at TD Securities, Midland Walwyn, BMO Nesbitt Burns and National Bank Financial.

**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 was 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 complexity of accounting issues that are generally comparable to those that can reasonably be expected to be raised in our financial statements.

#### 4.3 EXECUTIVE OFFICERS

The table below sets forth the following information about our executive officers as of February 24, 2020: his/her name, age, province/state of residence, his/her principal occupation, the year each Executive Officer joined the Corporation, his/her biography and the number of common shares (the only voting securities of the Corporation), DSUs, options and Notes beneficially held or controlled. The information about Mr. Luc Tanguay, the President and Chief Executive Officer of the Corporation, is found in the table above regarding information about our directors.

 <p><b>Jovan Antunovic</b> Age: 50 Montreal, Québec, Canada</p>	<b>Principal Occupation</b>		Senior Vice President and Chief Commercial Officer	
	<p>Mr. Antunovic has over 20 years of experience in the commercialization of innovative pharmaceutical products, medical equipment and diagnostics. Most of his career has been in specialty pharmaceuticals where he has held various senior management roles with increasing responsibility at Abbott in Canada, Europe and Japan and at Abbvie and Bristol-Myers Squibb in Canada. Mr. Antunovic has also been involved in several product launches in the U.S. and Europe and has worked in over 10 different therapeutic areas, including HIV.</p> <p>Mr. Antunovic graduated from McGill University in 1991 with a Bachelor's degree (Honours) in Biochemistry. He also completed a Master's degree at McGill University in 1994, during which he published three articles. He obtained a Master of Business Administration from McGill University in 1997 where he specialized in marketing.</p> <p>Mr. Antunovic joined Theratechnologies in December 2018.</p>			
	<b>Securities Held or Controlled</b>			
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
	Nil	Nil	33,000	Nil



**Denis Boucher**  
Age: 54  
Montreal, Québec,  
Canada

<b>Principal Occupation</b>		Vice President, Communications and Corporate Affairs	
Mr. Boucher joined the Corporation on January 8, 2018 and brings more than 30 years of experience in communications, government affairs and crisis management. Prior to joining Theratechnologies, Mr. Boucher practiced litigation and labor and employment law at a firm in the region of Montreal. He was previously a partner for 15 years at the largest public relations firm in Canada where he was in charge of the healthcare practice and business development. Mr. Boucher started his career as a television news reporter at Société Radio-Canada in Toronto and was then appointed press secretary to the President of the Treasury Board in Ottawa. Mr. Boucher holds a Bachelor of Arts Degree from Université Laval in Québec City and a Law Degree from Université de Montréal. He was called to the Quebec Bar in 2016. Upon completing a training at the Harvard Negotiation Institute in Cambridge, Massachusetts, in 2016, he was accredited by the Quebec Bar as a mediator in civil, commercial and labor law. Mr. Boucher sits on the fundraising organizing committee for the Fondation des étoiles.			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
5,980	Nil	40,222	40,000




**Marie-Noël Colussi**  
Age: 51  
Laval, Québec,  
Canada


<b>Principal Occupation</b>		Vice President, Finance	
Ms. Marie-Noël Colussi is a graduate of the <i>Université du Québec à Montréal</i> 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 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.			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
11,075	3,182	97,293	10,000



**Philippe Dubuc**  
Age: 53  
Montreal, Québec,  
Canada

<b>Principal Occupation</b>		Senior Vice President and Chief Financial Officer	
Mr. Dubuc brings more than 25 years of experience in investment banking in the healthcare sector and in management. He started his career as a management consultant at Groupe Secor, a well-known Quebec-based consulting firm which is now part of KPMG. He then served as Managing Director, Investment Banking at National Bank Financial. In this role, he headed the healthcare group and was involved in numerous financing and M&A transactions. He later founded a manufacturing company which he sold after seven years of successful operations. Mr. Dubuc holds a M.B.A. from McGill University and a B.Comm. from Concordia University.			
<b>Securities Held or Controlled</b>			
<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
26,000	Nil	277,286	25,000

 <p><b>Jocelyn Lafond</b> Age: 52 Montreal, Québec, Canada</p>	<b>Principal Occupation</b>		Vice President, Legal Affairs, and Corporate Secretary	
	<p>Mr. Lafond has over 20 years of experience in the fields of corporate and securities law. Mr. Lafond holds a law degree from the <i>Université Laval</i> and a Masters Degree in Law from the University of Toronto. He has been a member of the <i>Barreau du Québec</i> since 1992. Prior to joining us in 2007, Mr. Lafond was a partner with the international law firm of Fasken Martineau DuMoulin LLP.</p>			
	<b>Securities Held or Controlled</b>			
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
18,000	5,000	232,293	8,000	

 <p><b>Christian Marsolais</b> Age: 57 Town of Mount Royal, Québec, Canada</p>	<b>Principal Occupation</b>		Senior Vice President and Chief Medical Officer	
	<p>Dr. Christian Marsolais has over 25 years of experience in the research, development and commercialization of new drugs. He started his career in international pharmaceutical companies, including Sandoz, Biochem and Pfizer, where he held different positions from medical advisor to director clinical research and medical affairs. He was also appointed to the global oncology team at Pfizer, which managed the global oncology portfolio.</p> <p>Dr. Marsolais joined Theratechnologies in 2007 and leads the medical team which was central to the approval of <i>EGRIFTA</i>® by the FDA. He was also instrumental in the efforts that led to the US and European acquisition of the commercial rights to Trogarzo® and the approval of Trogarzo® by the FDA. More recently, he also led the team to pursue the approval of Trogarzo® in Europe.</p> <p>Dr. Marsolais holds a Ph.D. in biochemistry from the Université de Montréal</p>			
	<b>Securities Held or Controlled</b>			
	<b>Common Shares (#)</b>	<b>DSU (#)</b>	<b>Options (#)</b>	<b>Notes (US\$)</b>
54,297	6,312	312,286	15,000	

#### 4.4 CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

Except as described above in notes 1 to the table found under “Item 4 – Directors and Executive Officers – Section 4.1 – Directors”, to our knowledge, no director and executive officer (a) is, as at February 24, 2020, or has been within the ten (10) years before February 24, 2020, a director or executive officer of any company (including the Corporation) 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 (30) 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 (30) 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 February 24, 2020, 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.

As at February 24, 2020, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 1,087,232, which represented 1.41% of our outstanding common shares.

## ITEM 5 INTERESTS OF EXPERTS

KPMG LLP, our auditors, is the only person or company 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 are the auditors of the Corporation and have confirmed with respect to the Corporation that they are independent within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation or regulations and also that they are independent accountants with respect to the Corporation under all relevant U.S. professional and regulatory standards.

### *External Auditors Service Fees*

KPMG LLP have been acting as our auditors since 1993. In addition to performing the audit of our consolidated financial statements, KPMG LLP provided other services to us and they billed us the following fees in respect of each of our fiscal years ended November 30, 2019 and 2018:

<b>Fees</b>	<b>Fiscal Year Ended November 30, 2019 (CA\$)</b>	<b>Fiscal Year Ended November 30, 2018 (CA\$)</b>
Audit Fees(1)	377,500	254,000
Audit-Related Fees(2)	43,750	43,750
Tax Fees(3)	158,092	90,620
<b>Total:</b>	<b>579,342</b>	<b>388,370</b>

- (1) Refers to the aggregate fees billed by our external auditors for audit services, including interim reviews, accounting consultations and work performed in connection with securities filings.
- (2) Refers to the aggregate fees billed for professional services rendered by our external auditors for translation.
- (3) Refers to the aggregate fees billed for professional services rendered by our external auditors for tax compliance, transfer pricing, tax advice and tax planning.

**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 in Canada is Computershare Trust Company of Canada which holds, at its Montreal offices, the registers related to our common shares, notes, shareholders and transfers. Our transfer agent and registrar in the United States is Computershare Trust Company NA., which holds at its Canton (MA) offices, the registers related to our common shares, shareholders and transfers.

7.1 **PRICE RANGE AND TRADING VOLUME****Common Shares**

The following table sets forth the price range and trading volume of our common shares on the TSX and on NASDAQ for the periods indicated below. However, you should not view this presentation as an indication that the market price of our common shares will continue at such levels.

Period(1)	TSX			NASDAQ(2)		
	High (Cdn\$)	Low (Cdn\$)	Volume	High (US\$)	Low (US\$)	Volume
<b>2018</b>						
December	8.98	7.50	2,976,600	–	–	–
<b>2019</b>						
January	9.74	7.35	3,601,000	–	–	–
February	9.35	7.30	4,034,300	–	–	–
March	9.47	6.74	3,685,300	–	–	–
April	8.90	6.56	3,428,200	–	–	–
May	7.25	5.17	3,439,600	–	–	–
June	7.98	6.16	1,911,200	–	–	–
July	7.07	5.21	1,718,700	–	–	–
August	6.01	4.86	1,353,400	–	–	–
September	6.02	4.89	1,407,300	–	–	–
October	5.80	4.26	1,766,300	4.20	3.25	1,048,043
November	5.40	3.85	1,498,880	4.07	2.90	1,423,297
December	4.31	3.44	3,543,600	3.32	2.61	3,861,300
<b>2020</b>						
January	4.30	3.38	1,797,900	3.31	2.05	1,262,500
February (to February 21)	4.11	3.49	955,000	3.09	2.64	719,325

(1) High and low price based on intraday high and low trading prices. Source for TSX data in the above table is the TSX. Source for NASDAQ data in the above table is QuoteMedia.

(2) Our common shares began trading on NASDAQ on October 10, 2019.



## Notes

The Notes are listed on the TSX under the trading symbol “TH.DB.U”. The following table sets forth certain trading information for our Notes for the periods indicated as reported by the TSX.

Period(2)	5.75% Debentures(2)		
	High (US\$)	Low (US\$)	Volume
<b>2018</b>			
December	90.00	76.00	234,000
<b>2019</b>			
January	93.01	80.00	266,000
February	90.00	85.99	176,000
March	90.01	87.00	194,000
April	83.00	89.00	1,409,000
May	98.98	88.24	124,000
June	91.00	86.02	52,000
July	90.01	88.00	72,000
August	90.00	82.51	74,000
September	95.00	85.02	97,000
October	90.50	82.50	529,000
November	85.00	80.00	123,000
December	79.00	70.31	875,000
<b>2020</b>			
January	80.00	80.00	21,000
February (to February 21)	86.00	80.00	233,000

- (1) Price per US\$100.00 principal amount of the 5.75% Notes.  
(2) High and low price based on intraday high and low trading prices.  
Sources for data in the above table is Bloomberg.

## 7.2 PRIOR SALES

The following table summarizes the distribution of securities, other than those listed on a stock exchange, that we issued during the most recently completed financial year, identifying the type of security, the exercise price per security, the number of securities issued, and the date on which the securities were issued.

Date	Type of Security	Price per Security	Number of Securities
February 26, 2019	Stock Options	CA \$8.76	318,400
February 26, 2019	Stock Appreciation Rights(1)	CA \$8.76	30,000
May 7, 2019	Deferred Stock Units(1)	CA \$7.11	1,055
May 17, 2019	Stock Options	CA \$6.13	88,000
July 30, 2019	Deferred Stock Units	CA \$5.67	2,644
July 30, 2019	Stock Appreciation Rights	CA \$5.90	10,000
October 21, 2019	Deferred Stock Units	CA \$4.73	1,585

- (1) The stock appreciation rights and the deferred stock units are non-dilutive securities. They are redeemable for cash only.

**ITEM 8 LEGAL PROCEEDINGS**

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In the last financial year, we were not subject to any legal proceedings and, as at February 24, 2020, we are not subject to any such proceedings.

## ITEM 9 MATERIAL CONTRACTS

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### Bachem Agreement

We have an agreement with Bachem Americas, Inc., an American subsidiary of Swiss-based Bachem AG, providing for the manufacturing and supply of the active pharmaceutical ingredient of tesamorelin for *EGRIFTA*<sup>®</sup>. Bachem is our only validated supplier of raw materials. This agreement contains customary representations and warranties, indemnity provisions and is currently scheduled to expire in May 2020. We are currently discussing the renewal of this agreement.

### Jubilant Agreement

We have an agreement with Jubilant providing for the manufacture and supply of the finished form of *EGRIFTA*<sup>®</sup>. Under our agreement, Jubilant must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions. This agreement contains customary representations and warranties, indemnity provisions and was scheduled to expire in May 2020. However, on January 7, 2020, we entered into an amendment to the Jubilant Agreement pursuant to which we amended the minimum quantity of products to purchase for the calendar year 2019-2020 and to extend the term of the agreement until December 31, 2020. The agreement contains an automatic renewal provision providing for successive one-year terms unless a party gives the other a written notice within a certain period of time of its intent not to renew the agreement.

### RxCrossroads Agreements

On November 1<sup>st</sup>, 2017, we entered into an amended and restated master services agreement and amended and restated statements of work agreements with RxCrossroads appointing it as our exclusive third-party logistic service provider and exclusive third-party distributor of *EGRIFTA*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States. Effective November 1<sup>st</sup>, 2019, we amended the amended and restated statement of work agreements to add *EGRIFTA SV*<sup>TM</sup> as a new product RxCrossroads was entitled to distribute. The RxCrossroads Agreements will expire in April 2020. The RxCrossroads Agreements contain customary representations and warranties from both parties, indemnification provisions, as well as termination provisions in the event of the occurrence of certain stated events. We are currently discussing the renewal of this agreement.

### H.D. Smith Agreement

On September 1<sup>st</sup>, 2014, we entered into a wholesaler services agreement with H.D. Smith LLC., or H.D. Smith Agreement, appointing H.D. Smith as a non-exclusive authorized wholesaler for *EGRIFTA*<sup>®</sup> in the United States, or H.D. Smith Agreement.

The H.D. Smith Agreement has a one-year term and automatically renews for subsequent one-year period unless a party provides the other with a prior written notice within a confidential time period prior to the termination or renewal period of the agreement. The H.D. Smith Agreement contains customary representations and warranties from parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain stated events.

### Cardinal Agreements

On August 15, 2014 and on October 23, 2014, we entered into a wholesale drop shipment agreement and a drop ship only services agreement with Cardinal Health appointing Cardinal as a non-exclusive authorized wholesaler for *EGRIFTA*<sup>®</sup> in the United States, or Cardinal Agreements.

The Cardinal Agreements have a one-year term and automatically renew for subsequent one-year period unless a party provides the other with a prior written notice within a certain period of time prior to renewal period of these agreements. The Cardinal Agreements contain customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain events.

#### McKesson Corporation

On May 15, 2014, we entered into a core distribution agreement with McKesson Corporation appointing it as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States, or McKesson Agreement

The McKesson Agreement has an indefinite term but may be terminated at any time by either party upon written notice to the other. However, in the event that we were in the process of being acquired, the McKesson Agreement may not be terminated by us without cause for twelve (12) months following the acquisition. The McKesson Agreement contains customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain stated events.

#### Morris & Dickson Agreement

On March 21, 2018, we entered into a drop ship services agreement with Morris & Dickson Co. LLC appointing it as a non-exclusive authorized wholesaler for *EGRIFTA*® in the United States, or M&D Agreement.

The M&D Agreement has a one-year term and automatically renew for subsequent one-year terms unless a party provides the other with a prior written notice within a certain period of time prior to a renewal period. The M&D Agreement contains customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain events.

#### Cesar Castillo, Inc.

On July 12, 2018, we entered into a distribution agreement with Cesar Castillo, Inc. appointing it as a non-exclusive authorized wholesaler for *EGRIFTA*® in the territory of Puerto Rico and the U.S. Virgin Islands, or Cesar Castillo Agreement. On November 1<sup>st</sup>, 2018, the Cesar Castillo Agreement was amended to add Trogarzo® as a product authorized to be distributed thereunder, and, on October 31, 2019, it was further amended to add *EGRIFTA SV*™ as a product authorized to be distributed thereunder as well.

The Cesar Castillo Agreement has a three-year term and automatically renew for subsequent one-year terms unless a party provides the other with a prior written notice within a certain period of time prior to a renewal period. The Cesar Castillo Agreement contains customary representations and warranties from both parties, payment terms, indemnification provisions as well as termination provisions in the event of the occurrence of certain events.

#### Syneos Agreement

On December 4, 2016, we entered into an amended and restated master services agreement with Syneos, as amended on February 3, 2020, providing for the main terms and conditions under which Syneos would provide us with services to commercialize *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States. Each of those services has been described in specific project agreements. We have entered into project agreements relating to, amongst others, the provision of a sales force, medical science liaison personnel and other medical personnel, and reimbursement support personnel. The Syneos Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions. The Syneos Agreement is scheduled to expire on November 30, 2021, unless earlier terminated.

#### TaiMed Agreement

On March 18, 2016 and, thereafter, on March 6, 2017, we entered into the TaiMed Agreement pursuant to which we were granted the exclusive right to commercialize and distribute Trogarzo® in the United States, in Canada, the countries forming part of the European Union as well as Albania, Iceland, Israel, Liechtenstein, Norway, Russia, Sweden, Switzerland and Turkey. The TaiMed agreement was amended on November 6, 2018 to amend one of the definitions included in the TaiMed Agreement and was further amended on November 5, 2019 to set forth the obligations of the parties in connection with the payment of expenses and the delivery terms of Trogarzo® in the European Territory. For a description of the TaiMed Agreement, see “Item 2.5 – Commercialization Activities – Trogarzo®” above.

### MGH License Agreement

On February 3, 2020, we entered into an amended and restated license agreement with the MGH, or MGH License Agreement, granting us an exclusive, worldwide, royalty-bearing license under the MGH's rights to all data, inventions and patents rights, or Proprietary Rights, resulting from the study conducted by the MGH regarding "*Tesamorelin effects on liver fat and histology in HIV*". Under the terms of the MGH License Agreement, the MGH, through Dr. Steven Grinspoon, agreed to provide services related to the study design related to the study of tesamorelin for the potential treatment of NASH in the HIV population, selection of optimal patient population, dosing, study duration and other safety matters and to participate, if need be, in regulatory meetings with the FDA or the EMA. In consideration, we agreed to make certain milestone payments to the MGH related to the development of tesamorelin and a low single-digit royalty payment on all sales of *EGRIFTA*® above a certain threshold amount. The payment of the royalty will begin upon approval by the FDA or the EMA (the first to occur) of an expanded label of tesamorelin for the treatment of NAFLD or NASH in the HIV population. The MGH License Agreement is scheduled to expire on the latest of (i) the date on which all issued patents, if any, and filed patent applications have expired or been abandoned, and (ii) one year after the last sale for which a royalty is due under the MGH License Agreement, unless earlier terminated pursuant to certain customary termination provisions.

### Katana License Agreement

On February 25, 2019, we entered into an amended and restated royalty-bearing license agreement with Transfer Plus, or Katana License Agreement, providing us with the exclusive worldwide rights to develop, make, have made, use, sell, distribute, commercialize and import all of the technology related to the oncology platform that uses peptides as a vehicle to deliver existing cytotoxic agents to sortilin receptors which are overexpressed on cancer cells. The Katana License Agreement contains customary representations and warranties, intellectual property, confidentiality and indemnity provisions. The Katana License Agreement also provides for the payment of milestones and royalties to Transfert Plus. For a description of those milestones and of the royalties, see "Item 2.6 – Research and Development Activities – Oncology Platform" above. The Katana Licence Agreement is scheduled to expire on the latest of (i) February 2039, and (ii) the date of expiry of the last patents to be issued under the agreement or of any of the patents related to any improvements made under the licensed technology, unless earlier terminated pursuant to certain customary termination provisions.

### Accredo Agreement

We entered into an amendment to our existing contracted network pharmacy agreement with Accredo on January 2, 2018, or Accredo Agreement, pursuant to which we added Trogarzo® as a product that Accredo could purchase from RxCrossroads for resale in the United States and expanded the services to be provided by Accredo to take into consideration the mode of administration of Trogarzo®. On December 18, 2019, we further amended the Accredo Agreement to add *EGRIFTA* SV™ as a product that Accredo could purchase from RxCrossroads for resale in the United States. Prior to that, we entered into a contracted network pharmacy agreement with Accredo, effective November 24, 2015, as amended effective April 12, 2016, in connection with the commercialization of *EGRIFTA*®, or the Original Agreement. The Original Agreement appoints Accredo as a non-exclusive authorized purchaser of *EGRIFTA*®, contains a description of the services to be provided by Accredo in connection with the purchase and sale of *EGRIFTA*® in the United States and customary representations and warranties, provisions relating to indemnification, confidentiality, and audit rights. The Original Agreement had a one-year term with successive one-year term renewal periods. The Original Agreement has been renewed continuously and renews automatically unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew it. The Original Agreement, including the amendments thereto, contains termination provisions based on the occurrence of certain stated events.

### Option Care Agreement

We entered into a master services agreement, or MSA, and a statement of work, or SOW, with Option Care on January 31, 2018. Pursuant to the terms of the MSA and SOW, Option Care agreed to provide patients with various services in connection with the administration of Trogarzo®. The MSA contains, amongst others, customary

representations and warranties, provisions relating to indemnification, confidentiality, intellectual property ownership and audit rights of each party. The MSA and the SOW have a two-year term from their effective dates. The MSA and the underlying SOW will renew automatically for successive one-year term periods unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew the MSA and/or the SOW.

#### Curascript Agreement

We entered into an amended and restated wholesale product purchase agreement with Curascript on April 1, 2018 pursuant to which we added Trogarzo® as a product available for purchase and resale by Curascript. An additional amendment was entered into on October 31, 2019 pursuant to which we added *EGRIFTA SV*™ as a product available for purchase and resale by Curascript. No other major changes were made to the original wholesale product purchase agreement we had entered into with Curascript in March 2016. The amended and restated wholesale product purchase agreement has a one-year term and renews automatically for one-year term periods unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew it. The amended and restated wholesale product purchase agreement with Curascript contains, amongst others, customary representations and warranties, provisions relating to the purchase price of Trogarzo®, indemnification, confidentiality and audit rights.

#### Walgreen Agreement

We entered into an amended and restated contracted network pharmacy agreement with Walgreen effective March 6, 2018 pursuant to which we added Trogarzo® as a product available for purchase and resale by Walgreen. An additional amendment was entered into on November 18, 2019 pursuant to which we added *EGRIFTA SV*™ as a product available for purchase and resale by Walgreen. No other major changes were made to the original contracted network pharmacy agreement we had entered into with Walgreen in August 2015. The amended and restated contracted network pharmacy agreement has a one-year term and renews automatically for one-year term periods unless a party provides the other with a written notice within an undisclosed time period of its intent not to renew it. The amended and restated contracted network pharmacy agreement with Walgreen contains, amongst others, customary representations and warranties, provisions relating to the purchase price of Trogarzo®, indemnification, confidentiality and audit rights.

#### McKesson Canada Agreement

On June 3, 2015, we entered into a master services agreement with McKesson Canada pursuant to which McKesson Canada is providing us (through project agreements) with various services in connection with the commercialization of *EGRIFTA*® in Canada, or McKesson Canada Agreement. On June 15 and June 19, 2015, we entered into two project agreements with McKesson Canada defining the services to be provided to us under the McKesson Canada Agreement. The project agreement entered into on June 15, 2015 detailed the services to be provided through our *EGRIFTA Support*® call center whereas the project agreement entered into on June 19, 2015 appointed McKesson Canada as our distributor of *EGRIFTA*® in Canada. Effective November 17, 2017, we agreed to an assignment by McKesson Canada to McKesson Distribution of the project agreement dated June 19, 2015 appointing McKesson Canada as our distributor of *EGRIFTA*® in Canada, resulting in McKesson Distribution now being our distributor in Canada. The McKesson Canada Agreement, as well as the above-mentioned project agreements, were tacitly renewed.

#### Asembia Agreement

On July 15, 2019, we entered into a master services agreement with Asembia, or Asembia Agreement, pursuant to which Asembia agreed to provide us with various services through the entering into of statement of works. The Asembia Agreement contains, amongst others, customary representations and warranties, provisions relating to adverse event reportings, maintenance of cyber-security measures, intellectual property rights, confidentiality and indemnification provisions. The Asembia Agreement is scheduled to expire on July 14, 2022, unless earlier terminated. The Asembia Agreement renews automatically for one-year terms unless a party provides the other with a written notice within a certain period of time of its intent not to renew it. On July 16, 2019, we entered into

a statement of work with Asembia pursuant to which Asembia agreed to provide us with the services of a call center, *THERA Patient Support*<sup>®</sup>, for all of our commercialized products in the United States. For a description of our call center, see “Item 2.5 – Commercialization Activities – Marketing and Sales of our Products – North American Territory” above.

## ITEM 10 ADDITIONAL INFORMATION

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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. Our financial information is provided in our comparative financial statements and Management Discussion & Analysis for our financial year ended November 30, 2019.

Additional information regarding our Company is available on SEDAR at [www.sedar.com](http://www.sedar.com), or upon written request addressed to Jocelyn Lafond, Vice President, Legal Affairs, and Corporate Secretary, at 2015 Peel Street, 11<sup>th</sup> Floor, Montreal, Québec, Canada H3A 1T8. 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.



**I. Mandate**

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;
- D. the supervision of the Company’s Risk Management; and
- E. the review and approval of related party transactions.

**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 the fair presentation of the Company’s financial statements; at the same time evaluating the internal control process to determine the nature, extent and timing of the auditing procedures used for the financial statement audit. 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, as applicable, 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, as applicable, 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;
    - 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;
    - c. the external auditors' report to the Committee on the planning of external auditing; and
    - d. the external auditors' report to the Committee on the auditing results.
- B. Supervision of the Company's Internal Control Systems
  1. Review and discuss with management 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 copy of the minutes of the audit committees' meetings; and
      - ensure that the critical accounting policies and practices are identical to the Company's.
  2. 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, 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 or verbal statement i) describing all relationships between the external auditor and the Company that may reasonably be thought to bear on their independence; ii) assuring that lead audit partner rotation is carried out, as required by law; and iii) describing any other relationship that may reasonably be thought to 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;
3. the Company's insurance portfolio and the adequacy of the coverage; and
4. the Company's investment policy.

E. Review and Approval of Related Party Transactions

Review, approve and oversee any transaction between the Company and any related person (as defined in NASDAQ Listing Rule 5630) for potential conflicts of interest on an ongoing basis.

**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. At least one member of the Committee shall have past employment experience in finance or accounting, requisite professional certification in accounting or other comparable experience that leads to financial sophistication, as determined by the Board. No member of the Committee shall have participated in the preparation of the Company's or any of its subsidiaries' financial statements at any time during the past three years.

**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. 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. Chairman**

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. Secretary**

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 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. Annual Review**

The Committee shall review this Charter at least annually and recommend any proposed changes to the Board for approval.

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**XIII. 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, February 8, 2006, February 25, 2015 and August 7, 2019 Board meetings.

Consolidated Financial Statements  
(In thousands of United States dollars)

## **THERATECHNOLOGIES INC.**

November 30, 2019 and 2018 and as of December 1, 2017

# THE RATECHNOLOGIES INC.

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(In thousands of United States dollars)

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors  
Theratechnologies Inc.

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statement of financial position of Theratechnologies Inc. (the Company) as of November 30, 2019, the related consolidated statements of net loss and comprehensive loss, changes in equity, and cash flows for the year ended November 30, 2019 and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of November 30, 2019, and the financial performance and its cash flows for the year ended November 30, 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

### Change in Presentation Currency

As discussed in Note 1 to the consolidated financial statements, the Company has elected to change its presentation currency to the United States dollar in fiscal 2019 on a retrospective basis.

### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

(signed) KPMG LLP\*

We have served as the Company's auditor since 1993.  
Montréal, Canada

February 24, 2020

\* CPA auditor, CA, public accountancy permit No. A110592

## INDEPENDENT AUDITORS' REPORT

To the Shareholders of Theratechnologies Inc.

We have audited the accompanying consolidated financial statements of Theratechnologies Inc., which comprise the consolidated statements of financial position as at November 30, 2018 and December 1, 2017, the consolidated statements of net loss and comprehensive loss, changes in equity and cash flows for the year ended November 30, 2018, and notes, comprising a summary of significant accounting policies and other explanatory information.

### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

### Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with Canadian generally accepted auditing standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained in our audit is sufficient and appropriate to provide a basis for our audit opinion.

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Opinion

In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of Theratechnologies Inc. as at November 30, 2018 and December 1, 2017, and its financial performance for the year ended November 30, 2018 in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Comparative Information

Without modifying our opinion, we draw attention to Note 1 to the consolidated financial statements, which indicates that the comparative information presented as at and for the year ended November 30, 2018 has been adjusted for a change in presentation currency and that the comparative information presented as at December 1, 2017 has been derived from the consolidated financial statements as at and for the year ended November 30, 2017.

(signed) KPMG LLP\*

February 20, 2019

Montréal, Canada

\* CPA auditor, CA, public accountancy permit No. A110592

# THERATECHNOLOGIES INC.

Consolidated Statements of Financial Position  
(In thousands of United States dollars)

As at November 30, 2019, November 30, 2018 and December 1, 2017

	Note	November 30, 2019	November 30, 2018 (Recast – Note 1)	December 1, 2017 (Recast – Note 1)
<b>Assets</b>				
<b>Current assets</b>				
Cash		\$ 28,661	\$ 38,997	\$ 1,365
Bonds and money market funds	7	11,964	9,691	16,524
Trade and other receivables	8	10,116	10,952	7,553
Inventories	10	20,929	11,084	7,244
Prepaid expenses and deposits		3,874	1,595	785
Derivative financial assets	19(b)	637	1,287	1,120
<b>Total current assets</b>		<b>76,181</b>	<b>73,606</b>	<b>34,591</b>
<b>Non-current assets</b>				
Bonds and money market funds	7	619	5,200	7,653
Property and equipment	11	1,071	101	48
Intangible assets	12	27,480	15,121	16,888
Other asset	13	12,204	17,088	-
<b>Total non-current assets</b>		<b>41,374</b>	<b>37,510</b>	<b>24,589</b>
<b>Total assets</b>		<b>\$ 117,555</b>	<b>\$ 111,116</b>	<b>\$ 59,180</b>
<b>Liabilities</b>				
<b>Current liabilities</b>				
Accounts payable and accrued liabilities	14	\$ 31,173	25,830	\$ 17,997
Provisions	15	2,484	1,014	584
Current portion of long-term obligations	16	3,417	-	3,627
Deferred revenue		70	27	-
<b>Total current liabilities</b>		<b>37,144</b>	<b>26,871</b>	<b>22,208</b>
<b>Non-current liabilities</b>				
Long-term obligations	16	4,570	-	3,524
Convertible unsecured senior notes	17	50,741	49,233	-
Other liabilities	18	266	-	-
<b>Total non-current liabilities</b>		<b>55,577</b>	<b>49,233</b>	<b>3,524</b>
<b>Total liabilities</b>		<b>92,721</b>	<b>76,104</b>	<b>25,732</b>
<b>Equity</b>				
Share capital	19	287,035	286,828	281,743
Equity component of convertible unsecured senior notes		4,457	4,457	-
Contributed surplus		10,783	8,788	12,389
Deficit		(277,462)	(264,966)	(260,604)
Accumulated other comprehensive income (loss)	19(g)	21	(95)	(80)
<b>Total equity</b>		<b>24,834</b>	<b>35,012</b>	<b>33,448</b>
<b>Total liabilities and equity</b>		<b>\$ 117,555</b>	<b>\$ 111,116</b>	<b>\$ 59,180</b>

The accompanying notes are an integral part of these consolidated financial statements.

Approved by the Board of Directors

(signed) Paul Pommier Director

(signed) Gérald Lacoste Director

**THERATECHNOLOGIES INC.**

Consolidated Statements of Net Loss and Comprehensive Loss  
(In thousands of United States dollars, except per share amounts)

Years ended November 30, 2019 and 2018

	Note	2019	2018
			(Recast – Note 1)
<b>Revenue</b>	4	\$ 63,216	\$ 45,217
Operating expenses			
Cost of sales			
Cost of goods sold		21,125	9,376
Other production-related costs		67	105
Royalties		-	1,340
Amortization of other asset		4,884	2,442
Research and development expenses		10,841	7,994
Selling expenses		26,482	21,693
General and administrative expenses		8,330	5,828
<b>Total operating expenses</b>		<b>71,729</b>	<b>48,778</b>
<b>Loss from operating activities</b>		<b>(8,513)</b>	<b>(3,561)</b>
Finance income	6	1,097	608
Finance costs	6	(5,080)	(3,016)
		(3,983)	(2,408)
<b>Loss before income tax recovery</b>		<b>(12,496)</b>	<b>(5,969)</b>
<b>Income tax recovery</b>		<b>-</b>	<b>1,269</b>
<b>Net loss</b>		<b>(12,496)</b>	<b>(4,700)</b>
<b>Other comprehensive income (loss), net of tax</b>			
Items that may be reclassified to net profit (loss) in the future			
Net change in fair value of FVOCI financial assets, net of tax		83	(15)
Exchange difference on translation of foreign operations		33	-
		116	(15)
<b>Total comprehensive loss</b>		<b>\$ (12,380)</b>	<b>\$ (4,715)</b>
Loss per share			
Basic and diluted	19(f)	(0.16)	(0.06)

The accompanying notes are an integral part of these consolidated financial statements.

# THERATECHNOLOGIES INC.

Consolidated Statements of Changes in Equity  
(In thousands of United States dollars)

Years ended November 30, 2019 and 2018

	Note	Share capital		Equity component of convertible unsecured senior notes	Contributed surplus	Deficit	Accumulated other comprehensive income (loss)	Total
		Number of shares	Amount					
<b>Balance as at November 30, 2017 and December 1, 2017 (Recast – Note 1)</b>		74,962,050	\$ 281,743	\$ -	\$ 12,389	\$ (260,604)	\$ (80)	\$ 33,448
<b>Total comprehensive loss</b>								
Net loss		-	-	-	-	(4,700)	-	(4,700)
<b>Other comprehensive income</b>								
Net change in fair value of FVOCI financial assets, net of tax		-	-	-	-	-	(15)	(15)
<b>Total comprehensive loss</b>		-	-	-	-	(4,700)	(15)	(4,715)
<b>Transactions with owners, recorded directly in equity</b>								
Recognition of previously unrecognized tax assets from item originally recorded in equity		-	-	-	-	338	-	338
Equity component of convertible unsecured senior notes, net of income taxes of \$1,607		-	-	4,457	-	-	-	4,457
<b>Share-based compensation plan</b>								
Share-based compensation for stock option plan		-	-	-	851	-	-	851
<b>Exercise of stock options</b>								
Monetary consideration		412,734	538	-	-	-	-	538
Attributed value		-	426	-	(426)	-	-	-
Exercise of broker options		39,390	121	-	(26)	-	-	95
Issuance of common shares – TaiMed		1,463,505	4,000	-	(4,000)	-	-	-
<b>Total contributions by owners</b>		<b>1,915,629</b>	<b>5,085</b>	<b>4,457</b>	<b>(3,601)</b>	<b>338</b>	<b>-</b>	<b>6,279</b>
<b>Balance as at November 30, 2018 (Recast – Note 1)</b>		76,877,679	286,828	4,457	8,788	(264,966)	(95)	35,012
<b>Total comprehensive loss</b>								
Net loss		-	-	-	-	(12,496)	-	(12,496)
<b>Other comprehensive income</b>								
Net change in fair value of FVOCI financial assets, net of tax		-	-	-	-	-	83	83
Exchange differences on translation of foreign operations		-	-	-	-	-	33	33
<b>Total comprehensive loss</b>		-	-	-	-	(12,496)	116	(12,380)
<b>Transactions with owners, recorded directly in equity</b>								
Issuance of common shares of Katana	12	900	5	-	-	-	-	5
Share-based contingent consideration	12	-	-	-	1,028	-	-	1,028
<b>Share-based compensation plan</b>								
Share-based compensation for stock option plan		-	-	-	1,059	-	-	1,059
<b>Exercise of stock options</b>								
Monetary consideration		74,832	110	-	-	-	-	110
Attributed value		-	92	-	(92)	-	-	-
<b>Total contributions by owners</b>		<b>75,732</b>	<b>207</b>	<b>-</b>	<b>1,995</b>	<b>-</b>	<b>-</b>	<b>2,202</b>
<b>Balance as at November 30, 2019</b>		76,953,411	\$ 287,035	\$ 4,457	\$ 10,783	\$ (277,462)	\$ 21	\$ 24,834

The accompanying notes are an integral part of these consolidated financial statements.

# THERATECHNOLOGIES INC.

Consolidated Statements of Cash Flows  
(In thousands of United States dollars)

Years ended November 30, 2019 and 2018

	Note	2019	2018
			(Recast – Note 1)
<b>Cash flows from (used in)</b>			
<b>Operating</b>			
Net loss		\$ (12,496)	\$ (4,700)
Adjustments for			
Depreciation of property and equipment	11	199	21
Amortization of intangible assets and other asset	12, 13	7,296	4,209
Share-based compensation for stock option plan		1,087	851
Deferred income tax recovery		-	(1,269)
Write-down of inventories	10	16	144
Change in fair value of derivative financial assets	19(b)	647	(213)
Change in fair value of liability related to deferred stock unit plan	19(b)	(641)	210
Interest on convertible unsecured senior notes	6	3,317	1,486
Interest income	6	(1,097)	(608)
Accretion expense	6	1,673	1,041
Foreign exchange		32	271
Loss on repayment of long-term obligations	16	-	286
Lease inducements and amortization		238	-
		271	1,729
Change in operating assets and liabilities			
Trade and other receivables		831	(3,399)
Inventories		(9,861)	(3,984)
Prepaid expenses and deposits		(2,282)	(810)
Accounts payable and accrued liabilities		6,137	6,099
Provisions		1,470	430
Deferred revenue		43	27
		(3,662)	(1,637)
<b>Total cash from (used in) operating activities</b>		<b>(3,391)</b>	<b>92</b>
<b>Financing</b>			
Proceeds from issue of convertible unsecured senior notes		-	57,500
Convertible unsecured senior notes issuance costs		-	(2,825)
Interest paid on convertible unsecured senior notes		(3,417)	-
Repayment of long-term obligations		(3,500)	(7,850)
Proceeds from exercise of stock options		110	538
Proceeds from exercise of broker options		-	95
<b>Total cash from (used in) financing activities</b>		<b>(6,807)</b>	<b>47,458</b>
<b>Investing</b>			
Acquisition of other asset	13	-	(19,530)
Acquisition of intangible assets	12	(2,407)	(17)
Acquisition of property and equipment	11	(1,215)	(25)
Proceeds from sale of bonds and money market funds		2,482	26,525
Acquisition of bonds and money market funds		(192)	(17,625)
Interest received		1,199	762
Acquisition of derivative financial assets		(21)	(8)
Proceeds from sale of derivative financial assets		24	-
<b>Total cash used in investing activities</b>		<b>(130)</b>	<b>(9,918)</b>
<b>Net change in cash</b>		<b>(10,328)</b>	<b>37,632</b>
<b>Cash, beginning of year</b>		<b>38,997</b>	<b>1,365</b>
Effect of foreign exchange on cash		(8)	-
<b>Cash, end of year</b>		<b>\$ 28,661</b>	<b>\$ 38,997</b>

See Note 21 for supplemental cash flow disclosures.

The accompanying notes are an integral part of these consolidated financial statements.

# Theratechnologies Inc.

Notes to Consolidated Financial Statements  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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Theratechnologies Inc. is a specialty pharmaceutical company addressing unmet medical needs by bringing to market specialized therapies for people with orphan medical conditions, including those living with HIV.

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 governed by the *Business Corporations Act* (Quebec) and is domiciled in Quebec, Canada. The Company is located at 2015 Peel Street, Montréal, Quebec, H3A 1T8.

## 1. Basis of preparation

### Statement of compliance

The consolidated financial statements of the Company have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

The consolidated financial statements were authorized for issue by the Board of Directors on February 24, 2020.

### Basis of measurement

The Company's consolidated financial statements have been prepared on a going concern and historical cost basis, except for bonds and money market funds, derivative financial assets, liabilities related to cash-settled share-based arrangements and derivative financial liabilities, which are measured at fair value. Equity-classified share-based payment arrangements are measured at fair value at grant date pursuant to IFRS 2, *Share-based Payment*.

The methods used to measure fair value are discussed further in Note 24.

### Functional and presentation currency

The Company's functional currency is the United States dollar ("USD"). Prior to the issuance of these annual consolidated financial statements, the presentation currency was the Canadian dollar ("CAD"). In 2019, management decided to change the presentation currency from the CAD to the USD to better reflect the market the Company operates in, and this change was applied retrospectively, resulting in the recast of comparative information. As such, these consolidated financial statements are now presented in USD, together with the comparative numbers as at November 30, 2018. The Company has also presented an opening consolidated statement of financial position as at December 1, 2017 in USD, which has been derived from the consolidated financial statements as at and for the year ended November 30, 2017.

All financial information presented in USD has been rounded to the nearest thousand.



# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 1. Basis of preparation (continued)

### Initial application of new or amended accounting standards

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

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

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

#### IFRS 9, *Financial Instruments* ("IFRS 9")

The Company adopted all of the requirements of IFRS 9 with a date of initial application of December 1, 2018. IFRS 9 does not require restatement of comparative periods. This standard establishes principles for the financial reporting classification and measurement of financial assets and financial liabilities. This standard also incorporates a new hedging model which increases the scope of hedged items eligible for hedge accounting and aligns hedge accounting more closely with risk management. This standard also amends the impairment model by introducing a new "expected credit loss" model for calculating impairment. This new standard increases required disclosures about an entity's risk management strategy, cash flows from hedging activities and the impact of hedge accounting on the consolidated financial statements.

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

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 1. Basis of preparation (continued)

### Initial application of new or amended accounting standards (continued)

#### IFRS 9, *Financial Instruments* (continued)

The following summarizes the classification and measurement changes for the Company's non-derivative and derivative financial assets and financial liabilities as a result of the adoption of IFRS 9.

	IAS 39	IFRS 9
Financial assets:		
Cash	Loans and receivables	Amortized cost
Bonds	Available for sale	Fair value through other comprehensive income
Money market funds	Available for sale	Fair value through profit or loss
Trade and other receivables	Loans and receivables	Amortized cost
Non-hedge derivative financial assets	Fair value through profit or loss	Fair value through profit or loss
Financial liabilities:		
Accounts payable and accrued liabilities	Other financial liabilities	Amortized cost
Convertible unsecured senior notes	Other financial liabilities	Amortized cost
Long-term obligations	Other financial liabilities	Amortized cost

The accounting for these instruments and the line item in which they are included in the consolidated statement of financial position were unaffected by the adoption of IFRS 9, except for money market funds for which fair value was measured through other comprehensive income under IAS 39 and is now measured through profit or loss under IFRS 9. The impact of this change was not material to the consolidated financial statements.

The new expected credit loss ("ECL") impairment model applies to financial assets measured at amortized cost and debt investments at fair value through other comprehensive income ("FVOCI"). The Company has determined that the application of IFRS 9's impairment requirements as at December 1, 2018 results in no adjustment for the allowance for impairment on trade and other receivables. Over 97% of the Company's revenue is attributable to sales transactions with one customer: RxCrossroads (see Notes 4 and 26). As at December 1, 2017, November 30, 2018, and November 30, 2019, none of the trade and other receivables were overdue and the total allowance for impairment of receivables recorded during the period was nil.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 1. Basis of preparation (continued)

### Initial application of new or amended accounting standards (continued)

#### IFRS 15, *Revenue from Contracts with Customers* ("IFRS 15")

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

### Use of estimates and judgments

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

#### Judgments in applying accounting policies

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

#### *Milestone payments related to Trogarzo®*

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

#### *Contingent consideration related to oncology platform*

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

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 1. Basis of preparation (continued)

### Use of estimates and judgments (continued)

Judgments in applying accounting policies (continued)

#### *Convertible senior unsecured notes*

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

Key sources of estimation uncertainty

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

#### *Sales promotional programs*

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

#### *Other*

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

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

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

## 2. Significant accounting policies

The accounting policies have been applied consistently by the subsidiaries of the Company, except as otherwise noted for the initial application of new or amended accounting standards.

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Basis of consolidation

The financial statements of the subsidiaries of the Company 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 currently exercisable are taken into consideration. The accounting policies of subsidiaries are changed when necessary to align them with the policies adopted by the Company.

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

### Foreign currencies

Transactions in foreign currencies are translated to the functional currency at exchange rates in effect at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies at the reporting date are translated to the functional currency at the exchange rate in effect 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 reporting year, adjusted for effective interest and payments during the reporting year, and the amortized cost in foreign currency translated at the exchange rate in effect at the end of the reporting year.

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 in effect 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 in effect at the date of the transaction. Foreign currency differences arising on translation are recognized in net profit, except for differences arising on the translation of FVOCI financial instruments, which are recognized in other comprehensive income.

### Foreign operations

The assets and liabilities of foreign operations whose functional currency is not the USD are translated into USD at the reporting date. The income and expenses of foreign-currency denominated operations are translated at average rates for each reporting period. Foreign exchange differences arising on the translation of foreign operations are recognized directly in other comprehensive income. When a foreign subsidiary is disposed of, the cumulative amount recognized in the currency translative reserve forms part of the gain or loss on disposal.

# **THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## **2. Significant accounting policies (continued)**

### **Revenue recognition**

Revenue from contracts with customers – Net sales

The Company derives revenue from the sales of finished goods, which include Trogarzo® and EGRIFTA®. The Company recognizes revenue at a point in time when it transfers control of the finished goods to a customer, which generally occurs upon delivery of the finished goods to the customer's premises. Payment received from customers prior to the transfer of control of the goods is recorded as deferred revenue.

Some arrangements for the sale of finished goods provide for customer cash discounts for prompt payment, allowances, rights of return, rebates on sales made under governmental and commercial rebate programs, chargebacks on sales made to government agencies and retail pharmacies and distribution fees, which gives rise to variable consideration. At the time of sale, estimates are made for items giving rise to variable consideration based on the terms of the arrangement. The variable consideration is estimated at contract inception using the most likely amount method and revenue is only recognized to the extent that a significant reversal of revenue is not expected to occur. The estimate is based on historical experience, current trends, contractual terms with distributors and other known factors. Sales are recorded net of customer discounts, rebates, chargebacks, distribution fees and estimated sales returns, and exclude sales taxes. A refund liability and a right to recover returned goods asset are recognized for expected returns in relation to sales made before the end of the reporting period. The right to recover returned goods asset is measured at the former carrying amount of the inventory less any expected costs to recover goods. The Company reviews its estimate of variable consideration, including expected returns, on a quarterly basis, adjusting for the amounts of the asset and liability accordingly.

### **Cost of sales**

Cost of goods sold

Cost of goods sold includes the cost of raw materials, supplies, direct labour and overhead charges allocated to goods sold.

Other production related costs

Other production related costs include unallocated indirect costs related to production as well as write-downs of inventories.

Royalties

Royalties include royalties payable under the 2013 Termination Agreement (Note 13).

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Cost of sales (continued)

#### Amortization of the other asset

The amortization of the other asset relates to the repurchase of the future royalty rights under the 2013 Termination Agreement (Note 13).

### 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 employment 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.

### Finance income and finance costs

Finance income comprises interest income on financial assets and gains on the disposal of financial assets. Interest income is recognized as it accrues in net loss using the effective interest method.

Finance costs comprise bank charges, interest and accretion expense on convertible unsecured senior notes and long-term obligations, impairment losses on financial assets recognized in net loss, changes in fair value of liabilities and derivatives, unrealized foreign currency gain or loss on long-term obligations and other foreign currency gains and losses which are reported on a net basis.

# **THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## **2. Significant accounting policies (continued)**

### **Inventories**

Inventories are presented at the lower of cost, determined using the first-in, first-out method, and 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. The Company is responsible for coordinating the production and stability testing and for auditing suppliers at different times during the manufacturing process. Inventory costs also include the costs directly related to the conversion of materials into finished goods. 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.

Work in progress inventory appears from the moment third party suppliers use the material provided by the Company until the time the Company receives the finished product. The value of work in progress inventory is equal to the value of material provided by the Company plus all conversion work performed by third party suppliers.

### **Property and equipment**

#### Recognition and measurement

Items of property and equipment are recognized at cost less accumulated depreciation and accumulated impairment losses. Cost includes expenditures that are 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.

Construction in progress assets are capitalized during construction and depreciation commences when the asset is available for use.

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 or 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 items of property and equipment are recognized in net profit or loss as incurred.



## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 2. Significant accounting policies (continued)

#### Property and equipment (continued)

##### Depreciation

The methods of depreciation and depreciation rates and periods are as follows.

Asset	Method	Rate/period
Computer equipment	Declining balance	50%
Laboratory equipment	Declining balance and straight-line	20% 5 years
Office furniture and equipment	Declining balance	20%
Leasehold improvements	Straight-line	Lower of lease term and economic life

The method of depreciation is selected based on the most closely 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 year-end and adjusted if appropriate.

#### 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. A 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, 2019 and 2018, no development expenditures were capitalized.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Intangible assets (continued)

#### Commercialization rights and oncology platform

Commercialization rights and the oncology platform acquired by the Company have finite useful lives and are measured at cost less accumulated amortization and any accumulated impairment losses. Subsequent changes in the cash-based contingent consideration on the acquisition of intangible assets arising from the attainment of commercial milestones are recorded in the cost of the asset. Commercialization rights – *EGRIFTA*<sup>®</sup> are amortized at fixed rates based on their estimated useful life of 111 months on a straight-line basis. Commercialization rights – Trogarzo<sup>®</sup> North American Territory are amortized at fixed rates based on their estimated useful life of 142 months on a straight-line basis. Commercialization rights – Trogarzo<sup>®</sup> European Territory and the oncology platform will be amortized over their estimated useful lives on a straight-line basis when the assets are available for use.

The amortization method and useful life of intangible assets are reviewed every year and adjusted as required.

### Other asset

Other asset, which comprises the amount disbursed in connection with the repurchase of the future royalty rights under the 2013 Termination Agreement (Note 13), is amortized over its estimated useful life of 48 months.

### Impairment of 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.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Impairment of non-financial assets (continued)

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"). 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 or the cash-generating unit. Impairment losses recognized in prior years are determined by the Company at each reporting date for any indications that the loss has decreased or no longer exists. An asset's carrying amount, increased through the 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.

### Financial instruments

The Company initially recognizes financial assets on the trade date at which the Company becomes a party to the contractual provisions of the instrument. Financial assets are initially measured at fair value. If the financial asset is not subsequently accounted for at fair value through profit or loss, then the initial measurement includes transaction costs that are directly attributable to the asset's acquisition or issue. On initial recognition, the Company classifies its financial assets as measured at amortized cost, FVOCI or fair value through profit or loss ("FVPL"), depending on its business model for managing the financial assets and the contractual cash flow characteristics of the financial assets.

#### (i) Financial assets measured at amortized cost

A financial asset is measured at amortized cost, using the effective interest method and net of any impairment loss, if it meets both of the following conditions and is not designated at fair value through profit or loss:

- it is held within a business model whose objective is to hold assets to collect contractual cash flows; and
- its contractual terms give rise, on specified dates, to cash flows that are solely payments of principal and interest on the principal amount outstanding.

The Company currently classifies its cash and trade and other receivables as financial assets measured at amortized cost.

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Financial instruments (continued)

#### (ii) Financial assets, measured at fair value through other comprehensive income

A debt investment is measured at fair value through other comprehensive income if it meets both of the following conditions and is not designated at fair value through profit or loss:

- it is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets; and
- its contractual terms give rise, on specified dates, to cash flows that are solely payments of principal and interest on the principal amount outstanding.

These assets are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognized in profit or loss. Other net gains and losses are recognized in other comprehensive income. When an investment is derecognized, gains or losses accumulated in other comprehensive income are reclassified to profit or loss.

On initial recognition of an equity investment that is not held for trading, the Company may irrevocably elect to present subsequent changes in the investment's fair value in other comprehensive income. This election is made on an investment-by-investment basis. These assets are subsequently measured at fair value. Dividends are recognized in profit or loss, unless the dividend clearly represents a repayment of part of the cost of the investment, and other net gains and losses are recognized in other comprehensive income and are never reclassified in profit or loss.

The Company currently classifies its bonds as financial assets measured at fair value through other comprehensive income.

#### (iii) Financial assets measured at fair value through profit or loss

All financial assets not classified as measured at amortized cost or fair value through other comprehensive income as described above are measured at fair value through profit or loss. These assets are subsequently measured at fair value and changes therein, including any interest or dividend income, are recognized in profit or loss. The Company currently classifies its money market funds and non-hedge derivative financial assets as financial assets measured at fair value through profit or loss.

The Company derecognizes a financial asset when the contractual rights to the cash flows from the asset expire, or it transfers the rights to receive the contractual cash flows on the financial asset in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Financial instruments (continued)

#### (iv) Financial liabilities

Financial liabilities are classified into the following categories:

- Financial liabilities at fair value through profit or loss

A financial liability is classified at fair value through profit or loss if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at fair value are measured at fair value and net gains and losses, including interest expense, are recognized in profit or loss. The Company currently has no financial liabilities measured at fair value through profit or loss.

- Financial liabilities measured at amortized cost

This category includes all financial liabilities, other than those measured at fair value through profit or loss. A financial liability is subsequently measured at amortized cost using the effective interest method. The Company currently classifies accounts payable and accrued liabilities, convertible unsecured senior notes and long-term obligations as financial liabilities measured at amortized cost.

The Company derecognizes a financial liability when its contractual obligations are discharged or cancelled, or expired.

#### (v) Compound financial instruments

Compound financial instruments are instruments that contain both a liability component and an equity component, and the liability component can be converted into share capital at the option of the holder and the number of shares to be issued does not vary with changes in their fair value.

The liability component of a compound financial instrument is recognized initially at the fair value of a similar liability that does not have an equity conversion option. The equity component is recognized initially as the difference between the fair value of the compound financial instrument as a whole and the fair value of the liability component.

Any directly attributable transaction costs are allocated to the liability and equity component in proportion to their initial carrying amounts.

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Financial instruments (continued)

#### (vi) Derivative financial instruments

Derivative financial instruments are recorded as either assets or liabilities measured at their fair value unless exempted from derivative treatment as a normal purchase and sale. Certain derivatives embedded in other contracts must also be measured at fair value. The changes in the fair value of derivatives are recognized through profit or loss in the year in which they occur.

#### (vii) Offsetting of financial instruments

Financial assets and liabilities are offset and the net amount presented in the consolidated statement of financial position when, and only when, the Company has a legal right to set off the amounts and intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously.

#### (viii) Impairment of financial assets

At each reporting date, the Company recognizes loss allowances for ECLs on financial assets carried at amortized cost and debt securities at FVOCI. The Company's trade and other receivables are accounts receivable with no financing component and which have maturities of less than 12 months and, as such, the Company has chosen to apply the simplified approach for ECL. As a result, the Company does not track changes in credit risk related to its trade and other receivables, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date.

For other financial assets subject to impairment, the Company measures loss allowances at an amount equal to lifetime ECLs, except for the following, which are measured at 12-month ECLs:

- debt securities that are determined to have low credit risk at the reporting date; and
- other debt securities and bank balances for which credit risk (i.e. the risk of default occurring over the expected life of the financial instrument) has not increased significantly since initial recognition.

The Company considers a debt security to have a low credit risk when its credit risk rating is equivalent or above investment grade credit rating, such as its bonds classified at FVOCI.

The Company's approach to ECLs reflects a probability-weighted outcome, the time value of money and reasonable and supportable information that is available without undue cost or effort at the reporting date about past events, current conditions and forecasts of future economic conditions.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Leases

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

### 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.

#### Chargebacks and rebates

Chargebacks and rebates are estimated based on historical experience, relevant statutes with respect to governmental pricing programs, and contractual sales terms.

#### Returns

Provisions for returns are estimated based on historical return levels, taking into account additional available information on contract changes. The Company reviews its methodology and adequacy of the provision for returns on a quarterly basis, adjusting for changes in assumptions, historical results and business practices, as necessary.

#### Contingent liability

A contingent liability is a possible obligation that arises from past events and whose 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 because the amount of the obligation cannot be estimated reliably.

### Income taxes

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

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Income taxes (continued)

#### Current tax

Current tax is the expected tax payable or receivable on the taxable income or loss for the year 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 and deferred tax losses that can be used against taxable profit in future years. Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse and to fiscal losses when they will be used, 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 used. 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.

Deferred income tax is not recognized for the following temporary differences: the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting or taxable profit or loss at the time of the transaction, and, where the timing of the reversal of the temporary difference is controlled by the Company and it is probable that the temporary difference will not reverse in the foreseeable future. In addition, deferred tax is not recognized for taxable temporary differences arising from the initial recognition of goodwill.

### Share-based compensation

#### Share option plan

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 over the period in which employees unconditionally become entitled to the options. The amount recognized as an expense is adjusted to reflect the number of options 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 options that do meet the related service conditions at the vesting date.



# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Share-based compensation (continued)

#### Share option plan (continued)

Share-based payment arrangements in which the Company receives 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.

#### Deferred stock unit plan

The deferred stock units (“DSUs”) are totally vested on the date of grant and are settled in cash. In the case of the DSUs granted to officers for annual bonuses, a DSU liability is recorded on the date of grant at the market value of the common shares in place of the liability for the bonus payments. In the case of the directors, the expense related to DSUs and their liabilities are recognized on the date of grant. The liability is adjusted to reflect any change in the market value of common shares and such change is recorded in finance costs.

### Cash-settled stock appreciation rights

The stock appreciation rights (“SARs”) entitle the grantee to a cash payment based on the increase in the share price of the Company’s common shares from the grant date to the settlement date.

A liability is recognized for the services acquired and is recorded at the fair value of the SARs in other non-current liabilities, with a corresponding expense recognized in selling expenses over the period that the employees become unconditionally entitled to the payment. The fair value of the employee benefits expense of the SARs is measured using the Black-Scholes model.

Estimating fair value requires determining the most appropriate inputs to the valuation model including the expected life of the SARs, volatility, risk-free interest rate and dividend yield and making assumptions about them. At the end of each reporting period until the liability is settled, the fair value of the liability is remeasured, with any changes in fair value recognized in the consolidated statement of net earnings (loss) and comprehensive earnings (loss) of the current year.

### Research and development tax credits

The Company elected to account for non-refundable research and development tax credits under IAS 20, *Accounting for Government Grants and Disclosure of Governmental Assistance*. Non-refundable research and development tax credits are included in earnings against gross research and development expenses or deducted from the related assets, provided there is reasonable assurance that the Company has complied and will comply with the conditions related to the tax credits and that the credits will be received.

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 2. Significant accounting policies (continued)

### Share capital

Common shares

Common shares are classified as equity.

Transaction costs

Costs directly attributable to the issue of common shares are recognized in equity, net of any tax effects.

### 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 year. Diluted EPS is determined by adjusting the profit or loss attributable to common shareholders by taking the weighted average number of common shares outstanding and taking into consideration all dilutive potential common shares, which consist of the outstanding stock options and convertible unsecured senior notes.

## 3. New or revised standards and interpretations issued but not yet adopted

IFRS 16, *Leases* ("IFRS 16")

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

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

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

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

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 3. New or revised standards and interpretations issued but not yet adopted (continued)

IFRS 16, *Leases* ("IFRS 16") (continued)

The Company intends to adopt IFRS 16 in its consolidated financial statements for the annual period beginning on December 1, 2019 using the modified retrospective transition method. The extent of the impact of adoption of the standard has not yet been determined, but the Company expects the majority of its operating leases will need to be recognized in the consolidated statement of financial position on initial adoption. At December 1, 2019, the Company expects to record right-of-use assets and lease liabilities of approximately \$3,000. The Company also expects a decrease in operating lease costs, offset by an increase in depreciation and amortization and financial expenses resulting from the changes in the recognition, measurement and presentation requirements. However, no significant impact on net earnings is expected at this time. The Company is completing the assessment of the overall impact on the Company's disclosures and is addressing any system and process changes necessary to compile the information to meet the recognition and disclosure requirements of the new guidance starting in the first quarter of fiscal 2020.

## 4. Revenue and deferred revenue

On May 12, 2014, the Company entered into a master services agreement with RxC Acquisition Company ("RxCrossroads"), along with two statements of work ("RxCrossroads Agreements"). Under the terms of the RxCrossroads Agreements, RxCrossroads acts as the Company's exclusive third-party logistics service provider for all of the Company's products in the United States and, as such, provides warehousing and logistical support services to the Company, including inventory control, account management, customer support, product return management and fulfillment of orders.

Under the RxCrossroads Agreements, RxCrossroads also acts as the Company's exclusive third-party distributor of *EGRIFTA*® in the United States. In such a role, RxCrossroads purchases *EGRIFTA*® from the Company and takes title thereto when the goods arrive in their warehouse. RxCrossroads' purchases of *EGRIFTA*® are triggered by its expectations of market demand over a certain period of time. With respect to *EGRIFTA*®, RxCrossroads fulfills orders received from authorized wholesalers and delivers *EGRIFTA*® directly to that authorized wholesaler's client, namely, a specialty pharmacy forming part of our network of specialty pharmacies. See Note 26.

On November 1, 2017, the Company entered into amended and restated RxCrossroads Agreements to add Trogarzo® as a new product sold in the United States. These amended and restated RxCrossroads Agreements replaced the RxCrossroads Agreements entered into in May 2014. On November 1, 2019, the RxCrossroads Agreements were amended anew to include *EGRIFTA* SV™ as an additional product distributed by RxCrossroads in the United States.

The Company commercializes *EGRIFTA*® directly in Canada using a distributor.

Net sales by product were as follows:

		2019		2018
<i>EGRIFTA</i> ® net sales	\$	35,520	\$	36,329
Trogarzo® net sales		27,696		8,888
	\$	63,216	\$	45,217

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 4. Revenue and deferred revenue (continued)

Net sales by geography were as follows:

	2019		2018	
Canada	\$	295	\$	530
United States		62,921		44,687
	\$	63,216	\$	45,217

## 5. Personnel expenses

	Note	2019		2018	
Salaries and short-term employee benefits		\$	5,402	\$	4,307
Post-employment benefits			295		230
Share-based compensation	19(e)		1,059		851
Termination benefits			87		-
		\$	6,843	\$	5,388

## 6. Finance income and finance costs

	Note	2019		2018	
Interest income		\$	1,097	\$	608
Finance income			1,097		608
Accretion expense	16, 17		(1,673)		(1,041)
Interest on convertible unsecured senior notes			(3,317)		(1,486)
Loss on repayment of long-term obligations			-		(286)
Bank charges			(39)		(37)
Net foreign currency loss			(45)		(169)
(Loss) gain on financial instruments carried at fair value			(6)		3
Finance costs			(5,080)		(3,016)
Net finance cost recognized in net profit or loss		\$	(3,983)	\$	(2,408)

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 7. Bonds and money market funds

	November 30		December 1,
	2019	2018	2017
Bonds	\$ 5,246	\$ 7,746	\$ 12,878
Money market funds	7,337	7,145	11,299
	12,583	14,891	24,177
Current portion	11,964	9,691	16,524
Non-current portion	\$ 619	\$ 5,200	\$ 7,653

As at November 30, 2019, bonds were interest-bearing financial assets with stated interest rates ranging from 1.7% to 4.8% (2018 – 1.6% to 4.8%) and had an average maturity of 0.5 years (2018 – 1.2 years).

### 8. Trade and other receivables

	November 30		December 1,
	2019	2018	2017
Trade receivables	\$ 9,538	\$ 10,720	\$ 7,460
Sales tax receivable	253	98	71
Other receivables	325	134	22
	\$ 10,116	\$ 10,952	\$ 7,553

### 9. Tax credits receivable

Tax credits receivable comprise research and development investment tax credits receivable from the Quebec government which relate to eligible research and development expenditures under the applicable tax laws. The amounts recorded as receivables 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.

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 9. Tax credits receivable (continued)

The Company has unused and unrecorded non-refundable federal tax credits which may be used to reduce future income tax and expire as follows.

2024	\$	448
2025		1,336
2026		1,640
2027		2,260
2028		2,507
2029		1,689
2030		837
2031		585
2032		306
2033		202
	\$	11,810

### 10. Inventories

	November 30		December 1,
	2019	2018	2017
Raw materials	\$ 3,011	\$ 4,224	\$ 5,247
Work in progress	2,467	292	-
Finished goods	15,451	6,568	1,997
	\$ 20,929	\$ 11,084	\$ 7,244

Inventories were written down to net realizable value by an amount of \$16 in 2019 (2018 – \$144), of which nil (2018 – \$108) is recorded in cost of sales as other production-related costs and \$16 (2018 – \$36) was recorded in cost of goods sold.

The write-downs in 2019 and 2018 related to losses incurred during the conversion of raw materials to finished goods and losses associated with expired goods.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 11. Property and equipment

	Computer equipment	Laboratory equipment	Office furniture and equipment	Leasehold improvements	Total
<b>Cost</b>					
Balance as at December 1, 2017	\$ 77	\$ 47	\$ 71	\$ -	195
Additions	18	-	4	52	74
Disposals	(13)	-	-	-	(13)
Balance as at November 30, 2018	\$ 82	\$ 47	\$ 75	\$ 52	256
Additions	206	60	313	590	1,169
Disposals	(57)	-	(54)	-	(111)
Balance as at November 30, 2019	\$ 231	\$ 107	\$ 334	\$ 642	1,314
<b>Accumulated depreciation</b>					
Balance as at December 1, 2017	\$ 67	\$ 18	\$ 62	\$ -	147
Depreciation	12	7	2	-	21
Disposals	(13)	-	-	-	(13)
Balance as at November 30, 2018	\$ 66	\$ 25	\$ 64	\$ -	155
Depreciation	78	7	48	66	199
Disposals	(57)	-	(54)	-	(111)
Balance as at November 30, 2019	\$ 87	\$ 32	\$ 58	\$ 66	243
<b>Net carrying amounts</b>					
November 30, 2019	\$ 144	\$ 75	\$ 276	\$ 576	1,071
November 30, 2018	\$ 16	\$ 22	\$ 11	\$ 52	101
December 1, 2017	\$ 10	\$ 29	\$ 9	\$ -	48

**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**12. Intangible assets**

	Commercialization rights – Trogarzo® North American Territory	Commercialization rights – Trogarzo® European Territory	Commercialization rights – EGRIFTA®	Oncology platform	Total
<b>Cost</b>					
Balance as at December 1, 2017 and November 30, 2018	\$ 5,207	\$ 3,055	\$ 14,041	\$ -	22,303
Additions	6,765	4,557	-	3,449	14,771
Balance as at November 30, 2019	\$ 11,972	\$ 7,612	\$ 14,041	\$ 3,449	37,074
<b>Accumulated amortization</b>					
Balance as at December 1, 2017	\$ -	\$ -	\$ 5,415	\$ -	5,415
Amortization	257	-	1,510	-	1,767
Balance as at November 30, 2018	\$ 257	\$ -	\$ 6,925	\$ -	7,182
Amortization	901	-	1,511	-	2,412
Balance as at November 30, 2019	\$ 1,158	\$ -	\$ 8,436	\$ -	9,594
<b>Net carrying amounts</b>					
November 30, 2019	\$ 10,814	\$ 7,612	\$ 5,605	\$ 3,449	27,480
November 30, 2018	\$ 4,950	\$ 3,055	\$ 7,116	\$ -	15,121
December 1, 2017	\$ 5,207	\$ 3,055	\$ 8,626	\$ -	16,888

The amortization expense of \$2,412 (2018 – \$1,767) is included in selling expenses.



# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 12. Intangible assets (continued)

### Commercialization rights – Trogarzo®

On March 18, 2016, the Company entered into a distribution and marketing agreement with TaiMed Biologics, Inc. (“TaiMed”). On March 6, 2017, the Company entered into an amended and restated distribution and marketing agreement with TaiMed (“TaiMed Agreement”) granting the Company the exclusive right to market and distribute Trogarzo® in Canada and in the United States (collectively, the “North American Territory”) as well as in European Union countries and other countries such as Israel, Norway, Russia and Switzerland (collectively, the “European Territory”). The TaiMed Agreement has a 12-year term that will expire on a country-by-country basis calculated from the date of approval of Trogarzo® in each of the countries covered under the TaiMed Agreement. TaiMed is responsible for the manufacture and supply of Trogarzo® under the TaiMed Agreement.

### Commercialization rights – Trogarzo® in the North American Territory

Under the terms of the TaiMed Agreement, TaiMed is responsible for developing Trogarzo® and to seek its approval from the US Food and Drug Administration (“FDA”), whereas the Company is responsible, but has no obligation, for seeking the approval of Trogarzo® from Health Canada. The purchase price of Trogarzo® payable to TaiMed has been determined at 52% of its net selling price with an additional amount equal to 10% of its net selling price until such additional amount aggregates \$5,500, which was reached in November 2019.

### **Initial payments**

Under the TaiMed Agreement, the Company agreed to make an initial payment of US\$5,000 and will make several further milestone payments in exchange for the right to commercialize Trogarzo® and the right to use TaiMed’s trademark in the North American Territory.

The initial payment of \$5,000 was made in accordance with the following:

- (i) \$1,000 was paid in cash at the signature of the TaiMed Agreement entered into in March 2016;
- (ii) \$4,000 through the issuance of the Company’s common shares, payable after the first commercial sale of Trogarzo® in the United States. The \$4,000 payment was made on May 15, 2018 and resulted in the issuance of 1,463,505 common shares to TaiMed.

The Company recorded as additions to intangible assets during 2016 related to the TaiMed Agreement an amount of \$5,207, which comprises the cash payment of \$1,000 at the signature of the agreement, the share-based payment of \$4,000 and \$207 of acquisition costs.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 12. Intangible assets (continued)

### Commercial milestone payments

As further consideration under the TaiMed Agreement, the Company shall make the following one-time payments upon the first occurrence of the following commercial events:

Commercial milestone	Commercial milestone payment
(i) Achieving aggregate net sales of \$20,000 over four consecutive quarters of the Company's financial year	\$7,000 payable in two equal annual installments of \$3,500
(ii) Upon first achieving annual net sales of \$200,000	\$10,000
(iii) Upon first achieving annual net sales of \$500,000	\$40,000
(iv) Upon first achieving annual net sales of \$1,000,000	\$100,000

In 2019, the Company accrued and recorded the first commercial milestone payment under the TaiMed Agreement at a discounted value of \$6,765 (Note 16) as the Company determined that it was probable that the milestone would be paid.

The Company will also pay TaiMed development milestones for Trogarzo®. A \$3,000 milestone (payable in two equal annual installments of \$1,500) is due upon the date of the first commercial sale of a once every two weeks intramuscular, subcutaneous or intravenous-push (either fast or slow) injection formulation. TaiMed is also planning a larger Phase III trial using Trogarzo® with a once every four weeks intramuscular, subcutaneous or intravenous-push (either fast or slow) injection formulation to address a much broader patient population. This development milestone will consist of an upfront milestone payment of up to \$50,000 depending on the size of the newly targeted population, which will be paid quarterly, based on a percentage of net sales generated by Trogarzo®.

### Commercialization rights – Trogarzo® in the European Territory

On September 26, 2019, Trogarzo® was approved for sale in Europe by the European Medicines Agency (the "EMA").

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 12. Intangible assets (continued)

### Commercial milestone payments (continued)

#### Commercialization rights – Trogarzo® in the European Territory (continued)

The purchase price of Trogarzo® for sales occurring in a country forming part of the European Territory is set at (i) 52% of the net selling price of Trogarzo® in such country on annual net sales in such country up to, or equal to, \$50,000 and (ii) an amount equal to 57% of the net selling price of Trogarzo® in such country on the portion of annual net sales of Trogarzo® in the European Territory that exceeds annual net sales of Trogarzo® in the European Territory of \$50,000.

#### Initial and milestone payments

The TaiMed Agreement also provides for the following development, launch and sales milestones paid or to be paid by the Company to TaiMed:

- An upfront payment of \$3,000, which was paid through the issuance of 906,077 common shares of the Company on March 17, 2017;
- An approval milestone payment representing 50% of the costs of the clinical trials and all associated development activities regulated by the EMA and incurred by TaiMed, if any, to obtain marketing approval of Trogarzo® in the European Territory countries, payable quarterly and equal to 5% of net sales recorded in each quarter;
- A launch milestone payment of \$10,000 payable to TaiMed as follows:
  - \$5,000 one year after the first commercial sale of Trogarzo®; and
  - \$5,000 one year after reaching net sales in the European Territory aggregating \$50,000 over four consecutive quarters;
- A milestone of \$10,000 upon net sales in the European Territory aggregating \$150,000 over four consecutive quarters;
- A milestone of \$20,000 upon net sales in the European Territory aggregating \$500,000 over four consecutive quarters; and
- A milestone of \$50,000 upon net sales in the European Territory aggregating \$1,000,000 over four consecutive quarters.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 12. Intangible assets (continued)

Commercialization rights – Trogarzo® in the European Territory (continued)

### Initial and milestone payments (continued)

As a result of the TaiMed Agreement, the Company recorded as additions to intangible assets during 2017 an amount of \$3,055, which comprises the payment of \$3,000 paid through the issuance of 906,077 common shares of the Company and \$55 of acquisition costs.

The commercial milestone payments payable in cash are accrued and recorded in the cost of the intangible asset when it is probable that they will be paid. The commercial milestone payments represent licence fee consideration and, therefore, will be added to the cost of the intangible asset. In order to demonstrate that the commercial milestone payment is probable, the product will need to have been launched and there should be a sufficient history of sales to have a reasonable expectation that the commercial milestone payments will be reached.

In 2019, the Company accrued and recorded the first \$5,000 payable one year after the first commercial sale of Trogarzo® at a present value of \$4,557 as the Company determined that it was probable that the milestones would be achieved (note 16).

### Oncology platform

On February 25, 2019, the Company acquired Katana Biopharma Inc. (“Katana”). On May 21, 2019, Katana was wound up into the Company and then dissolved.

Katana (now the Company) is the worldwide exclusive licensee of a technology platform using peptides as a vehicle to specifically deliver existing cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells. The license was entered into on February 25, 2019 with Transfert Plus, L.P. (“Transfert Plus”), an affiliate of Aligo Innovation, a university research company that commercializes the research results of universities and other institutional partners from various areas of innovation, including life sciences (the “Licence Agreement”).

Under the terms of the acquisition agreement, the purchase price is also subject to two share-based milestone payments. The first milestone payment will occur when the first patient is enrolled in a Phase 1 clinical study. At that time, CAD2 million will be paid through the issuance of common shares of the Company.

The second milestone payment of CAD2.3 million will occur when the proof of concept is demonstrated in human subjects and will be satisfied through the issuance of common shares of the Company.

This acquisition was accounted for as an asset acquisition. The Company recorded additions to intangible assets during 2019 of \$3,073, which comprised the payment at closing of \$1,965 in cash, \$5 through the issuance of 900 common shares of the Company, the estimated fair value of the share-based contingent consideration of \$1,028, and \$75 of acquisition costs. As the share-based payments are equity settled, the Company recognized a corresponding increase in equity, and no remeasurement of the fair value will occur regardless of whether the milestones are achieved. Since the common shares have not been issued yet, the increase in equity is recorded in contributed surplus. Upon the issuance of the common shares, this amount will be reclassified to share capital. The intangible asset is currently not being amortized. Amortization will begin when the asset is available for use.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 12. Intangible assets (continued)

### Oncology platform (continued)

In August 2019, the acquisition agreement was amended to provide for an adjustment to the purchase price of CAD1.08 million in the event the Company could indirectly benefit from a CAD1.2 million subsidy in connection with its research and development activities. The subsidy was granted in October 2019. The adjustment will be payable in two installments. The first installment of CAD500 thousand was paid in cash in October 2019, whereas the second installment of CAD580 thousand will be paid at the same time as the CAD2.3 million milestone referred to above is achieved and will be satisfied through the issuance of common shares of the Company. The cash payment of \$376 (CAD500 thousand) was recognized as an addition to intangible assets during 2019.

Under the Licence Agreement, Katana (now the Company) obtained the exclusive worldwide rights to develop, make, have made, use, sell, offer to sell, distribute, commercialize and import the technology related to the technology platform that uses peptides as a vehicle to deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells.

Annual maintenance fees amount to CAD25 thousand for the first five years and CAD100 thousand thereafter, until royalties become payable beginning with the first commercial sale of a product developed using the licenced technology.

The royalties payable under the Licence Agreement vary between 1% and 2.5% on net sales of a product based on the licenced technology. If the Company enters into a sublicense agreement, it must then pay amounts varying between 5% and 15% of revenues received from such sublicense agreement.

The Company must also pay Transfert Plus the following milestone payments upon the occurrence of the following development milestones for the first product developed in the field of oncology:

- (i) First milestone payment: CAD50 thousand upon the successful enrolment of the first patient in the first Phase 1 human clinical trial;
- (ii) Second milestone payment: CAD100 thousand upon the successful enrolment of the first patient in the first Phase 2 human clinical trial;
- (iii) Third milestone payment: CAD200 thousand upon the successful enrolment of the first patient in the first Phase 3 human clinical trial.

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 12. Intangible assets (continued)

#### Oncology platform (continued)

Also, the Company must pay CAD200 thousand for each product upon receiving the first approval for such product by a regulatory authority. The approval shall entitle the holder thereof to commercialize the product in the territory in which the approval was obtained.

The Company must also pay Transfert Plus the same milestone payments upon the occurrence of any of those development milestones for the first product developed outside the field of oncology.

### 13. Other asset

<b>Cost</b>		
Balance as at November 30, 2018 and 2019	\$	19,530
<b>Accumulated amortization</b>		
Balance as at November 30, 2017	\$	-
Amortization		2,442
Balance as at November 30, 2018	\$	2,442
Amortization		4,884
Balance as at November 30, 2019	\$	7,326
<b>Net carrying amounts</b>		
November 30, 2019	\$	12,204
November 30, 2018	\$	17,088
December 1, 2017	\$	-

On May 29, 2018, the Company entered into an agreement (the "Renegotiated Agreement") with EMD Serono, Inc. to settle all outstanding cash payment obligations stemming from a termination and transfer agreement dated December 13, 2013, as amended (the "2013 Termination Agreement"). The remaining contractual obligations under the 2013 Termination Agreement totalled approximately \$28,200, which was comprised of a \$4,000 payment due in May 2019 and \$24,200 in estimated royalties on future sales of *EGRIFTA*® payable over the next four to five years. The Renegotiated Agreement allowed the Company to make one lump sum payment of \$23,850 in settlement of the long-term obligation of \$4,000 and to eliminate all of the royalty payments due on sales of *EGRIFTA*® in the United States. The payment made in connection with the settlement of the future royalty obligation has been accounted for as an other asset on the consolidated statement of financial position.

**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**14. Accounts payable and accrued liabilities**

	Note	November 30		December 1,
		2019	2018	2017
Trade payables		\$ 13,106	\$ 15,583	\$ 5,405
Accrued liabilities and other payables		15,028	6,575	10,582
Salaries and benefits due to related parties	27	555	485	512
Employee salaries and benefits payable		473	433	395
Liability related to deferred stock unit plan	19(b)	625	1,268	1,103
Accrued interest payable on convertible unsecured senior notes	17	1,386	1,486	-
		\$ 31,173	\$ 25,830	\$ 17,997

**15. Provisions**

		Chargebacks and rebates	Returns	Other	Total
Balance as at December 1, 2017	\$	495	\$ 89	\$ -	\$ 584
Provisions made		7,144	657	-	7,801
Provisions used		(6,744)	(627)	-	(7,371)
Balance as at November 30, 2018	\$	895	\$ 119	\$ -	\$ 1,014
Provisions made		10,818	174	55	11,047
Provisions used		(9,531)	(46)	-	(9,577)
Balance as at November 30, 2019	\$	2,182	\$ 247	\$ 55	\$ 2,484

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 16. Long-term obligations

The movement in the long-term obligations is as follows.

	Note	Commercialization rights – Trogarzo® North American Territory	Commercialization rights – Trogarzo® European Territory	Early termination fee EMD Serono Inc.	Total
Balance as at December 1, 2017		\$ -	\$ -	\$ 7,151	\$ 7,151
Payment, as originally contemplated in 2013 Termination Agreement	13	-	-	(4,000)	(4,000)
Payment, as per Renegotiated Agreement	13	-	-	(3,850)	(3,850)
Accretion expense		-	-	413	413
Loss on repayment of long-term obligations		-	-	286	286
Balance as at November 30, 2018		-	-	-	-
Additions	12	6,765	4,557	-	11,322
Accretion expense		152	13	-	165
Payment		(3,500)	-	-	(3,500)
Balance as at November 30, 2019		3,417	4,570	-	7,987
Current portion		(3,417)	-	-	(3,417)
Non-current portion		\$ -	\$ 4,570	\$ -	\$ 4,570

Early termination fee – EMD Serono Inc.

Under the Renegotiated Agreement (Note 13), the Company paid \$3,850 to reimburse the remaining amount payable of \$4,000 due in May 2019.

The difference of \$286 between the consideration transferred of \$3,850 and the carrying amount of the long-term obligation of \$3,564 (on date of settlement) was recognized as a loss on repayment of long-term obligations and included in "Finance costs" on the consolidated statement of net loss and comprehensive loss for the year ended November 30, 2018.

Commercialization rights – Trogarzo® North American Territory

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



# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 16. Long-term obligation (continued)

Commercialization rights – Trogarzo® European Territory

Under the terms of the TaiMed agreement, a launch milestone of \$5,000 is payable one year after the first commercial sale of Trogarzo®. The Company accrued the discounted value of the obligation in 2019 in the amount of \$4,557 because it was probable it would be achieved.

## 17. Convertible unsecured senior notes

On June 19, 2018, the Company closed a notes offering of convertible unsecured senior notes having an aggregate principal amount of \$57,500. The notes bear interest at an annual rate of 5.75% (effective interest rate of 9.95%) and are convertible into common shares at the option of the holder at any time at a conversion price of \$14.85 per common share, representing 3,872,053 common shares. The maturity date of the notes is June 30, 2023. The Company may redeem the notes prior to maturity at any time on or after June 30, 2021 if the current market price of the common shares is at least 130% of the conversion price. The notes are repayable at par value plus accrued and unpaid interest.

The movement in the carrying value of the convertible unsecured senior notes is as follows.

Proceeds allocated to liability component	\$	51,122
Transaction costs related to liability		(2,517)
As at June 19, 2018 (date of issuance)		48,605
Accretion expense		628
Convertible unsecured senior notes as at November 30, 2018		49,233
Accretion expense		1,508
Convertible unsecured senior notes as at November 30, 2019	\$	50,741

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 18. Other liabilities

	Note	November 30, 2019
Deferred lease inducements		\$ 238
Stock appreciation rights	19(c)	28
		\$ 266

### 19. Share capital

Authorized in unlimited number and without par value

Common shares; and

Preferred shares, issuable in one or more series.

All issued shares were fully paid on November 30, 2019 and 2018.

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.

(a) Issuance of common shares

*TaiMed*

On May 15, 2018, the Company issued 1,463,505 common shares with a value of \$4 million, in connection with an initial payment and milestone payment under the TaiMed Agreement. The share-based payment of \$4 million was initially recognized as contributed surplus, pending the issuance of the common shares. As the common shares have been issued, the Company has reclassified the amount within its equity accounts from contributed surplus to common shares.

*Oncology platform*

On February 25, 2019, the Company issued 900 common shares with a value of \$5 in connection with the acquisition of Katana (note 12).

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 19. Share capital (continued)

### (b) DSU plan

On December 10, 2010, the Board of Directors adopted a deferred stock unit plan (the "DSU Plan") for the benefit of its directors and officers (the "Beneficiaries") and, in April 2013, the Board of Directors suspended the issuance of DSUs. In May 2018, the Board of Directors decided to resume the granting of DSUs. The goal of the DSU Plan is to increase the Company's ability to attract and retain high-quality individuals to act as directors or officers and to better align their interests with those of the shareholders of the Company in the creation of long-term value. Under the terms of the DSU Plan, Beneficiaries who are directors are entitled to elect to receive all or part of their annual retainer to act as directors or Chair of the Board in DSUs. Beneficiaries who act as officers are entitled to elect to receive all or part of their annual bonus, if any, in DSUs. The value of a DSU is used to determine the number of DSUs a Beneficiary may be granted or the value to be paid to a Beneficiary upon redemption. This value is equal to the average closing price of the common shares on the Toronto Stock Exchange on the date on which the Company is entitled to grant DSUs, or on the date on which a Beneficiary redeems them, and during the four previous trading days.

DSUs may only be redeemed when a Beneficiary ceases to act as a director or an officer of the Company. Upon redemption, the Company must provide a Beneficiary with an amount in cash equal to the DSU value on the redemption date. Beneficiaries may not sell, transfer or otherwise assign their DSU or any rights associated therewith other than by will or in accordance with legislation regarding the vesting and partition of successions.

DSUs are totally vested at the grant date. In the case of DSUs granted to officers for annual bonuses, a DSU liability is recorded at the grant date in place of the liability for the bonus payments. In the case of directors, the expense related to DSUs and their liabilities is recognized at the grant date. During the year ended November 30, 2019, \$23 (2018 – \$35) was recorded as an expense and is included in general and administrative expenses. The liability related to DSUs is adjusted periodically to reflect any change in the market value of the common shares. As at November 30, 2019, a gain of \$641 (2018 – charge of \$210) was recognized within finance costs (Note 6). As at November 30, 2019, the Company had a total 204,357 DSUs outstanding (2018 – 205,522 DSUs) and a liability related to the DSUs of \$625 (2018 – liability of \$1,268).

#### *Cash-settled forward stock contracts*

To protect against fluctuations in the value of DSUs, the Company entered into cash-settled forward stock contracts. They were not designated as hedging instruments for accounting purposes. As at November 30, 2019, the cash-settled forward stock contracts outstanding correspond to a total of 204,357 common shares (2018 – 205,522 common shares) at a price of \$5.86 per share (2018 – \$5.98 per share) expiring on December 21, 2020 (2018 – December 17, 2019). As at November 30, 2019, the fair value of cash-settled forward stock contracts was \$637 (2018 – \$1,287) and is recorded in derivative financial assets. During the year ended November 30, 2019, a loss of \$647 (2018 – gain of \$213) related to the change in fair value of derivative financial assets was recognized within finance costs (Note 6).

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 19. Share capital (continued)

### (c) SARs

On October 4, 2018, the Company's Board of Directors approved a SARs plan for its consultants that entitles the grantee to receive a cash payment based on the increase in the stock price of the Company's common shares from the grant date to the settlement date. The exercise date of an SAR may not be later than 10 years after the grant date. Generally, the SARs vest over a period up to three years.

For the year ended November 30, 2019, \$28 (2018 – nil) was recorded as share-based compensation expense for the SARs plan. Since these awards will be cash-settled, the fair value of SARs granted in 2019 is estimated at each reporting period using the Black-Scholes model and the following weighted average assumptions.

	<b>Measurement date as at November 30, 2019</b>
Risk-free interest rate	1.46%
Expected volatility	58%
Average option life in years	8 years
Grant-date share price	\$ 3.06 (CAD 4.06)
Option exercise price	\$ 3.06 (CAD 4.06)

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 SAR. The volatility is based on weighted average historical volatility adjusted for changes expected due to publicly available information. The life of the SAR is estimated taking into consideration the vesting period at the grant date, the life of the SAR 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 grant date weighted average fair value of SARs granted during the year ended November 30, 2019.

	<b>Number of SARs</b>	<b>Weighted average grant date fair value</b>
2019	40,000	\$ 1.29 (CAD 1.71)

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
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Years ended November 30, 2019 and 2018

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## 19. Share capital (continued)

### (d) Shareholder rights plan

On April 10, 2019, the Company's Board of Directors approved the amendment and renewal of the shareholder rights plan and, on the same date, the Company and Computershare Trust Services of Canada entered into an amended and restated shareholder rights plan agreement (the "Plan"). The Plan was approved by the shareholders on May 15, 2019. The Plan is designed to provide adequate time for the Board and the shareholders to assess an unsolicited takeover bid for the Company. In addition, the Plan provides the Board 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 closure of the Company's annual meeting of shareholders in 2022 unless the Plan is reconfirmed and approved by shareholders at such meeting.

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 an acquiring 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. Subject to the terms and conditions set out in the Plan, each right would, upon exercise and payment of \$5.00 per right, entitle a rights holder, other than the acquiring person and related parties, to purchase a number of common shares at twice the exercise price of \$5.00 per right based on the average weighted market price of the common shares for the last 20 trading days preceding the common share acquisition date (as defined in the Plan's rights).

Under the Plan, a Permitted Bid is a bid made to all holders of common shares and which is open for acceptance for no less than 105 days. If, at the end of 105 days, at least 50% of the outstanding common shares, other than those owned by the offeror and certain related parties, has 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.

### (e) Stock option plan

The Company has established a stock option plan under which it can grant 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 6,580,000 options can be granted under the stock option plan. Generally, the options vest at the grant date or over a period of up to three years. As at November 30, 2019, 1,632,851 options could still be granted by the Company (2018 – 1,950,762).

All options are to be settled by the physical delivery of the common shares.

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 19. Share capital (continued)

(e) Stock option plan (continued)

Changes in the number of options outstanding during the past two years were as follows:

	Number of options	Weighted average exercise price per option	
		CAD	USD
Options as at December 1, 2017	2,335,895	\$ 2.21	\$ 1.71
Granted	251,544	9.56	7.49
Expired	(2,000)	8.50	6.74
Exercised (share price: CAD 9.14 (USD 7.07))	(412,734)	1.69	1.30
Options outstanding as at November 30, 2018	2,172,705	3.15	2.37
Granted	406,400	8.19	6.20
Forfeited	(88,489)	6.07	4.56
Exercised (share price: CAD 7.78 (USD 5.82))	(74,832)	1.96	1.46
Options outstanding as at November 30, 2019	2,415,784	\$ 3.94	\$ 2.96
Options exercisable as at November 30, 2019	1,864,727	\$ 2.69	\$ 2.02
Options exercisable as at November 30, 2018	1,676,057	\$ 2.09	\$ 1.57

**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**19. Share capital (continued)**

## (e) Stock option plan (continued)

The following table provides stock option information as at November 30, 2019.

Price range		Number of options outstanding	Weighted average remaining life (years)	Weighted average exercise price	
CAD	USD			CAD	USD
0.25 – 1.19	0.19 – 0.90	814,660	3.95	0.64	0.48
2.01 – 3.75	1.51 – 2.82	530,000	6.38	2.07	1.56
3.76 – 4.60	2.83 – 3.46	110,000	0.02	3.84	2.89
4.61 – 6.00	3.47 – 4.52	260,000	6.57	5.82	4.38
6.01 – 9.00	4.53 – 6.78	479,900	9.01	8.00	6.03
9.01 – 10.00	6.78 – 7.53	221,224	8.36	9.56	7.20
		2,415,784	6.00	3.94	2.96

For the year ended November 30, 2019, \$1,059 (2018 – \$851) was recorded as share-based compensation expense for the stock option plan. The fair value of options granted in 2019 and 2018 was estimated at the grant date using the Black-Scholes model and the following weighted average assumptions.

	2019	2018
Risk-free interest rate	2.15%	1.46%
Expected volatility	57%	58%
Average option life in years	8 years	8 years
Grant-date share price	\$ 6.15 (CAD 8.19)	\$ 7.49 (CAD 9.56)
Option exercise price	\$ 6.15 (CAD 8.19)	\$ 7.49 (CAD 9.56)

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 19. Share capital (continued)

### (e) Stock option plan (continued)

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 on weighted average historical volatility adjusted for changes expected due to publicly available information. The life of the options is estimated taking into consideration 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 30, 2019 and 2018.

	Number of stock options granted	Weighted average grant date fair value
2019	406,400	\$ 3.69 (CAD 4.92)
2018	251,544	\$ 3.63 (CAD 4.63)

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.



**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**19. Share capital (continued)**

## (f) Loss per share

The calculation of basic earnings per share was based on the net loss attributable to common shareholders of the Company of \$12,496 (2018 – \$4,700) and a weighted average number of common shares outstanding of 76,928,287 (2018 – 75,942,385), calculated as follows.

	2019	2018
Issued common shares as at December 1	76,877,679	74,962,050
Effect of share options exercised	49,920	153,325
Effect of public issue common shares	688	-
Effect of broker options exercised	-	25,089
Effect of issuance of common shares – TaiMed	-	801,921
<b>Weighted average number of common shares, basic and diluted</b>	<b>76,928,287</b>	<b>75,942,385</b>

For the year ended November 30, 2019, a number of the 2,415,784 (2018 – 2,172,705) share options and 3,872,053 common shares potentially issuable from the conversion of the \$57,500 aggregate principal amount of convertible unsecured senior notes (Note 17), that may potentially dilute earnings per share in the future, were excluded from the weighted average number of diluted 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.

## (g) Accumulated other comprehensive income (loss)

	November 30		December 1,
	2019	2018	2017
Unrealized losses on FVOCI financial assets, net of tax	\$ (12)	\$ (95)	\$ (80)
Cumulative exchange difference on translation of foreign operations	33	-	-
	\$ 21	\$ (95)	\$ (80)

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 20. Income taxes

The following table presents the components of the current and deferred tax expenses.

	2019	2018
Current tax expense	\$ -	\$ -
Deferred tax expense		
Origination and reversal of temporary differences	\$ 2,484	\$ (874)
Change in unrecognized deductible temporary differences	(2,484)	(395)
Total deferred tax recovery	\$ -	\$ (1,269)
Total current and deferred tax recovery	\$ -	\$ (1,269)

Reconciliation between effective and applicable tax amounts

	2019	2018
Income taxes at domestic tax statutory rate	\$ (3,324)	\$ (1,564)
Change in unrecognized deductible temporary differences	2,484	(395)
Impact of differences in statutory tax rates	518	-
Non-deductible expenses and other	323	690
	\$ -	\$ (1,269)

The applicable statutory tax rates were 26.6% in 2019 and 26.7% in 2018. The Company's applicable tax rate is the Canadian combined rates applicable in the jurisdictions in which the Company operates.

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 20. Income taxes (continued)

Unrecognized deferred tax assets

As at November 30, unrecognized deferred tax assets were as follows.

	2019	2018
Research and development expenses	\$ 23,262	\$ 27,455
Non-capital losses	30,470	23,236
Property and equipment	282	357
Intellectual property and patent fees	2,900	2,885
Available deductions and other	3,335	3,345
	\$ 60,249	\$ 57,279

Given the Company's past losses, management does not believe that it is probable that the Company can realize its deferred tax assets and, therefore, no amount has been recognized in the consolidated statements of financial position.

The generation of future taxable profit is dependent on the successful commercialization of the Company's products and technologies.

**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**20. Income taxes (continued)**

Unrecognized deferred tax assets (continued)

As at November 30, 2019 and 2018, the amounts and expiry dates of Canadian tax attributes for which no deferred tax asset was recognized were as follows:

	2019		2018	
	Federal	Provincial	Federal	Provincial
Research and development expenses, without time limitation	\$ 79,698	\$ 98,321	\$ 79,614	\$ 98,216
Losses carried forward				
2027	414	407	414	406
2028	34,876	16,975	34,839	16,957
2029	14,671	12,400	14,656	12,386
2030	8,614	8,611	8,605	8,602
2031	17,740	15,748	17,721	15,731
2032	12,019	11,036	12,007	11,024
2033	8,636	8,555	8,627	8,546
2034	7,909	7,839	7,900	7,831
2037	7,057	6,973	7,050	6,965
2038	1,964	1,886	1,962	1,884
2039	6,024	5,952	-	-
Other temporary differences, without time limitation				
Excess of tax value of property and equipment over carrying value	1,128	998	1,440	1,240
Excess of tax value of intellectual property and patent fees over carrying value	10,897	10,892	10,895	10,881
Available deductions and other	43,291	1,430	43,388	1,572

As at November 30, 2018, deferred tax assets relating to loss carried forward and financing costs of \$1,269 and \$338, respectively, were recognized to offset deferred tax liabilities for an amount of \$1,607, resulting from the issuance of the convertible unsecured senior notes.

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 21. Supplemental cash flow disclosures

The Company entered into the following transactions which had no impact on its cash flows.

	2019	2018
Additions to property and equipment included in accounts payable and accrued liabilities	\$ 3	\$ 49
Additions to intangible assets included in accounts payable and accrued liabilities	9	-
Reclassification of contributed surplus upon issuance of common shares to TaiMed	-	4,000
Convertible unsecured senior notes issuance costs included in accounts payable and accrued liabilities	6	6
Recognition of previously unrecognized tax assets from item originally recorded in equity	-	338
Additions to intangible assets included in long-term obligations	7,822	-
Additions to intangible assets included in contributed surplus	1,028	-
Issuance of shares in connection with acquisitions of intangible assets	5	-

## 22. 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.

### Credit risk

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

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 22. Financial instruments (continued)

### Credit risk (continued)

The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 26) and derivative financial assets which it manages by dealing only with highly-rated Canadian financial institutions. Included in the consolidated statements of financial position are trade receivables of \$9,538 (2018 – \$10,720), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the years ended November 30, 2019 and 2018. Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consist principally of bonds and money market funds. The Company invests its available cash in highly liquid fixed income instruments from governmental, paragonovernmental, municipal and high-grade corporate bodies and money market funds (2019 – \$12,583; 2018 – \$14,891). As at November 30, 2019, the Company believes it was not exposed to any significant credit risk. The Company's maximum credit exposure corresponded to the carrying amount of these financial assets.

### Liquidity risk

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

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

**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**22. Financial instruments (continued)****Liquidity risk (continued)**

The following are amounts due on the contractual maturities of financial liabilities as at November 30, 2019 and 2018.

						<b>2019</b>
	<b>Carrying amount</b>	<b>Total contractual amount</b>	<b>Less than 1 year</b>	<b>From 1 to 2 years</b>	<b>More than 3 years</b>	
Accounts payable and accrued liabilities	\$ 31,173	31,173	\$ 31,173	\$ -	\$ -	
Convertible unsecured senior notes, including interest	50,741	70,725	3,306	6,613	60,806	
Long-term obligations	7,987	8,500	3,500	5,000	-	
	<b>\$ 89,901</b>	<b>\$ 110,398</b>	<b>\$ 37,979</b>	<b>\$ 11,613</b>	<b>\$ 60,806</b>	

						<b>2018</b>
	<b>Carrying amount</b>	<b>Total contractual amount</b>	<b>Less than 1 year</b>	<b>From 1 to 2 years</b>	<b>More than 3 years</b>	
Accounts payable and accrued liabilities	\$ 25,830	\$ 25,830	\$ 25,830	\$ -	\$ -	
Convertible unsecured senior notes, including interest	49,233	74,131	3,406	6,613	64,112	
	<b>\$ 75,063</b>	<b>\$ 99,961</b>	<b>\$ 29,236</b>	<b>\$ 6,613</b>	<b>\$ 64,112</b>	

**Currency risk**

The Company is exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of the Company's business transactions denominated in currencies other than USD, primarily cash, sale of goods and expenses incurred in CAD and Euro.

**THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

**22. Financial instruments (continued)****Currency risk (continued)**

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

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

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

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

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



# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 22. Financial instruments (continued)

### Currency risk (continued)

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

	CAD	2019 EURO	2018 CAD
Positive impact	147	16	283

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

### Interest rate risk

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

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

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 22. Financial instruments (continued)

### Interest rate risk (continued)

Based on the value of the Company's short- and long-term bonds as at November 30, 2019, an assumed 0.5% decrease in market interest rates would have increased the fair value of these bonds and the accumulated other comprehensive income by approximately \$14 (2018 – \$46); an assumed increase in market interest rates of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

Cash and money market funds bear interest at a variable rate. Trade and other receivables, accounts payable and accrued liabilities and provisions bear no interest.

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

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

## 23. Capital management

The Company's objective in managing its capital is to ensure a liquidity position sufficient to finance its business activities. The Company depends primarily on revenue generated by sales of *EGRIFTA*® and Trogarzo® in the United States and, from time to time, on public offerings of securities in North America to finance its activities.

The capital management objectives remain the same as for the previous year.

As at November 30, 2019, cash, bonds and money market funds amounted to \$41,244 (2018 – \$53,888). The Company believes that its cash position and future operating cash flows will be sufficient to finance its operations and capital needs for at least the next 12 months.

Currently, the Company's general policy on dividends is to retain cash to keep funds available to finance its growth.

The Company defines capital to include total shareholders' equity and convertible unsecured senior notes.

The Company is not subject to any externally imposed capital requirements.

# THE RATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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## 24. 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 measured at fair value

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 their own assumptions.

### Other financial assets and financial liabilities

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

Bonds and money market funds and derivative financial assets and liabilities are stated at fair value, determined by inputs that are primarily based on broker quotes at the reporting date (Level 2).

The fair value of the convertible unsecured senior notes, including the equity portion, as at November 30, 2019 was approximately \$44,275 (Level 1) based on market quotes.

### Share-based payment transactions

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

# THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

## 24. Determination of fair values (continued)

### Share-based payment transactions (continued)

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

## 25. Commitments

### (a) Leases

As at November 30, 2019, the minimum payments required under the terms of non-cancellable leases are as follows.

Less than one year	\$	680
One to five years		2,944
More than five years		1,153
	\$	4,777

### (b) Long-term procurement agreements and research agreements

The Company has long-term procurement agreements with third party suppliers in connection with the commercialization of *EGRIFTA SV<sup>TM</sup>* and Trogarzo<sup>®</sup>. As at November 30, 2019, the Company had outstanding purchase orders and minimum payments required under these agreements amounting to \$20,311 (2018 – \$6,353) for the manufacture of Trogarzo<sup>®</sup>, *EGRIFTA SV<sup>TM</sup>* and for various services.

The Company also has research commitments and outstanding clinical material purchase orders amounting to \$1,045 in connection with the oncology platform.

### (c) Credit facilities

The Company has a CAD1,500 revolving credit facility bearing interest at Canadian prime rate plus 1% and a \$1,000 revolving credit facility bearing interest at US prime rate plus 1%. The Company's assets have been given as collateral to secure these credit facilities. As at November 30, 2019, the Company did not have any borrowings outstanding under these facilities.

## THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

### 26. Operating segments

The Company has a single operating segment. As described in Note 4, almost all of the Company's revenues are generated from one customer, RxCrossroads, which is domiciled in the United States.

	2019	2018
RxCrossroads	\$ 60,853	\$ 44,548
Others	2,363	669
	\$ 63,216	\$ 45,217

All of the Company's non-current assets are located in Canada, as is the Company's head office.

### 27. Related parties

The key management personnel of the Company are the directors, the President and Chief Executive Officer and all of the Senior Vice Presidents.

Key management personnel compensation comprises:

	2019	2018
Short-term employee benefits	\$ 2,016	\$ 2,047
Post-employment benefits	67	77
Share-based compensation	847	746
	\$ 2,930	\$ 2,870

As at November 30, 2019, the key management personnel controlled 1.4% (2018 – 1.5%) of the voting shares of the Company and held 0.3% (2018 – 0.3%) of the convertible unsecured senior notes.

## **THERATECHNOLOGIES INC.**

Notes to Consolidated Financial Statements (continued)  
(In thousands of United States dollars, unless otherwise stated)

Years ended November 30, 2019 and 2018

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### **28. Subsequent event**

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

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

## MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEAR ENDED NOVEMBER 30, 2019

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

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

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

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

### Forward-Looking Information

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

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

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

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

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

### **Business Overview**

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

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

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



## Our Products

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

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

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

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

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

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

## Our Pipeline

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

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

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

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

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

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

### **Fiscal 2019 Highlights**

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

#### ***EGRIFTA*<sup>®</sup> and *EGRIFTA SVTM***

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

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

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

In Fiscal 2019, we also regained all of our worldwide distribution rights to *EGRIFTA*<sup>®</sup>.

#### **Trogarzo<sup>®</sup>**

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

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

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

### **Research and Development Activities**

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

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

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

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

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

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

## Corporate Developments

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

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

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

## Outlook

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

## 2020 Revenue Guidance

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

## Selected Annual Information

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

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

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

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

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

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

### Cost of Sales

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

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

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

## **R&D Expenses**

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

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

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

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

## **Selling Expenses**

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

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

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

## **General and Administrative Expenses**

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

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

## **Finance Income**

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

## **Finance Costs**

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

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

## **Adjusted EBITDA**

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

### Net loss

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

### Fourth quarter comparison

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

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

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

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

### Cost of Sales

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



### **R&D Expenses**

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

### **Selling Expenses**

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

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

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

### **General and Administrative Expenses**

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

### **Finance Income**

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

### **Finance Costs**

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

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

### **Adjusted EBITDA**

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

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

## Net loss

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

## Financial Position

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

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

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

## Quarterly Financial Information

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

(In thousands of dollars, except per share amounts)

	2019				2018			
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
<b>Revenue</b>	16,400	16,111	15,609	15,096	13,983	13,523	9,598	8,113
<b>Operating expenses</b>								
<b>Cost of sales</b>								
Cost of goods sold	5,754	5,215	5,346	4,810	3,516	3,325	1,594	941
Other production-related costs	14	1	18	34	14	91	127	(127)
Royalties	-	-	-	-	-	-	450	890
Amortization of other asset	1,221	1,221	1,221	1,221	1,221	1,221	-	-
R&D	3,877	2,152	2,285	2,527	2,063	2,130	1,897	1,904
Selling	7,673	6,389	6,972	5,448	5,233	5,189	5,957	5,314

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<b>General and administrative</b>	3,258	1,772	1,784	1,516	1,865	1,482	1,279	1,202
<b>Total operating expenses</b>	21,797	16,750	17,626	15,556	13,912	13,438	11,304	10,124
<b>Finance income</b>	217	253	292	335	276	175	77	80
<b>Finance costs</b>	(1,275)	(1,253)	(1,449)	(1,103)	(1,330)	(1,247)	(283)	(156)
<b>Net (loss) profit</b>	(6,455)	(1,639)	(3,174)	(1,228)	(983)	282	(1,912)	(2,087)
<b>Basic and diluted (loss) earnings per share</b>	(0.08)	(0.02)	(0.04)	(0.02)	(0.01)	0.00	(0.03)	(0.03)

### *Factors Affecting the Variability of Quarterly Results*

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

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

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

### **Liquidity and Capital Resources**

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

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

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

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

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

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

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

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

### **Subsequent Event**

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

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

## Commitments

### Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

### Contractual obligations

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

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

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

#### Credit facility:

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

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

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

## Financial Risk Management

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

### Credit Risk

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

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

### Liquidity Risk

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

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

### Currency Risk

The Company is exposed to financial risk related to the fluctuation of foreign exchange rates and the degree of volatility of those rates. Currency risk is limited to the portion of the Company's business transactions denominated in currencies other than USD, primarily cash, sale of goods and expenses incurred in CAD and Euro.

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

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

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

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

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

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

	2019		2018
	CAD	EURO	CAD
Positive impact	147	16	283

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

#### Interest Rate Risk

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

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

Based on the value of the Company's short- and long-term bonds as at November 30, 2019, an assumed 0.5% decrease in market interest rates would have increased the fair value of these bonds and the accumulated other comprehensive income by approximately \$14,000 (2018 – \$46,000); an assumed increase in the interest rate of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

Cash and money market funds bear interest at a variable rate. Trade and other receivables, accounts payable and accrued liabilities and provisions bear no interest.

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

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

#### **Fair Values of Financial Instruments**



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

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

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

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

## **Share-based payment transactions**

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

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

## **Related party transactions**

Refer to Note 27 of the Audited Financial Statements

## **Critical Accounting Estimates**

### **Use of estimates and judgments**

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

### **Judgments in applying accounting policies**

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

### **Milestones payments related to Trogarzo®**

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

## **Contingent consideration related to oncology platform**

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

## **Convertible senior unsecured notes**

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

## **Key sources of estimation uncertainty**

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

### **Sales promotional programs**

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

### **Other**

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

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

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

## **Recent Changes in Accounting Standards**

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

On October 22, 2018, the IASB issued amendments to IFRS 3, Business Combinations that seek to clarify whether a transaction results in an asset or a business acquisition. The amendments apply to businesses acquired in annual reporting periods beginning on or

after January 1<sup>st</sup>, 2020. Early application is permitted. The amended definition emphasizes that the output of a business is to provide goods and services to customers, whereas the previous definition focused on returns in the form of dividends, lower costs or other economic benefits to investors and others.

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

### **IFRS 9, Financial Instruments**

The Company adopted all of the requirements of IFRS 9, Financial Instruments ("IFRS 9") with a date of initial application of December 1<sup>st</sup>, 2018. IFRS 9 does not require restatement of comparative periods. This standard establishes principles for the financial reporting classification and measurement of financial assets and financial liabilities. This standard also incorporates a new hedging model which increases the scope of hedged items eligible for hedge accounting and aligns hedge accounting more closely with risk management. This standard also amends the impairment model by introducing a new "expected credit loss" model for calculating impairment. This new standard increases required disclosures about an entity's risk management strategy, cash flows from hedging activities and the impact of hedge accounting on the consolidated financial statements.

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

### **IFRS 15, Revenue from Contracts with Customers**

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

### **IFRS 16, Leases**

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

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

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

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

The Company intends to adopt IFRS 16 in its consolidated financial statements for the annual period beginning on December 1<sup>st</sup>, 2019 using the modified retrospective transition method. The extent of the impact of adoption of the standard has not yet been determined, but the Company expects the majority of its operating leases will need to be recognized in the consolidated statement of financial position on initial adoption. At December 1<sup>st</sup>, 2019, the Company expects to record right-of-use assets and lease liabilities of approximately \$3,000,000. The Company also expects decrease of its operating lease costs, offset by an increase of its depreciation and amortization and financial expenses resulting from the changes in the recognition, measurement and presentation requirements. However, no significant impact on net earnings is expected at this time. The Company is completing the assessment of the overall impact on the Company's disclosures and is addressing any system and process changes necessary to compile the information to meet the recognition and disclosure requirements of the new guidance starting in the first quarter of Fiscal 2020.

### **Outstanding Securities Data**

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

### **Disclosure Controls and Procedures and Internal Control over Financial Reporting**

#### Disclosure Controls and Procedures

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

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have evaluated, or caused the evaluation of, under their direct supervision, the design and operating effectiveness of the Company's disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure in Issuer's Annual and Interim Filings as at November 30, 2019. Based upon that evaluation, our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have concluded that, as of November 30, 2019, our disclosure controls and procedures were designed and operating effectively.

#### Internal Control over Financial Reporting

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

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

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, assessed the design and operating effectiveness of our internal controls over financial reporting as of the end of Fiscal 2019 based on the criteria established in the "*Internal Control - Integrated Framework*" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Management's assessment included an evaluation of the design of our internal controls over financial reporting and testing of the operating effectiveness of our internal control over financial reporting. Based on that assessment, our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, concluded that as of November 30, 2019, our internal controls over financial reporting were appropriately designed and operating effectively.

### Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting that occurred during the period from September 1<sup>st</sup>, 2019 to November 30, 2019 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

### **Non-IFRS Financial Measures**

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

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

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

**Adjusted EBITDA**  
(In thousands of dollars)

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

**Risks and Uncertainties**

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

**RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS**

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



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

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

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

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

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

There can be no assurance that sales of our products to customers in the United States and in the European territory will increase in the future or that we will generate sales at a profitable level. If sales of our products decrease, our revenue would be adversely affected which, in turn, could materially adversely affect our business, financial condition and operating results.

Because we expect to be dependent on revenues from *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® for the foreseeable future, any negative developments relating to these products, such as safety or efficacy issues, manufacturing issues, the introduction or greater acceptance of competing products, or adverse regulatory or legislative

developments, or our inability to successfully manage any of the abovementioned factors, will have a material adverse effect on our business and our future business prospects.

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

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

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

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

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

We do not own or operate manufacturing facilities for the production of EGRIFTA®, EGRIFTA SV™ and tesamorelin, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely on Bachem Americas Inc., or Bachem, and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for sales of EGRIFTA® and EGRIFTA SV™. Our agreement with Bachem will expire in May 2020 and our agreement with Jubilant will expire in December 2020. Although we are in discussions with Bachem and Jubilant to extend the term of these agreements, our inventory of drug product is high and potential alternative suppliers and manufacturers have been identified, but we have not entered into any agreements with them. Also, we have not qualified these alternative manufacturers to date and no assurance can be given that such manufacturers will be qualified in the future or receive necessary regulatory approvals. The replacement of a third-party manufacturer is time-consuming and costly due to the required validation of their capabilities. The validation process includes an assessment of the capacity of such third-party manufacturer to produce the quantities that we may request from time to time, the

manufacturing process and its compliance with current good manufacturing practice, or GMP, regulations. In addition, the third-party manufacturer would have to familiarize itself with our technology. Validation of an additional third-party manufacturer takes at least twenty-four (24) months and could take as long as thirty-six (36) months or more.

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

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

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

We do not employ sales, medical service liaison and reimbursement personnel in the United States and in the European territory in connection with the commercialization of our products in these territories. We rely on Syneos to provide us with all of the services related to the commercialization of our products, namely sales personnel, medical science liaison personnel, reimbursement specialists and other individuals whose roles and functions pertain to the commercialization of our products. Although we are aware that there exists other third-party services providers that could provide the same services as Syneos, we have not entered into any agreements with them nor conducted any audit on

them. If we need to find another third-party service provider for some or all of the services provided by Syneos, it will be time-consuming and will be disruptive to our business. In addition, there can be no assurance that we will be able to find such third-party service provider if we are unable to agree on the terms and conditions of an agreement with them.

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

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

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> in the United States if RxCrossroads:

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

We may be subject to a decrease in sales of our products in the United States or in the European territory or we may face reimbursement challenges if Syneos:

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

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

New safety issues may arise as *EGRIFTA*<sup>®</sup>, *EGRIFTA SV*<sup>™</sup> and Trogarzo<sup>®</sup> are used over longer periods of time by a wider group of patients, some of whom may be taking numerous other medicines, or may suffer from additional underlying health problems. Such safety issues could include an increase in the severity or frequency of known

problems or the discovery of previously unknown problems, and may result in a variety of adverse regulatory actions. For instance, under U.S. laws, the FDA has broad authority over drug manufacturers to compel any number of actions if safety problems arise, including, but not limited to: (i) requiring manufacturers to conduct post-approval clinical studies to assess known risks or signals of serious risks, or to identify unexpected serious risks; (ii) mandating labeling changes to a product based on new safety information; or (iii) requiring manufacturers to implement a risk evaluation mitigation strategy where necessary to assure safe use of the drug. Similar laws and regulations exist in countries outside of the United States. Previously unknown safety problems could also result in product recalls, restrictions on the products' permissible uses, or withdrawal of the products from the territory(ies) where they are approved for commercialization. If new safety issues are discovered, sales of *EGRIFTA*®, *EGRIFTA SV*™ and/or Trogarzo® may decrease and result in a material adverse effect on our business, financial condition and operating results.

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

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

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

In the European territory, sales of Trogarzo® will be highly dependent on obtaining reimbursement. The process of seeking reimbursement for a new drug is complex and varies from one EU Member State to another. In many EU Member States, pricing plays an important role in the evaluation of prescription drugs for reimbursement. There can be no assurance that Trogarzo® will be reimbursed by all or any EU Member State.

Even if Trogarzo® is reimbursed, in EU Member States, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures to keep healthcare costs down, due in part to the attention being paid to healthcare cost containment in the European Union. Certain of these changes could impose limitations on the prices we will be able to charge for Trogarzo® or the amounts of reimbursement available for Trogarzo® from governmental agencies or third-party payors. Further, an increasing number of EU Member States and other foreign countries use prices for

medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere. In addition, the ongoing budgetary difficulties faced by a number of EU Member States have led and may continue to lead to substantial delays in payment and payment partially with government bonds rather than cash for medicinal drug products, which could negatively impact our potential revenues and profitability from Trogarzo®. Moreover, in order to obtain reimbursement for Trogarzo® in some EU Member States, we may be required to conduct clinical trials that compare the cost-effectiveness of Trogarzo® to other available therapies. There can be no assurance that Trogarzo® will obtain favorable reimbursement status in any EU Member States.

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

Sales of EGRIFTA®, EGRIFTA SV™ and Trogarzo® will depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of any of our products will depend on a number of factors, including:

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

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

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

The biopharmaceutical and pharmaceutical industries are highly competitive and we must compete with pharmaceutical companies, biotechnology companies, academic and research institutions as well as governmental agencies for the development and commercialization of products, most of which have substantially greater financial, technical and personnel resources than us. We believe there is currently no approved drug product competing directly with our approved products. However, with respect to *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>™</sup>, we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching antiretrovirals, or ARTs, or liposuction. With respect to Trogarzo<sup>®</sup>, we are aware that dolutegravir and darunavir are being used in regimens to treat MDR HIV-1 and that attachment inhibitors, long-acting ARTs and broadly working antibody products are under development. We are also aware that the manufacturer of fostemsavir has filed a new drug application with the FDA and a marketing authorization application with the EMA.

#### **RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES**

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

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

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

In connection with the development of a new treatment or a new drug, such as the development of tesamorelin for the potential treatment of NASH in patients living with HIV and the development of our proprietary peptides resulting from our oncology platform, we must conduct clinical trials. Clinical trials require the enrolment of patients and we may have difficulties enrolling patients for those clinical trials. These difficulties may arise as

a result of design protocol, the size of the patient population, the eligibility criteria to participate in the clinical trials, the availability of competing therapies, the patient referral practices of physicians and the availability of clinical trial sites. Difficulty in enrolling patients in connection with the conduct of clinical trials could result in their cancellation or delays in completing them. Once patients are enrolled in a clinical trial, the occurrence of any adverse drug effects or side effects observed during the trial could also result in the clinical trial being cancelled. The cancellation of clinical trials for the foregoing reasons could lead to our forfeiting the development of the product candidate tested in those clinical trials and have a material adverse effect on our long-term growth and revenue prospect.

## **RISKS RELATED TO OUR INTELLECTUAL PROPERTY**

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

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

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

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

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties who have access to such confidential



information, such as our current and prospective suppliers, distributors, manufacturers, commercial partners, employees and consultants. Any of these parties may breach the agreements and disclose confidential information to our competitors. It is possible that a competitor will make use of such information, and that our competitive position could be disadvantaged.

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

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

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

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

For example, EMD Serono has listed a patent held by one of its affiliates in the Orange Book under the *Hatch-Waxman Act* with respect to *EGRIFTA*® and *EGRIFTA SV*™ in HIV-associated lipodystrophy. With the termination of the EMD Serono Agreement, EMD Serono could assert that such patent would be infringed by our continued sale of *EGRIFTA*® and *EGRIFTA SV*™ in the United States for the treatment of lipodystrophy. To counter that risk, we have obtained a non-exclusive licence from EMD Serono's affiliate under the EMD Serono Termination Agreement in order to continue selling *EGRIFTA*® and *EGRIFTA SV*™ in the United States. The termination of that licence could prevent us from selling *EGRIFTA*® and *EGRIFTA SV*™ in the United States for the treatment of lipodystrophy if we were found to infringe the patent listed by one of EMD Serono's

affiliates in the Orange Book and this could have a material adverse effect on our business, financial condition and operating results.

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

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

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

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

## **REGULATORY RISKS**

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

Our promotional materials and training methods must comply with the *Federal Food, Drug and Cosmetic Act*, as amended, of the United States, or FFDCA, as well as with laws in

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

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

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

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

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

- European Union's, EU Member States' and U.S. States' law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other

remuneration to certain healthcare professionals. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of our products in the United States, which could harm the commercial sales of our products and materially affect our business, financial condition and results of operations. We cannot guarantee that we will be able to mitigate all operational risks. In addition, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on *EGRIFTA*®, *EGRIFTA SV*™, Trogarzo® or their respective manufacturing processes, withdrawal of *EGRIFTA*®, *EGRIFTA SV*™ or Trogarzo® from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material adverse effect on our product sales, business and results of operations.

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

## **LITIGATION RISKS**

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

We rely on third-party service providers for sales, marketing, distribution and manufacturing activities related to *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States. Under our agreements with our third-party service providers, we have assumed certain obligations, undertakings and covenants which, if breached by us and not remedied within the agreed upon periods, could expose us to claims for damages and/or termination of these agreements. If we are unable to meet our obligations under any of our agreements with TaiMed as well as with third-party service providers which results in termination of such agreements, this will materially adversely affect our business, financial condition and operating results since we rely on single third-party

service providers, each of whom performing key services for the success of our business plan.

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

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

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

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

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

## **GEO-POLITICAL RISKS**

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

International business relationships in the United States, Europe, China, Taiwan and elsewhere subject us to additional risks, including:

- disruptions of important government services;
- differing regulatory requirements for drug approvals in foreign countries;

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

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

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

As of January 31, 2020, the United Kingdom left the European Union, or Brexit. There is a transition period until December 31, 2020, during which the European Union's pharmaceutical laws will continue to apply in the United Kingdom. However, as of February 1st, 2020, the United Kingdom will no longer be able to participate in European Union's institutions and their decision making. Based on publicly available information, the European Union and the United Kingdom are set to begin discussions on their future relationship in March 2020. As a result, the effects of Brexit are currently unknown to us and will depend on the agreement the United Kingdom, or UK, will enter into with the European Union. The Medicines and Healthcare Products Regulatory Agency, or MHRA, published guidelines on how it would treat drugs having been issued a marketing authorization prior to Brexit, but we are unable to confirm how these guidelines will apply. We may have to incur various costs to keep Trogarzo®'s marketing authorization valid in the UK through the filings of various documents with the MHRA. In addition, various

requirements regarding the UK residency of individuals and entities carrying out pharmacovigilance activities, batch analysis, release of batches, and other similar functions may force us to contract with additional suppliers. We may not be able to negotiate the terms and conditions of such contracts to our advantage or enter into any contract at all. Under both circumstances, our management team will have to spend time not otherwise spent on other projects. Overall, we may incur additional costs that may adversely impact our business, operating results and financial condition.

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

#### **OTHER RISKS RELATED TO OUR BUSINESS**

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

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

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

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



The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. Unauthorized access to data files held in our information technology systems or those of third parties could result in inappropriate use, change or disclosure of sensitive and/or personal data of our customers, employees, suppliers and patients. Any such access, disclosure or other loss of information could subject us to litigation, regulatory fines, penalties or reputational damages, any of which could have a material adverse effect on our competitive position, reputation, business, financial condition and operating results.

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

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

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States. In addition, there is no guarantee that we will be able to successfully launch and commercialize Trogarzo® in the European territory. If revenues grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, financial condition and operating results could be materially adversely affected and we may never sustain profitability.

***We may not be able to generate sufficient cash from our operating activities to service our debt obligations.***

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

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

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

We may need financing in order to fund all or part of our capital requirements to sustain our growth, to develop our marketing and commercial capabilities, to meet our compliance obligations with various rules and regulations to which we are subject, to conduct our

research and development activities, and to in-licence or acquire new molecules or approved products. However, our business performance may prevent us from generating enough cash-flow to meet our obligations and the market conditions may also prevent us from having access to the public market in the future at the times or in the amounts necessary. Therefore, there can be no guarantee that we will be able to continue to raise additional capital by way of public or private offerings in the future. In such a case, we would have to use other means of financing, such as entering into private financing or credit agreements, the terms and conditions of which may not be favorable to us. In addition, the issuance and sale of substantial amounts of equity, or other securities, or the perception that such issuances and sales may occur could adversely affect the market price of our common shares.

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

Because of the specialized nature of our business, our success depends to a significant extent on the continued service of our key employees and on our ability to be able to attract, retain and motivate qualified manufacturing, managerial and scientific personnel. We have entered into employment agreements with our executive officers and provided them with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers will remain employed by us for any significant period of time, or at all. In addition, we have a limited workforce to pursue our business plan and the loss of any of our key employees could materially adversely affect our business. Our third-party service provider, Syneos, has hired sales representatives and other qualified individuals to assist us with the commercialization of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo® in the United States. Syneos has also hired medical science liaison personnel in the European territory. Although these individuals are not our employees, the loss of any of those individuals and the inability of Syneos to attract and retain these individuals could have a material adverse effect on the commercialization of *EGRIFTA*®, *EGRIFTA SV*™ and Trogarzo®, and, accordingly, our business, financial condition and operating results. In addition, it could adversely affect the market price of our common shares.

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

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

From time to time, we publicly announce the timing of certain events to occur or the attainment of certain commercial objectives. These statements are forward-looking and are based on the best estimate of management at the time, relating to the occurrence of such events. However, the actual timing of such events or our ability to achieve these objectives may differ from what has been publicly disclosed. Events such as beginning of

commercialization of a product, levels of sales, revenues and other financial metrics may vary from what is publicly disclosed. These variations may occur as a result of a series of events, including problems with a supplier or a commercial partner, change in the procurement policy of a commercial partner or any other event having the effect of delaying the publicly announced timeline or reducing the publicly announced commercial objective. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. Any variation in the timing of certain events having the effect of postponing such events or any variation in the occurrence of certain events having the effect of altering publicly announced commercial objectives could have a material adverse effect on our business, financial condition and operating results. In addition, it could adversely affect the market price of our common shares.

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

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

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

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

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

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

## **RISKS RELATED TO OUR COMMON SHARES**

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

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

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

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

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

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

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

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

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

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

***Our shareholder rights plan and certain Canadian laws could delay or deter a change of control.***

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

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

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

## CERTIFICATION

I, Luc Tanguay, certify that:

1. I have reviewed this annual report on Form 40-F of Theratechnologies Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;
4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the issuer and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and
5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: February 25, 2020

By: /s/ Luc Tanguay  
Luc Tanguay  
President and Chief Executive Officer  
(Principal Executive Officer)

## CERTIFICATION

I, Philippe Dubuc, certify that:

1. I have reviewed this annual report on Form 40-F of Theratechnologies Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;
4. The issuer's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the issuer and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and
5. The issuer's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involved management or other employees who have a significant role in the issuer's internal control over financial reporting.

February 25, 2020

/s/ Philippe Dubuc

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Philippe Dubuc  
Senior Vice President and Chief Financial Officer  
(Principal Executive Officer)

CERTIFICATION PURSUANT TO  
18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Theratechnologies Inc. (the "Company") on Form 40-F for the period ended November 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Luc Tanguay, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 25, 2020

/s/ Luc Tanguay

\_\_\_\_\_  
Luc Tanguay  
President and Chief Executive Officer  
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Theratechnologies Inc. and will be retained by Theratechnologies Inc. and furnished to the Securities and Exchange Commission or its staff upon request.



CERTIFICATION PURSUANT TO  
18 U.S.C. §1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Theratechnologies Inc. (the "Company") on Form 40-F for the period ended November 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Philippe Dubuc, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 25, 2020

/s/ Philippe Dubuc

\_\_\_\_\_  
Philippe Dubuc  
Senior Vice President and Chief Financial Officer  
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Theratechnologies Inc. and will be retained by Theratechnologies Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

## MASTER SERVICES AGREEMENT

This Master Services Agreement (“Agreement”) is made as of this 15<sup>th</sup> day of July, 2019 (the “Effective Date”) by and between Asembia LLC, a limited liability corporation incorporated under the laws of the State of Delaware having an address of 200 Park Avenue, Suite 300, Florham Park, New Jersey 07932, its affiliate under common majority control and ownership ASPN Pharmacies, LLC (collectively, “Provider”) and Theratechnologies Inc., a corporation governed by the *Business Corporations Act* (Québec) having an address of 2015 Peel, Suite 1100, Montreal, Québec H3A 1T8, including any and all affiliates (“Company”). Provider and Company may be referred to in this Agreement individually as a “Party” or collectively as the “Parties”.

### 1. Services; Incorporation of Terms

- 1.1. **Scope of Work.** During the term of this Agreement, Provider shall provide to Company the services (the “Services”), described in one or more Statements of Work (each, an “SOW”) that may be executed from time to time by Provider and Company. The terms and conditions of this Agreement shall apply to any and all SOWs executed by the Parties that reference this Agreement. An affiliate of Company may execute an SOW with Provider and, in such circumstances, all references in this Agreement to Company shall be deemed to be to the applicable affiliate of Company, which affiliate shall be entitled to enforce this Agreement with respect to such SOW in its own name and which shall be solely liable to Provider for any obligations and liabilities undertaken pursuant to such SOW.
- 1.2. **Hierarchy of Terms.** In the event that there are any conflicts between the terms of this Agreement and the terms of any SOW, the terms of this Agreement shall control. The terms of this Agreement and the SOW shall be controlling over any terms of any purchase order, sales acknowledgement, invoice or other such documents issued by either Party.
- 1.3. **No Guarantee of Work.** Notwithstanding anything in this Agreement to the contrary, until the Parties have executed and delivered an SOW, nothing in this Agreement shall be construed as the engagement by Company of Provider for the provision of any Services.

### 2. Provider’s Responsibilities

- 2.1. **Provider to Control.** Provider shall have the complete professional, managerial and technical responsibility for the quality, validity, accuracy, timeliness and reliability of the Services and the Work Product (as defined in Section 6.1), whether such Services and Work Product are performed by employees or agents of Provider, its affiliates or its subcontractors (all collectively referred to as “Provider” or “its Personnel”).
- 2.2. **Provider to Designate Manager.** Provider shall designate a manager in charge of the Services on a continuous basis with responsibility for providing adequate supervision or direction and having authority to take all action that may be required in performance of the applicable SOW.
- 2.3. **AE Reporting.** Provider agrees to maintain, on a continuous basis, designated staff and resources for prompt management of technical complaints and adverse event reports related to the Product. Provider shall within **[REDACTED: Time Period]** notify Company, if it receives any information that relates, refers or pertains to adverse events. Reporting shall be done based on the Company’s policy and using the form provided by Company. Adverse event reports shall be faxed to **[REDACTED: Fax Number]**. An adverse event shall include, but is not limited to, the following:

- 2.3.1. An adverse or unexpected event in humans occurring while patient is using the Product;
- 2.3.2. A technical complaint relating to the Product;
- 2.3.3. Any report of any other problem involving the Product (e.g., contamination, discoloration, improper labeling, adulteration, etc.);
- 2.3.4. Any complaint or the initiation of any claim, lawsuit, or other proceeding against Provider that relates to the Product; or
- 2.3.5. Any local, state or federal investigation of or request for information sent to Provider or its pharmacists or other employees relating to Company or the Product.

2.4. **Company Policies.** Provider shall ensure that Provider and its employees and subcontractors comply with all of the policies, regulations and directives of Company, including but not limited to compliance with laws and regulations, and security (including data security), as such policies may be revised from time-to-time and provided to Provider.

2.5. **Due Diligence.** Provider acknowledges that Company is subject to various governmental and regulatory compliance requirements. Accordingly, Provider agrees that it shall, as reasonably requested by Company, provide information regarding Provider and its operations that will assist Company in its efforts to ensure compliance with various laws and regulations, including but not limited to Provider's interaction with government officials and Provider's data security controls and procedures.

### 3. Company's Responsibilities

3.1. **Company's Representative.** Company shall designate a person to act as Company's representative who shall have the authority to transmit instructions, receive information, interpret and define Company's policies and make decisions and in general to act as liaison between Company and Provider relating to this Agreement. In addition, for each SOW, Company shall designate its representative who shall act as a liaison between Company and Provider relating to such SOW.

### 4. Payments

4.1. **Fees.** As full and complete compensation for satisfactory performance of the Services, Company shall pay provider the fees and other compensation set forth in the applicable SOW. Provider shall be entitled to reimbursement of out-of-pocket expenses directly related to performing the Services, subject to Company's prior written approval of such expenses. Out-of-pocket expenses shall include reasonable and verifiable coach class travel, hotel accommodations and meal expenses that are incurred by Provider and are directly related to the Services. All such expenses shall be reimbursed at cost; no mark-up shall be permitted.

4.2. **Invoicing.** Provider shall invoice Company for all fees and expenses payable by Company under this Agreement as set forth in the applicable SOW. Such invoices shall set forth in detail the basis for the charges reflected therein. Each invoice shall include copies of receipts for all out-of-pocket expenses incurred. Provider shall send all invoices to the address set forth in the relevant Company purchase order or SOW. All invoices shall be payable within the period set forth in the applicable SOW. Notwithstanding the foregoing, if an applicable SOW does not contain a payment schedule and invoice address, Company shall pay any undisputed amounts via wire transfer within **[REDACTED: Time Period]** of receipt of Provider's invoice to the following bank account:

Asembia, LLC.

[REDACTED: Bank Account Information]

Company shall provide a confirming email that the invoice has been paid to [REDACTED: Email Address] the same day that the wire transfer is performed.

- 4.3. **Taxes.** The fee set forth in each SOW shall include all applicable taxes, including without limitation, ail sales and use taxes and value-added taxes that Provider is required to collect from Company. Provider shall be solely responsible for the timely payment of ail such taxes to the applicable taxing authority, and Provider shall be responsible for the payment of any penalties, interest or additional taxes that may be levied or assessed as a result of the failure or delay of Provider to pay any taxes.

## 5. Scope Changes

- 5.1. **Changes by Company; Adjustments Due to Changes.** Company may, from time to time, by written order, and without invalidating this Agreement or the applicable SOW, or any portion thereof, make changes in the Services, or the conditions under which Services are to be performed, or may increase or decrease the Services to be performed. No change shall be made by Provider in its performance or its manner of performance of the Services without prior written authorization or instructions from Company, specifying the details of the change, and specifying whether there is to be an adjustment in the price or time for performance. If such changes increase or decrease either the cost or time required to perform the Services, then the Parties will mutually agree to an equitable adjustment to the price and/or the time to perform the Services.

- 5.2. **Changes to be in Writing.** Any change to any SOW shall be in writing, shall define the extent of the change, the price or basis of pricing the change, the impact of the change on the schedule, and shall be signed by the Parties. No additional work by Provider shall be paid for unless authorized in advance, in writing, by Company or its affiliate.

## 6. Representations and Warranties

### 6.1. **Provider's Representations and Warranties**

6.1.1. Provider represents and warrants to Company that:

- (a) **Performance Standards.** Provider shall perform, and shall cause Provider's Personnel to perform, all of its obligations under this Agreement: (i) in strict accordance with the terms of this Agreement and the applicable SOW, including all amendments, work orders and other related documents; and (ii) in a professional, commercially diligent basis, in accordance with the generally accepted industry and professional standards, procedures and practices.
- (b) **Qualifications of Provider's Personnel.** All of Provider's Personnel shall be well qualified to perform such Services and shall maintain ail professional licenses, permits, certificates and registrations required for their performance of the Services.
- (c) **Compliance with Laws.** Provider shall comply and shall cause Provider's Personnel to comply, with all applicable laws, ordinances, codes, rules and

regulations. Provider shall have all professional licenses, permits, certificates and registrations required for its performance of the Services during the term of this Agreement and that of any SOW.

- (d) **Anti-Bribery.** Provider has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value or improperly seek to influence any Government Official. For purposes of this Section, a “Government Official” is broadly defined as and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health) and (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; where “government” is meant to include all levels and subdivisions of non-US governments (i.e., local, regional, or national and administrative, legislative or executive).
- (e) **Work Product.** All Work Product shall be performed in strict conformity with the specifications or descriptions of the Work Product or Services set forth in the applicable SOW and shall not infringe upon the patent, copyright or other intellectual property rights of any third party.
- (f) **Conflicts.** The execution, delivery and performance of this Agreement by Provider does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over Provider. Provider is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement or any SOW.
- (g) **Authority.** Provider is validly existing and in good standing under the laws of the jurisdiction of its organization and has the power and authority to enter into this Agreement. This Agreement has been duly executed and delivered by Provider and constitutes the valid and binding obligation of Provider, enforceable against it in accordance with its terms. The execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Provider, its officers and directors.
- (h) **Debarment.** Provider is not debarred by any applicable authority, including without limitation under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act (as amended, the “Act”) and Provider has not and will not use in any capacity the services of any person or entity who has been debarred by any applicable authority with respect to Services. Provider will immediately notify Company in the event that Provider, or any of its Personnel becomes debarred or excluded during the term of this Agreement. Provider acknowledges that debarment of the Company shall be grounds for termination of this Agreement and any or all SOWs by Company for cause.
- (i) **No Actions Pending.** There is no action, suit or proceeding, at law or in equity, before or by any court or governmental authority, pending or, to the best of Provider’s knowledge, threatened against Provider, wherein an unfavorable decision, ruling or filing would materially adversely affect the performance by Provider of its obligations hereunder or the other

transactions contemplated hereby, or which, in any way, would adversely affect the enforceability of this Agreement, or any other agreement or instrument entered into by Provider in connection with the transactions contemplated hereby. In the event Provider becomes aware of such action, suit or proceeding, Provider shall immediately notify Company.

- (j) **Security Measures.** Provider has implemented and maintains technical and organizational measures that are consistent with best industry practices and designed to protect the security of Company data, including measures designed to protect Company data from unauthorized access, use, modification, deletion, loss or disclosure and Provider shall maintain such security standards, including those described in Schedule “A” hereto, at all times during the term of the Agreement as well as any period beyond the term during which Provider holds Company data.
- (k) **Description of Security Measures.** The security measures currently implemented by Provider are described in Schedule “A” to this Agreement and Provider acknowledges that it has an ongoing obligation to update such security measures over the term of the Agreement in light of the evolution of technologies, internal and external circumstances and of the nature of ongoing threats.
- (l) **Certification.** Provider shall maintain at all times during the term of this Agreement **[REDACTED: Type of Certification]**.
- (m) **Third-Party Reports.** Provider shall provide to Company copies of reports from a qualified third-party assessment organization in the form of: **[REDACTED: Form of Third-Party Report]**.
- (n) **Third-Party Auditor.** **[REDACTED: Time Period]**, Provider will engage a qualified third-party auditor to perform **[REDACTED: Type of Audit]**. On Company’s written request, not more than **[REDACTED: Time Period]**, Provider will provide to Company the auditor’s summary of the test results.
- (o) **Breach of Security.** In the event of a breach of security that may reasonably impact Company’s data, Provider shall promptly advise Company of the breach of security, provide all details regarding such breach, extend its full cooperation to Company, at no cost to Company, in order to investigate the root cause of the breach and define a plan to mitigate the consequences of the breach and prevent future similar breaches. Provider shall diligently implement the plan at its sole cost and expense and will keep Company apprised of developments on a regular basis.

## 6.2. Company Representations and Warranties

### 6.2.1. Company represents and warrants to Provider that:

- (a) **Conflicts.** The execution, delivery and performance of this Agreement by Company does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental

body or administrative or other agency having authority over it. Company is not currently a party to, and during the term of this Agreement will not enter into any agreements, oral or written, that are inconsistent with its obligations under this Agreement or any SOW.

- (b) **Authority.** Company is validly existing and in good standing under the laws of the jurisdiction of its organization and has the power and authority to enter into *this* Agreement. This Agreement has been duly executed and delivered by Company and constitutes the valid and binding obligation of Company, enforceable against it in accordance with its terms. The execution, delivery and performance of this Agreement has been duly authorized by all necessary actions on the part of Company, its officers and directors.
- (c) **No Actions Pending.** There is no action, suit or proceeding, at law or in equity, before or by any court or governmental authority, pending or, to the best of Company's knowledge, threatened against Company, wherein an unfavorable decision, ruling or filing would materially adversely affect the performance by Company of its obligations hereunder or the other transactions contemplated hereby, or which, in any way, would adversely affect the enforceability of this Agreement, or any other agreement or instrument entered into by Company in connection with the transactions contemplated hereby. In the event Company becomes aware of such action, suit or proceeding, Company shall immediately notify Provider.

### 6.3. Provider and Company Representations and Warranties

- 6.3.1. **Non-Solicitation.** Each Party covenants and agrees that neither it, nor any of its affiliates will, from the Effective Date until **[REDACTED: Time Period]** immediately following the termination of this Agreement, directly or indirectly, for whatever reason, whether for their own account or for the account of any other person or entity: (a) induce or attempt to induce any employee of the other Party to leave the employ of such Party or (b) solicit, employ or otherwise engage as an employee, independent contractor or otherwise hire any person who was an employee of the other Party.

## 7. Proprietary Rights

- 7.1. **Company's Materials.** All drawings, materials, specifications, designs and other data of any nature furnished by Company to Provider for the performance of the Services may be used by Provider only in connection with its performance of the Services and shall remain the property of Company. Company shall retain all rights, title and interest in and to such materials, including, without limitation, patents, copyrights and other intellectual property rights in any ideas, concepts, designs, inventions and expressions embodied in such materials.
- 7.2. **Pre-existing or independent Intellectual Property.** No rights are hereby given to Company in any intellectual property conceived and evidenced in an invention, record or disclosure, or under any patents or patent applications that Provider may own prior to the Effective Date of this Agreement or may subsequently acquire which do not arise out of and are not derived from the performance of the Services under this Agreement.

## 8. Insurance Requirements

- 8.1. Prior to the commencement of any Services under this Agreement or any SOW, Provider shall provide and maintain such insurance coverage as will protect it and Company from all claims which may arise out of or result from Provider's performance under this Agreement and any SOW, whether such operations be by itself or by its Personnel or by anyone directly or indirectly employed by any of them, or by anyone for whose acts they may be liable. Provider shall add Company as additional insured under the insurance referred to in section 8.2 below.
- 8.2. The insurance required under Section 8.1 above shall be written for not less than any limits of liability specified herein or as required by Law, whichever is greater. Provider shall have the right to provide the total limits required by any combination of primary and Umbrella/Excess coverage; said insurance to include, without limitation, the following:
- (a) Insurance for liability under the Workers' Compensation or occupational disease laws of any state or other jurisdiction in which the Services are performed (or be a qualified self-insurer in those states and jurisdictions) or otherwise applicable with respect to persons performing the Services and Employer's Liability insurance covering all claims by or in respect to the employees of Provider and all Consultants, providing:
    - (i) **[REDACTED: Type of Coverage and Amount of Coverage]**
    - (b) **[REDACTED: Type of Coverage and Amount of Coverage]**
  - (c) In the event Provider is furnishing design services or other professional services, Provider shall obtain **[REDACTED: Type of Coverage and Amount of Coverage]**.
  - (d) **[REDACTED: Type of Coverage]** in an amount not less than **[REDACTED: Amount of Coverage]** per occurrence.
  - (e) If Provider has care, custody or control of Company property or inventory, Provider shall be responsible for any loss or damage to it, and provide all risk Property Coverage at full replacement cost for same.
  - (f) **[REDACTED: Type of Coverage]** providing for a minimum coverage of **[REDACTED: Amount of Coverage]** per occurrence. Coverage shall be maintained for as long as Provider holds Company data.

## 9. Records and Audits

- 9.1. **Records.** Provider will maintain complete and accurate records of all matters relating to Services that enable Provider to demonstrate compliance with its obligations under this Agreement and any SOW, including, without limitation, Provider's compliance with applicable laws and regulations. Financial records such as, but not limited to, time sheets, billing records, invoices, payment applications, payments of consultants and receipts relating to reimbursable expenses shall be maintained in accordance with generally accepted accounting principles. As used in this provision, records include books, documents, accounting procedures and practices, and other data regardless of type or form. Provider shall maintain such records for a period of **[REDACTED: Time Period]** after the expiration or termination of (x) this Agreement or (y) the last SOW in effect, whichever occurs later.



- 9.2. **Audits.** Company or its representatives including but not limited to Company's external auditors, may audit such records of Provider at any time during the term of this Agreement during normal business hours and upon reasonable notice to Provider. Provider shall make such records readily available for such audit.

## 10. **Term and Termination**

- 10.1. **Term.** This Agreement shall be effective as of the Effective Date and shall remain in effect for a period of three (3) years, unless sooner terminated as provided under this Agreement (the "Initial Term"). This Agreement shall automatically renew for additional one (1) year terms thereafter, unless either Party delivers written notice of non-renewal to the other Party at least **[REDACTED: Time Period]** prior to the expiration of the initial or any renewal term or this Agreement is otherwise terminated as set forth herein.
- 10.2. **Termination for Convenience.** Company may terminate all or any part of any SOW at any time without cause and in its sole discretion upon **[REDACTED: Time Period]** prior written notice to Provider. Provider may terminate all or any part of any SOW at any time without cause and in its sole discretion upon **[REDACTED: Time Period]** prior written notice to Company. In the event of such termination of any SOW by either Party for convenience, Company shall pay Provider in accordance with the terms of this Agreement and the applicable SOW for all Services performed in conformance with the terms of this Agreement and the applicable SOW prior to the effective date of such termination.
- 10.3. **Termination for Cause.** Either Provider or Company may terminate this Agreement and/or any and all SOWs for cause immediately upon written notice to the other Party in the event that such other Party materially breaches this Agreement, which breach remains uncured for **[REDACTED: Time Period]** following written notice to such Party of the deficiency. In the event the material breach solely relates to a SOW, then the non-breaching Party may only terminate such SOW under this Section. In the event of termination of any SOW by Company under this Section, Company shall pay Provider in accordance with the terms of this Agreement and the applicable SOW for Services performed in conformance with the terms of this Agreement and the applicable SOW prior to the effective date of such termination.
- 10.4. **Termination for Insolvency.** In the event that either Party (the "Insolvent Party"): (i) becomes insolvent, or institutes or has instituted against it a petition for bankruptcy or is adjudicated bankrupt; (ii) executes a bill of sale, deed of trust, or a general assignment for the benefit of creditors; (iii) is dissolved or transfers a substantial portion of its assets to a third party; or (iv) a receiver is appointed for the benefit of its creditors, or a receiver is appointed on account of insolvency; then the Insolvent Party shall immediately notify the other Party of such event and such other Party shall be entitled to: (a) terminate this Agreement and/or any or all SOWs for cause immediately upon written notice to the Insolvent Party or (b) request that the Insolvent Party or its successor provide adequate assurances of continued and future performance in form and substance acceptable to such other Party, which shall be provided by the Insolvent Party within **[REDACTED: Time Period]** of such request, and the other Party may terminate this Agreement and/or any or all SOWs for cause immediately upon written notice to the Insolvent Party in the event that the Insolvent Party fails to provide such assurances acceptable to the other Party within such **[REDACTED: Time Period]** period.
- 10.5. **Effect of Termination or Expiration.** Any termination or expiration of this Agreement

shall not terminate or affect the obligations of the Parties to each other under existing SOWs issued pursuant to this Agreement, and such SOWs shall continue in full force and effect and shall continue to be governed by the terms of this Agreement until their expiration or completion or until any such SOWs are themselves terminated pursuant to this Article.

**10.6. Transitional Services.** Provider, if requested by Company, agrees to use reasonable commercial efforts to assist Company in the transition of the performance of the Services in those instances where Company elects to use another provider or its own employees to perform the Services (“Transitional Services”). Provider’s compensation for such Transitional Services shall be comparable to the rates for similar services provided by Provider, but shall in no event exceed the rates Provider charges for the Services.

**10.7. Survival of Obligations.** The termination or expiration of this Agreement or any SOW shall not affect the survival and continuing validity of Articles 4 (Payments), 6.3 (Provider and Company Representations and Warranties), 7 (Proprietary Rights), 8 (Insurance Requirements), 9 (Records and Audits), 10.5 (Term and Termination), 11 (Confidentiality), 12 (Indemnification) and 13 (Miscellaneous).

## **11. Confidentiality**

**11.1. Confidential Information.** “Confidential Information” shall mean all information relating to Company’s or Provider’s business or business plans, including but not limited to suppliers, customers, prospective customers, contractors, clinical data, the content and format of various clinical and medical databases, utilization data, cost and pricing data, disease management data, software products, programming techniques, data warehouse and methodologies, all proprietary information, know-how, trade secrets, technical and non-technical materials, products, specifications, processes, sales and marketing plans and strategies, designs, and any discussions and proceedings relating to any of the foregoing, whether disclosed in oral, electronic, visual, written or any other form, disclosed to the other Party. Confidential Information includes, without limitation, the terms and conditions of this Agreement and any SOW. Confidential Information shall not include information which is: (i) known to a Party or its Personnel which have been reduced to writing prior to disclosure by the Party and that are not subject to another obligation of secrecy; (ii) hereafter lawfully obtained from other sources on a non-confidential basis; or (iii) otherwise generally available to the public, absent any breach of this Section 11 by the Party.

**11.2. Restricted Disclosure and Use of Confidential Information.** Provider and Company shall keep strictly confidential and not disclose to any third-party Confidential Information of the other Party. Each Party shall not use, and shall not permit its Personnel to use, the Confidential Information except in accordance with this Agreement. In the event a Party becomes aware of any breach of the confidentiality and non-use obligation contained in this Section by it or its Personnel, the Party shall promptly notify the other Party of such breach.

**11.3. Permitted Disclosures.** Notwithstanding the foregoing, Confidential Information may be disclosed by a Party to the extent required: (a) for the performance of Provider’s Services; (b) in order to comply with professional standards of conduct to which Provider may be bound by law for preservation of the public safety, health, and welfare; and (c) in order to comply with any court order, statute or governmental directive. In the event that such court order, statute or governmental directive requires disclosure of Confidential Information, the disclosing Party shall provide prompt notice to the other Party, to the extent legally permissible, before such Confidential Information is disclosed and cooperate with the other Party if the other Party seeks a protective order or other appropriate remedy for such

Confidential Information, and if no such protective order or other remedy is obtained, the disclosing Party will furnish only that portion of the Confidential Information which it is advised by its counsel it is legally required to furnish.

**11.4. Precautions.** In order to comply with its confidentiality and non-use obligations, each Party shall take at least the following precautions: (a) exercise all reasonable efforts to prevent unauthorized employees and unauthorized third parties from gaining access to Confidential Information; (b) disclose Confidential Information only to such of its Personnel who have a need to know such Confidential Information; provided, however, before any release of Confidential Information, each Party shall bind its Personnel receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as this Agreement; and (c) prior to any disclosure, each Party shall instruct its Personnel of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. Each Party shall be responsible for all actions of its Personnel, including without limitation any breach of the terms hereof.

**11.5. Survival.** Upon the later of a Party's request or termination or expiration of this Agreement, the other Party shall promptly return all of the Confidential Information. However, each Party may retain one copy of any written documents containing Confidential Information in its confidential files for the sole purpose of determining its continuing obligations under this Agreement.

## **12. Indemnification; Limitation of Liability**

**Indemnification.** Each party shall indemnify and hold harmless the other party, its affiliates and their respective officers, directors, managers, members, employees and other agents and representatives, from and against any claims, liabilities, damages, judgments or other losses (including reasonable attorneys' fees) imposed upon or incurred by them arising out of or as a result of any acts or omissions of the other party, or its affiliates or their respective officers, directors, managers, members, employees or other agents and representatives in connection with the performance of any of their respective obligations under this Agreement, or a breach of their respective covenants, representations and warranties and undertakings under this Agreement, except to the extent that such claims, liabilities, damages, judgments or other losses arise from the bad faith, willful misconduct or gross negligence of the party seeking indemnification hereunder.

**12.1. Limitation of Liability.** EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS or USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, LOST GOODWILL, LOST REVENUE AND LOST OPPORTUNITY) ARISING OUT OF ANY OF THE TERMS OR CONDITIONS OF THIS AGREEMENT OR WITH RESPECT TO ITS PERFORMANCE HEREUNDER. The foregoing limitation of liability and exclusion of damages applies even if a Party had or should have had knowledge, actual or constructive, of the possibility of such damages. The foregoing limitation of liability and exclusion of damages shall apply whether a claim is based on breach of contract, breach of warranty, tort (including negligence), product liability, strict liability or otherwise, and notwithstanding any failure of essential purpose of any limited remedy herein.

### 13. Miscellaneous

- 13.1. **Notices.** Any notice required to be given hereunder shall be in writing and deemed to have been sufficient[y given, (i) when delivered in person, (ii) on the fifth business day after mailing by registered or certified mail], postage prepaid, return receipt requested, or (iii) on the next business day after mailing by overnight courier service, to the addresses specified below:

If to Company: Theratechnologies Inc.

Attn: [REDACTED: Address]

If to Provider: Assembia LLC

Attn: [REDACTED: Address]

Provider or Company may, by notice to the other, change the addresses and names given above.

### 13.2. **Governing Law, Waiver of Jury Trial and Dispute Resolution.**

13.2.1. **Negotiations of Dispute.** With respect to any controversy, claim, counterclaim, dispute, difference or misunderstanding arising out of or relating to the interpretation or application of any term or provisions of this Agreement or an SOW or any related documents, a Party shall provide written notice to the other Party of the existence of such dispute. The Parties shall for a period of [REDACTED: Time Period] following such notice, enter into good faith discussions and negotiations in an attempt to resolve such dispute. If, by the end of such [REDACTED: Time Period] period, unless such period is extended by mutual agreement of the Parties, the Parties have been unable to resolve such dispute, either Party may initiate litigation. The procedures specified in this Section is a precondition to the initiation of litigation by a Party, in connection with disputes between the Parties arising out of or relating to this Agreement and any SOW; provided, however, that a Party may seek a preliminary injunction or other preliminary judicial relief, without attempting to resolve such dispute as provided in this Section, if in its judgment such action is necessary to avoid irreparable harm. Further, the requirement to attempt to resolve a dispute in accordance with this Section 13.2.1 does not affect a party's right to terminate this Agreement or a SOW as provided in Section 10 hereof.

13.2.2. **Governing Law.** The validity, interpretation and performance of this Agreement shall be governed by and construed in accordance with the laws of the State of New Jersey without regard to the principles of conflicts of law.

13.2.3. **Waiver of Jury Trial.** In any controversy or claim, whether based in contract, tort or other legal theory, arising out of or relating to this Agreement, SOWs or any related documents, their negotiation, enforceability or validity, or the performance or breach thereof or the relationships established thereunder, ail Parties hereby waive their right to trial by jury.

- 13.3. Independent Contractor.** Provider shall perform the Services as an independent contractor with exclusive control of the manner and means of performing the SOW in accordance with the requirements of this Agreement and the SOW. Provider has no authority to act or make any agreements or representations on behalf of Company or its affiliates. This Agreement or SOW is not intended to create, and shall not be construed as creating, between Company and Provider, the relationship of principal and agent, joint venturers, co-partners or any other such relationship, the existence of which is hereby expressly denied. No employee, or agent engaged by Provider shall be, or shall be deemed to be, an employee or agent of Company or its affiliate and shall not be entitled to any benefits that the Company or its affiliate provides to its own employees.
- 13.4. No Publicity.** Neither Party shall not use the name, trade name, service marks, trademarks, trade, dress or logos of the other Party in publicity releases, advertising or any other publication without the prior written consent of that Party.
- 13.5. Amendments.** No modification, alteration of this Agreement or any SOW, amendments, work orders or other related documents shall be binding upon the Parties unless contained in a writing signed by a duly authorized agent for each respective Party and specifically referring hereto or thereto.
- 13.6. Force Majeure.** No Party shall be liable for any failure to perform or any delays in performance, and no Party shall be deemed to be in breach or default of its obligations set forth in this Agreement and any SOWs, if, to the extent, and for as long as such failure or delay is due to any causes that are beyond its reasonable control and not to its acts or omissions, including, without limitation, such causes as acts of God, fire, flood, severe storm, earthquake, civil disturbance, lockout, riot, order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, or other similar causes ("Force Majeure Event"). For clarity, labor disputes shall not be deemed a Force Majeure Event. In the event of a Force Majeure Event, the Party prevented from or delayed in performing shall promptly give notice to the other Party and shall use commercially reasonable efforts to avoid or minimize the delay. The Party affected by the other Party's delay may elect to: (a) suspend performance and extend the time for performance for the duration of the Force Majeure Event or (b) cancel all or any part of the unperformed part of this Agreement or any applicable SOW.
- 13.7. Rule of Construction.** The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event that an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.
- 13.8. No Waiver.** A waiver by a Party of any term or condition of this Agreement or SOW in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof.
- 13.9. Severability.** If and to the extent that any court or tribunal of competent jurisdiction holds any provision of this Agreement or any SOW to be unenforceable in a final non-appealable order, such unenforceable provision shall be stricken, and the remainder of this Agreement shall not be affected thereby. Company and Provider shall in good faith attempt to replace any unenforceable provision of this Agreement or the SOW with a provision that is enforceable and that comes as close as possible to expressing the intention of the original provision.

- 13.10. Headings.** Headings of sections or other parts of this Agreement and SOWs are included herein for convenience of reference only and shall not constitute a part of this Agreement and SOWs or change the meaning of this Agreement and SOWs, as the case may be.
- 13.11. Entire Agreement.** This Agreement, together with any SOW, amendments, work orders or other related documents, constitutes the entire agreement of the Parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect thereto.
- 13.12. Binding Effect.** This Agreement shall apply to, inure to the benefit of and be binding upon the Parties hereto and upon their respective successors and permitted assigns. The Parties agree that this Agreement is not intended by any Party to give any benefits, rights, privileges, actions or remedies to any person or entity, partnership, firm or corporation as a third-party beneficiary or otherwise under any theory of law.
- 13.13. Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original, and all of which shall together constitute one and the same agreement, and shall become effective when signed by each of the parties hereto and delivered to the other party in person or by facsimile or other reliable electronic means. The parties agree that this Agreement, once validly executed, may be stored by electronic means and that either an original or an electronically stored copy of this Agreement can be used for all purposes, including in any proceeding to enforce the rights and/or obligations of the parties to this Agreement.

IN WITNESS WHEREOF, Provider and Company have caused this Agreement to be duly executed and delivered as of the date first written above.

**ASEMBIA LLC**

**THERATECHNOLOGIES INC.**

By: (signed) Brian W. Burke

By: (signed) Jovan Antunovic

Name: Brian W. Burke

Name Jovan Antunovic

Title: Vice President Trade Relations

Title: Senior Vice President and  
Chief Commercial Officer

Date: July 15, 2019

Date: July 15, 2019

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**Schedule A**  
Asembia's Security Measures

**[REDACTED: Description of Security Measures]**

**Amendment No. 1 to Amended and Restated Statement of Work #1**

[3PL]

This Amendment No. 1 (Amendment #1) to the Amended and Restated Statement of Work #1 (“SOW”) is entered into with an effective date of November 1, 2019 (the “Amendment #1 Effective Date”) pursuant to and shall be governed by the terms and conditions set forth in that certain Amended and Restated Master Services Agreement by and between Theratechnologies Inc. (“Customer”) and RxC Acquisition Company d/b/a RxCrossroads by McKesson (“RxCrossroads”) with an effective date of November 1, 2017 (the “Agreement”). All capitalized terms used herein shall have the same meanings as set forth in the Agreement unless otherwise specifically defined herein.

WHEREAS, Customer and RxCrossroads entered into the SOW with an effective date of November 1, 2017 regarding 3PL services to be provided by RxCrossroads;

WHEREAS, Customer and RxCrossroads desire to add an additional product to the list of products for which RxCrossroads provides 3PL services under the SOW;

NOW, THEREFORE, for good and valuable consideration, Customer and RxCrossroads hereby agree as follows:

**1.0 Addition of Product**

Customer and RxCrossroads hereby agree to add *EGRIFTA SV<sup>TM</sup>* under the SOW as an additional Product for which RxCrossroads will provide Services to Customer. Accordingly, Section 1.0 of SOW is hereby deleted and replaced with the following:

**1.0 Services.**

RxCrossroads will provide the warehousing and logistical support services set forth in Section 2.0 (collectively, the “Services”) to support the storage and distribution of Customer’s prescription drug products in their finished forms: *EGRIFTA*, the *EGRIFTA* injection kits, *EGRIFTA SV<sup>TM</sup>*, the *EGRIFTA SV<sup>TM</sup>* injections kits, and ibalizumab (collectively, the “Products”). New Products may be added upon the mutual agreement of the parties and pursuant to a written amendment to this SOW. RxCrossroads shall be Customer’s exclusive 3PL provider for all of Customer’s products, in the United States. RxCrossroads shall make available the appropriate personnel necessary for successful implementation of all Services, including a project manager. RxCrossroads shall conduct regular business reviews and quality improvement reviews to assure mutual success.



## **2.0 Fees**

Customer and RxCrossroads hereby agree to update Fees related to the addition of Product under this SOW. Accordingly, Section 5.0 of SOW is hereby amended to add the following:

Add *EGRIFTA SV*<sup>TM</sup> to Ambient or Controlled Product, within the Warehouse Storage section of Fees.

## **3.0 No other Amendment**

The amendment contained in this Amendment #1 is the only amendment made to the terms and conditions of the SOW. Except as amended herein, all of the terms and conditions of the SOW remain in full force and effect and shall govern this Amended SOW.

**RxC ACQUISITIONS COMPANY  
d/b/a RxCROSSROADS BY  
MCKESSON**

**THERATECHNOLOGIES INC.**

**BY:** (signed) Layne H. Martin

**BY:** (signed) Marie-Noël Colussi

**NAME:** Layne H. Martin

**NAME:** Marie-Noël Colussi

**TITLE:** Vice President/ GeneralManager

**TITLE:** Vice President Finance

**DATE:** November 11, 2019

**DATE:** November 6, 2019

**Amendment No. 1 to Amended and Restated Statement of Work #2**

[Title Model]

This Amendment No. 1 to the Amended and Restated Statement of Work #2 (“Amendment #1”) is entered into with an effective date of November 1, 2019 (the “Amendment #1 Effective Date”) pursuant to and shall be governed by the terms and conditions set forth in that certain Amended and Restated Master Services Agreement by and between Theratechnologies Inc. (“Customer”) and RxC Acquisition Company d/b/a RxCrossroads by McKesson (“RxCrossroads”) with an effective date of November 1, 2017 (the “Agreement”). All capitalized terms used herein shall have the same meanings as set forth in the Agreement unless otherwise specifically defined herein.

WHEREAS, Customer and RxCrossroads entered into an Amended and Restated Statement of Work #2 with an effective date of November 1, 2017 (“SOW #2”) regarding distribution services to be provided by RxCrossroads;

WHEREAS, Customer and RxCrossroads desire to add an additional Product to be distributed by RxCrossroads under the SOW #2;

NOW, THEREFORE, for good and valuable consideration, Customer and RxCrossroads hereby agree as follows:

**1.0 Addition of Product**

Customer and RxCrossroads hereby agree to add *EGRIFTA SV*<sup>TM</sup> under the SOW as an additional Product to be distributed by RxCrossroads under the SOW.

**2.0 Section 1.4 – Products**

Section 1.4 of the SOW #2, the definition of Products, shall be amended to include *EGRIFTA SV*<sup>TM</sup>. Accordingly, Section 1.4 is hereby deleted and replaced with the following:

1.4 “Products” shall mean *EGRIFTA*, together with its injection kits, *EGRIFTA SV*, together with its injection kits, and Ibalizumab.

**3.0 Section 1.5 – Unit**

Section 1.5 of the SOW #2, the definition of Unit, shall be amended to include *EGRIFTA SV*<sup>TM</sup>. Accordingly, Section 1.5 is hereby deleted and replaced with the following:

1.5 “Unit” shall mean either a box of *EGRIFTA*, an *EGRIFTA* injection kit box, a box of *EGRIFTA SV*, an *EGRIFTA SV* injection kit box, or a box of Ibalizumab. Each Unit shall be packaged and labeled in accordance with the requirements of the approval for the marketing and sale of the Products received by Customer from the U.S. Food and Drug Administration. (“FDA”)

#### **4.0 Section 7.1.1 – Service Fees Charged to Customer**

Section 7.1.1 of the SOW #2 shall be amended to add Service fees applicable to the new Product, EGRIFTA SV. Accordingly, subsection 7.1.1.3 shall be added to Section 7.1.1, as follows:

##### **7.1.1.3 EGRIFTA SV**

The fee for Services related to EGRIFTA SV shall be equal to 1.6% of the greater of (a) the gross sales price per Unit of EGRIFTA SV sold in the prior month or (b) \$2,100 per Unit of EGRIFTA SV sold in the prior month.

#### **5.0 Addition of Exhibit D**

Exhibit D to the SOW #2 shall be added by inserting the attached EGRIFTA SV™ Returns Policy after the EGRIFTA® Returns Policy and before the Ibalizumab Returned Goods Policy.

#### **6.0 No other Amendment**

The amendment contained in this Amendment #1 is the only amendment made to the terms and conditions of the SOW #2. Except as amended herein, all of the terms and conditions of the SOW #2 remain in full force and effect and shall govern this Amended SOW #2.

***[Voluntarily Left Blank]***

**RxC ACQUISITIONS COMPANY**  
**d/b/a RxCROSSROADS BY**  
**MCKESSON**

**THERATECHNOLOGIES INC.**

**BY:** (signed) Layne H. Martin

**BY:** (signed) Marie-Noël Colussi

**NAME:** Layne H. Martin

**NAME:** Marie-Noël Colussi

**TITLE:** Vice President/General Manager

**TITLE:** Vice President Finance

**DATE:** November 11, 2019

**DATE:** November 6, 2019

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*Exhibit D*  
**EGRIFTA SV™ RETURNS POLICY**

**[REDACTED: EGRIFTA SV™ Returns Policy]**

**SECOND AMENDMENT TO  
AMENDED AND RESTATED  
MASTER SERVICES AGREEMENT**

This Second Amendment to Amended and Restated Master Services Agreement (this “Amendment 2”) dated February 3, 2020 (the “Amendment 2 Effective Date”) is made by and between inVentiv Commercial Services, LLC, a Syneos Health™ group company with an office located at 500 Atrium Drive, Somerset, NJ 08873 (“Syneos Health”) and Theratechnologies Inc., a Canadian corporation with offices located at 2015 Peel Street, 11th Floor, Montreal, Quebec, Canada H3A 1T8 (“Client”). Client and Syneos Health may each be referred to herein as a “Party” and collectively, the “Parties”.

**RECITALS**

**WHEREAS**, Syneos Health and Client are Parties to that certain Amended and Restated Master Services Agreement effective as of December 14, 2016, as amended by the First Amendment dated February 27, 2019 (the “Agreement”); and

**WHEREAS**, the Parties desire to further amend the Agreement as set forth herein.

**NOW THEREFORE**, in consideration of the above Recitals, the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby understand and agree as follows:

1. **Capitalized Terms.** All capitalized terms used but not otherwise defined in this Amendment 2 have the same meaning given to such terms in the Agreement.
2. **Additional Section.** The Section below shall be inserted in the Agreement as a new Section 14(l):

“inVentiv will ensure that its personnel providing the Services under the applicable Project Agreement (including, as applicable to the Services, its Affiliate, its Affiliate’s personnel and subcontractors) are capable professionally, duly trained and qualified, and have reasonable resources for prompt management of adverse event reports and quality complaints related to Client’s products. Adverse Events shall mean any “Adverse Drug Experience,” as defined in 21 C.F.R. 310.305(b) and 21 C.F.R. 314.80(a) and/or “Adverse experience” as defined in 21 C.F.R. 600.80(a), (as applicable) and/or “Adverse Reaction”, including “Special Situations” as defined in DIR 2001/83/EC Art 1(11), EMA/876333/2011 Rev 4 and EMA/873138/2011 Rev 2; or any replacements thereto. inVentiv shall within one business day of becoming aware of an Adverse Event notify Client by contacting 1-833-238-4372, or such other phone numbers or addresses as provided by Client if it receives any information that relates, refers or pertains to: (i) an adverse or unexpected event in humans relating to the Product; (ii) a complaint relating to the Product quality; or (iii) any report of any other problem involving Client’s product (e.g., contamination, discoloration, improper labeling, adulteration, etc.). Client will be responsible for the reporting of any potential adverse events or complaints to appropriate government agencies, with exception in cases where inVentiv has been contracted for pharmacovigilance services.”

3. **Term:** Section 11 of the Agreement is hereby deleted in its entirety and replaced with the following:

“The Agreement shall be in effect as of the Effective Date and shall remain in effect until November 30, 2021 (the “Term”) or until such later date as may be set forth in a Project Agreement

(it being understood that this Agreement will not terminate in the event the term set forth in a Project Agreement is longer than the term set forth herein). The Parties may extend this Agreement for additional periods of one year each (each an "Additional Term") by mutual written agreement not less than [REDACTED: Time Period] prior to end of the then current term."

4. **Miscellaneous.**

- a. Except as specifically amended or modified in this Amendment 2, each term of the Agreement shall continue to be in full force and effect.
- b. This Amendment 2 may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Execution and delivery of this Amendment 2 by exchange of facsimile copies or via pdf file bearing the signature of a party hereto shall constitute a valid and binding execution and delivery of this Amendment 2 by such party. Such facsimile copies and or pdf versions shall constitute enforceable original documents.
- c. The terms of this Amendment 2 are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this Amendment 2 constitute the complete and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.

**IN WITNESS WHEREOF**, the parties hereto have executed this Amendment 2 to the Agreement to be effective as of the Amendment 2 Effective Date.

**THERATECHNOLOGIES INC.**

**INVENTIV COMMERCIAL SERVICES, LLC**

By: (signed) Luc Tanguay  
Name: Luc Tanguay  
Title: President and Chief Executive Officer  
Date: February 3, 2020

By: (signed) Philip P. Moussally  
Name: Philip P. Moussally  
Title: CFO Deployment Solutions  
Date: February 3, 2020

By: (signed) Philippe Dubuc  
Name: Philippe Dubuc  
Title: Senior Vice President and Chief  
Financial Officer  
Date: February 3, 2020

EXECUTION  
COPY

**AMENDED AND RESTATED  
LICENSE AGREEMENT**  
MGH Agreement No. 2020-1109

This Amended and Restated License Agreement (“**A&R Agreement**”) is made as of the 3<sup>rd</sup> day of February, 2020 (“**Effective Date**”), between Theratechnologies Inc., a Québec company, having a principal place of business at 2015 Peel Street, 11<sup>th</sup> Floor, in the City of Montréal, Province of Québec, H3A 1T8, Canada (“**Company**”) and The General Hospital Corporation, d/b/a Massachusetts General Hospital, a not-for-profit Massachusetts corporation, with a principal place of business at 55 Fruit Street, Boston, Massachusetts 02114 (“**Institution**”), each referred to herein individually as a (“**Party**”) and, collectively, as the (“**Parties**”).

**RECITALS**

Institution and Company entered into a Research Material Transfer Agreement effective on June 4, 2015 and amended on August 2, 2017 (“**MTA**”; MGH Agreement No. 2014D006969) whereby Company supplied its approved proprietary drug, tesamorelin, and placebo, to Institution for use in a human research study funded by the National Institutes of Health, a federal agency of the United States government, and conducted at Institution through and under the direction of Dr. Steven Grinspoon (the “**Principal Investigator**”) entitled, “*Tesamorelin effects on liver fat and histology in HIV: A collaborative UO1 grant*” (the “**Study**”);

Institution and Company previously entered into a License Agreement effective on June 4, 2015 (“**Original Agreement**”; MGH Agreement No. 2020-0378), whereby Institution licensed all Proprietary Rights (as defined below) to Company that were developed in the performance of the Study (both as defined below);

Institution, through research conducted by its Principal Investigator in the Study, developed certain Patent Rights and Technological Information (both as defined below) related to the use of tesamorelin in patients with fatty liver disease and infected with the human immunodeficiency virus (“**HIV**”) and became the owner of such Patent Rights;

Company intends to pursue the development of tesamorelin in a Pivotal Clinical Trial (defined below) for the treatment of fatty liver disease in the HIV-patient population and using the Patent Rights developed by Hospital;

Institution, through its Principal Investigator, has agreed to provide Company with additional Technological Information (listed in Appendix B) pertaining to the design of a Pivotal Clinical Trial (defined below) testing the efficacy of tesamorelin as a treatment for fatty liver disease(s) such as NAFLD and NASH (defined below) in patients infected with HIV in order to expand the FDA-approved indication of tesamorelin for this patient population.

Institution and Company have entered into an Institutional Consulting Agreement effective on February 3, 2020 (“**Consulting Agreement**”; MGH Agreement No. 2019) in which Principal Investigator shall provide to Company expertise and assistance on current developments regarding HIV disease and its treatments, as well as potential relevant designs for future studies using tesamorelin; and

The Parties desire to amend and restate the Original Agreement with this A&R Agreement further to discussions held between them;



For good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereto agree as follows:

## 1. CERTAIN DEFINITIONS

The following terms shall have the meanings ascribed to them in this A&R Agreement, unless the context requires otherwise.

- 1.1 “**Affiliate**”, with respect to either Party, shall mean any corporation or other legal entity other than that of a Party in whatever country organized, controlling, controlled by or under common control with that Party. The term “control” shall mean the power, direct or indirect, to elect or appoint more than fifty percent (50%) of the directors or trustees, or to cause direction of management and policies, whether through the ownership of voting securities, by contract or otherwise.
- 1.2 “**Business Day**” shall mean any day of a calendar year other than a Saturday, Sunday and a statutory civil holiday in the province of Québec and in the State of Massachusetts.
- 1.3 “**Claim**” shall mean any pending or unexpired issued claim of any Patent Right that has not been permanently revoked, nor held unenforceable or invalid by a decision of a court or other Governmental Body of competent jurisdiction that is unappealable or unappealed in the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.
- 1.4 “**Clinical Milestone**” shall have the meaning ascribed thereto in Section 3.1.
- 1.5 “**Clinical Milestone Payment**” shall have the meaning ascribed thereto in Section 3.1.
- 1.6 “**Company’s Fiscal Year**” shall mean the fiscal year of Company which is currently from December 1st of a calendar year to November 30<sup>th</sup> (inclusively) of the ensuing calendar year, as may be amended from time to time.
- 1.7 “**Confidential Information**” shall mean any information, including but not limited to, intellectual property, technologies, clinical development plans, including the development of the Study Drug for the treatment of fatty liver disease in the HIV and non-HIV patient populations and the Technological Information, know-how, business plans, data, results, commercial information, trade secrets, and other business, financial, commercial or technical information disclosed by one Party to the other Party in connection with the terms of the A&R Agreement. Institution’s Confidential Information shall also include all information disclosed by Institution to Company in connection with the Patent Rights.
- 1.8 “**Demand**” shall have the meaning ascribed thereto in Section 8.1.
- 1.9 “**Distributor**” shall mean any Third Party entity to whom Company, Company Affiliate, or a Sublicensee has granted, express or implied, the right to distribute any Product pursuant to Section 2.1(b).

- 1.10 “**EMA**” shall mean the European Medicines Agency and any successor thereto.
- 1.11 “**FDA**” shall mean the United States Food and Drug Administration, and any successor thereto.
- 1.12 “**Governmental Body**” shall mean any (a) nation, principality, state, commonwealth, province, territory, municipality, district or other jurisdiction or any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal; (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority.
- 1.13 “**Institution Indemnities**” shall have the meaning ascribed thereto in Section 10.1(a).
- 1.14 “**Invention**” shall mean all inventions, discoveries and improvements licensed, conceived, generated or reduced to practice by Institution, the Principal Investigator or someone under Institution or Principal Investigator’s supervision as a result of the performance of the Study using the Study Drug that are solely and jointly owned by Institution.
- 1.15 “**Label Expansion**” shall mean the first date of regulatory approval, including conditional approval, of the Product by the FDA and/or the EMA, as applicable, for the treatment of any fatty liver disease, including NASH and NAFLD, in HIV-infected patients.
- 1.16 “**Law**” or “**Laws**” shall mean all laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any applicable Governmental Body.
- 1.17 “**License Field**” shall mean all uses of the Proprietary Rights for treatment of diseases in humans or animals.
- 1.18 “**License Territory**” shall mean worldwide.
- 1.19 “**Loss**” or “**Losses**” shall have the meaning ascribed in Section 8.1(a).
- 1.20 “**Market Exclusivity**” shall mean orphan designated drug, Hatch-Waxman or any other statutory or regulatory exclusivity covering the Product.
- 1.21 “**NAFLD**” shall mean non-alcoholic fatty liver disease.
- 1.22 “**NASH**” shall mean non-alcoholic steatohepatitis.
- 1.23 “**Net Sales**” shall be calculated as [REDACTED: Method of Calculation].
- 1.24 “**Patent Rights**” shall mean Institution’s rights in [REDACTED: List of patents/patent

**applications].**

- 1.25 **“Pivotal Clinical Trial”** shall mean an adequate and well-controlled human clinical study of the Product or Process, as outlined under 21 C.F.R §314.126 or its foreign equivalent, the results of which are intended to form the basis for regulatory approval. For avoidance of doubt, a clinical trial that meets the foregoing criteria shall be deemed a Pivotal Clinical Trial regardless of whether it is characterized as a “Phase 2b”, or “Phase 2b/3”, or “Phase 3”.
- 1.26 **“Process”** shall mean any process, method or service, the use or performance of which, in whole or in part, absent the license granted hereunder would infringe, or is covered by, one or more Claims of Patent Rights.
- 1.27 **“Product”** shall mean (i) any pharmaceutical product containing or comprising the Study Drug, including any dosage, derivative, formulation or presentation thereof, and associated drug device therefor, used for the treatment of patients; or (ii) any article, device or composition, the manufacture, use, or sale of which, in whole or in part, absent the license granted hereunder would infringe, or is covered by, one or more Claims of the Patent Rights.
- 1.28 **“Proprietary Rights”** shall mean all of the rights owned, or to be owned by Institution, including Patent Rights, Inventions, Study Data and Processes generated in the performance of the Study.
- 1.29 **“Regulatory Milestone”** shall have the meaning ascribed thereto in Section 3.1.
- 1.30 **“Regulatory Milestone Payment”** shall have the meaning ascribed thereto in Section 3.1.
- 1.31 **“Royalty Payments”** shall have the meaning ascribed in Section 3.2.
- 1.32 **“Sell”** (and “Sale” and “Sold” as the case may be) shall mean to sell or have sold, to lease or have leased, to import or have imported or otherwise to transfer or have transferred any Product for valuable consideration (in the form of cash or otherwise), and further in the case of a Process to use or perform such Process for the benefit of a Third Party. The term “Sell” (and “Sale” and “Sold”, as the case may be) shall not include the transfer, use or disposition of a Product or Process at no cost to a Third Party pursuant to (a) clinical trials, research collaborations, regulatory, or governmental purposes, and (b) compassionate use programs. Hospital shall not construe such transfers as “in kind” benefits or compensation.
- 1.33 **“Study Data”** shall mean all data, unpublished results, and case reports forms generated during the Study using the Study Drug and all rights of Institution in such Study Data.
- 1.34 **“Study Drug”** shall mean Company’s approved proprietary drug, tesamorelin, or any analog, derivative, or new formulation thereof.

- 1.35 “**Sublicensee**” shall mean any Third Party sublicensee of the rights granted to Company under Section 2.1(a)(ii). For the purpose of this A&R Agreement, a distributor of a product or process shall not be included in the definition of Sublicensee unless such Distributor (i) is granted any right to make, have made, use or have used Products or Processes in accordance with Section 2.1(b), or (ii) has agreed to pay Company or its Affiliates milestones and/or royalties on such Distributor’s sales of Products or Processes, in which case such Distributor shall be a Sublicensee for all purposes of this A&R Agreement.
- 1.36 “**Technological Information**” shall mean the Study Data provided to Company under the Original Agreement, as well as additional research data, designs, formulae, process information and other information created by Principal Investigator, or their successor, at Institution and which is provided to Company pursuant to (i) the upcoming Pivotal Clinical Trial supporting Label Expansion of the Product, or (ii) the invention(s) claimed in the Patent Rights for which Institution or the Principal Investigator (or its successor) reasonably believes is necessary in order for Company to utilize the licenses granted hereunder, both (i) and (ii) as further described in **Exhibit “B”**.
- 1.37 “**Term**” shall have the meaning ascribed thereto in Section 10 hereof.
- 1.38 “**Third Party**” shall mean any legal entity other than Company, Institution or Affiliate of either of them.
- 1.39 “**Type C Meeting**” shall mean a type C meeting, including face-to-face, by teleconference, or video conference, within the meaning of the “Guidance for Industry, Formal Meetings between the FDA and Sponsors or Applicants” as published by the U.S. Department of Health and Human Services of the FDA, May 2009, Revision 1, and the equivalent thereof in the European Union.

## 2. LICENSE

### 2.1 Grant of License.

- (a) Subject to the terms of this A&R Agreement and Institution’s rights in the Patent Rights and the rights retained by Institution pursuant to Section 2.3, Institution hereby grants to Company in the License Field in the License Territory:
- (i) an exclusive, royalty-bearing license under Institution’s rights in the Proprietary Rights to develop, make, have made, use, have used, Sell and have Sold any Product or Process;
  - (ii) the right to grant sublicenses under the rights granted in Section 2.1(a)(i) to Sublicensees, provided that in each case Company shall be responsible for the performance of any obligations of Sublicensees relevant to this A&R Agreement as if such performance were carried out by Company itself, including without limitation, the payment of any royalties or other payments provided for hereunder, regardless of whether the terms of any sublicense

provide for such amounts to be paid by the Sublicensee directly to Institution; and

(iii) the exclusive right to use the Technological Information for the Label Expansion of the Study Drug in accordance with this A&R Agreement and/or under the MTA.

(b) The licenses granted in Section 2.1(a) above include the right to grant to the purchaser of any Product or Process from Company, Affiliates and Sublicensees, the right to use such purchased Product or Process in a method coming within the scope of the Patent Rights; and the right to grant a Distributor the right to Sell (but not to make, have made, use or have used) such Products and/or Processes for or on behalf of Company, its Affiliates, and Sublicensees in a manner consistent with this A&R Agreement.

(c) The foregoing license grant shall include the grant of said license to any Affiliate of Company, provided that such Affiliate shall assume the same obligations as those of Company and be subject to the same terms and conditions hereunder and further provided that Company shall be responsible for the performance by said Affiliate of said obligations and for compliance by said Affiliate with said terms and conditions.

2.2 Sublicenses. All sublicenses granted hereunder shall be consistent with and comply with all the terms of this A&R Agreement, shall incorporate terms and conditions sufficient to enable Company to comply with this A&R Agreement. Any further sublicense by a Sublicensee shall not be prohibited. Company shall provide to Institution a fully signed, non-redacted copy of all sublicense agreements and amendments thereto that provide a Sublicensee with the right to Sell the Product, including all exhibits, attachments and related documents, within **[REDACTED: Time Period]** of executing the same. Upon termination of this A&R Agreement or any license granted hereunder for any reason, any sublicenses shall be addressed in accordance with Section 10.7. Any sublicense which is not in accordance with the forgoing provisions shall be null and void.

2.3 Retained Rights; Requirements. Any and all licenses granted hereunder are subject to:

(a) Institution's and Institution's Affiliates' right to use the subject matter described and/or claimed in the Patent Rights for non-commercial research and educational purposes; provided, however, that any Invention not forming part of the Patent Rights be forthwith disclosed to Company and that such Invention be dealt with pursuant to the terms of Sections 5 hereof;

(b) Institution's and Institution's Affiliates' right to use the subject matter described in Technological Information for research and educational purposes only;

(c) for Patent Rights and Technological Information supported by federal funding, the rights, conditions and limitations imposed by U.S. law (see 35 U.S.C. § 202 et seq.

and regulations pertaining thereto); and

(d) Institution's right to protect Patent Rights under Section 6.2 of this A&R Agreement.

2.4 No Additional Rights. It is understood that nothing in this A&R Agreement shall be construed to grant Company a license express or implied under any patent owned solely or jointly by Institution other than on the Patent Rights licensed hereunder.

2.5 Institution Transferring Its Interest. Company shall have the right of first refusal should Institution desire to Sell or assign its ownership interest in a Proprietary Right. Should Company desire to exercise its option, the consideration shall be one dollar (\$1.00), and Company shall exercise its option within **[REDACTED: Time Period]** of receiving written notice of Institution's desire to Sell or assign the Proprietary Rights.

### 3. PAYMENTS AND ROYALTIES

3.1 Milestone Payments. Company shall pay Institution milestone payments totaling **[REDACTED: Amount]**, as detailed below.

Clinical Development Milestones. Company shall pay Institution **[REDACTED: Amount]** in three (3) equal installments upon occurrence of each of the following clinical development milestones (each, a "**Clinical Milestone**", and each such amount, a "**Clinical Milestone Payment**"):

- (a) **[REDACTED: Amount]** upon public announcement by Company of the launch of a Pivotal Clinical Trial seeking Label Expansion of the Product following a Type C Meeting;
- (b) **[REDACTED: Amount]** upon the first patient dosed with the Product in a Pivotal Clinical Trial seeking the Label Expansion; and
- (c) **[REDACTED: Amount]** following the last visit of the last patient enrolled in the Pivotal Clinical Trial seeking the Label Expansion.

Regulatory Approval Milestones. Company shall pay Institution an aggregate fee of **[REDACTED: Amount]** in three (3) equal installments upon the first occurrence of each of the following regulatory approval milestones for the Product (each, a "**Regulatory Milestone**", and each such amount, a "**Regulatory Milestone Payment**"):

- (d) **[REDACTED: Amount]** upon achieving Label Expansion of the Product by either the FDA and/or the EMA (the first to occur);
- (e) **[REDACTED: Amount]** one (1) year following Label Expansion of the Product by either the FDA and/or the EMA (the first to have occurred); and
- (f) **[REDACTED: Amount]** two (2) years following Label Expansion of the Product by either the FDA and/or the EMA (the first to have occurred).

For the avoidance of doubt, each Regulatory Milestone shall only be paid once upon the first of the EMA or the FDA to approve the Label Expansion of the Product.

- 3.2 Royalty Payments. Upon Label Expansion of the Product, Company shall pay Institution a royalty of **[REDACTED: Amount]** on the portion of Net Sales of the Product that exceeds **[REDACTED: Amount]** during Company's Fiscal Year that was Sold by Company, its Affiliates, or Sublicensees (the "**Royalty Payments**").
- (a) Company's obligation to pay royalties shall commence upon achieving Label Expansion of the Product and shall continue until *the later of*: (a) the date on which there ceases to be Patent Rights on the Product; (b) the expiration of all applicable periods of Market Exclusivity; and (c) ten (10) years after Label Expansion of the Product, as applicable.
  - (b) In Company's Fiscal Year during which Label Expansion is obtained, the Royalty Payments shall be computed on Net Sales of the Product Sold by Company, its Affiliates, or Sublicensees (i) between the date of Label Expansion and the end of Company's Fiscal Year (inclusively), and (ii) on Net Sales of Product exceeding **[REDACTED: Amount]**. For each subsequent year, Royalty Payments shall be computed on Net Sales of the Product sold by Company, its Affiliates, or Sublicensees that exceed **[REDACTED: Amount]** during Company's Fiscal Year. By way of example, if Label Expansion of the Product is obtained on October 1, 2022 and Company, its Affiliates, or Sublicensees have Sold **[REDACTED: Computation of Royalty]**.
  - (c) In the event that the Product is no longer covered by Patent Rights in a given country, Company shall be entitled to reduce the royalty rate due to Institution in such country, as provided above, by **[REDACTED: Amount]** until the later of: (a) ten (10) years after Label Expansion is achieved; or (b) the expiration of all applicable periods of Market Exclusivity covering the Product in such country.
- 3.3 Payments. The Clinical Milestone Payments and the Regulatory Milestone Payments shall be made within **[REDACTED: Time Period]** after receipt from Institution of an invoice for the achievement of each Clinical Milestone and Regulatory Milestone. The Royalty Payments shall be made within **[REDACTED: Time Period]** after delivery of the Sales Report to Institution pursuant to Section 4.3. Payments shall be drawn on a United States bank and shall be payable in United States dollars. Each payment shall reference this A&R Agreement, Agreement Number **2020-1109**, and identify the obligation under this A&R Agreement that the payment satisfies. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States, as reported in The Wall Street Journal, over the Company's Fiscal Year using the average conversion rate for that period. Subject to applicable Laws and except as permitted in the definition of Net Sales, such payments shall be without deduction of exchange, collection or other charges. For the avoidance of doubt, Company shall have no obligation to gross-up the amount of any payment to be made thereunder if the Laws applicable to such payment require Company to withhold money on such payment and remit any amount to a Governmental Body.

Checks for all payments due to the Institution under this A&R Agreement shall be made payable to "The General Hospital Corporation" and addressed as set forth below:

**Massachusetts General Hospital**  
**[REDACTED: Address]**

Payments via wire transfer should be made as follows:

**[REDACTED: Wire Instructions]**

- 3.4 Overdue Payments. The payments due under this A&R Agreement shall, if overdue, bear interest beginning on the first day following their due dates at a per annum rate equal to the **[REDACTED: Time Period]** United States prime rate in effect on the due date as reported by The Wall Street Journal, such interest rate being compounded until payment is made, not to exceed the maximum permitted by Law. Any such overdue payments when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not preclude Institution from exercising any other rights it may have as a consequence of the lateness of any payment.

**4. REPORTS AND RECORDS**

- 4.1 Notice. Company shall promptly notify Institution in writing upon the occurrence of any Clinical Milestone and any Regulatory Milestone, as well as any Label Expansion within **[REDACTED: Time Period]** after occurrence thereof.
- 4.2 Sales Reports. In Company's Fiscal Year in which Royalty Payments are due, Company shall deliver reports to Institution within **[REDACTED: Time Period]** following each Company's Fiscal Year. Each report under this Section 4.2 shall have substantially the format outlined in **Exhibit "C"**, shall be certified as correct by an officer of the Company and shall contain at least the following information as may be pertinent to a royalty accounting hereunder for the immediately preceding Company's Fiscal Year:

**[REDACTED: Content of Certification]**

If no amounts are due to Institution for any Reporting Period, the report shall so state. The information contained in such report shall be Confidential Information of Company and shall be treated as such pursuant to the terms of Section 7 herein.

- 4.3 Audit Rights. Company shall maintain and shall cause each of its Affiliates and Sublicensees to maintain, complete and accurate records relating to the rights and obligations under this A&R Agreement and any amounts payable to Institution in relation to this A&R Agreement, which records shall contain sufficient information to permit Institution and its representatives to confirm the accuracy of any payments and reports delivered to Institution and compliance in all other respects with this A&R Agreement. Company shall retain and make available, and shall cause each of its Affiliates and Sublicensees to retain and make available, such records for at least **[REDACTED: Time Period]** following the end of Company's Fiscal Year to which they pertain, to Institution and/or its representatives and upon at least **[REDACTED: Time Period]** advance written notice, for inspection during normal business hours, to verify any reports and payments made and/or compliance in other respects under this Agreement. Any audit conducted by a Third Party on behalf of Institution pursuant to this Section shall be subject to such Third Party entering into a non-disclosure agreement with Company upon terms and conditions mutually satisfactory to Company and such Third Party. If any examination conducted by Institution or its representatives pursuant to the provisions of this Section 4.3 show an underreporting or underpayment of **[REDACTED: Threshold percentage]** or more in any payment due to Institution hereunder, Company shall bear the full cost of such audit and shall remit any amounts due to Institution (including interest due in accordance with Section 3.4 within **[REDACTED: Time Period]** of receiving notice thereof from Institution.



## 5. PATENT PROSECUTION AND MAINTENANCE

- 5.1 Patent Prosecution. Company shall be responsible for the preparation, filing, prosecution, issuance, and maintenance of all Patent Rights licensed to Company under this A&R Agreement in any country of its choice and for which Company chooses to file Patent Rights. Company will pay for all costs and expenses related thereto. Institution and Company agree to cooperate and sign all documents as requested for any patent filing, prosecution, issuance, maintenance of Patent Rights and, if applicable, surrendering Patent Rights under Section 5.3
- 5.2 Copies of Documents. With respect to any Patent Right licensed hereunder, Company shall instruct patent counsel prosecuting such Patent Right to (i) copy Institution on patent prosecution documents that are received from or filed with any government patent and trademark office; (ii) provide Institution with copies of draft submissions to any government patent and trademark office prior to filing; and (iii) give consideration to the comments and requests of Institution and its patent counsel. Institution hereby undertakes to provide comments to Company within **[REDACTED: Time Period]** of receipt of all draft submissions. If Institution does not provide comments to Company within such **[REDACTED: Time Period]** period, Institution shall be deemed to have waived its right to comment on the draft submission received and Company shall be free to file such draft submission with any amendment it deems appropriate.
- 5.3 Company's Election Not to Proceed. Company may elect to surrender any patent or patent application under this A&R Agreement in any country where such patent was issued or patent application filed upon **[REDACTED: Time Period]** advance written notice to Institution. Such U.S. or foreign patent or patent application shall thereupon cease to be a Patent Right licensed hereunder. Company shall have no further rights in such patent or patent application, and Institution shall have the right but not the obligation to continue maintenance and/or prosecution of such patent or patent application and shall be responsible for all subsequent costs and expenses relating to such patent or patent application. Institution shall then be free to license its rights to that particular U.S. or foreign patent or patent application to any other party on any terms without accounting to Company.
- 5.4 Confidentiality of Prosecution Information. Each Party agrees to treat all information related to prosecution and maintenance of Patent Rights as Confidential Information in accordance with the provisions of Section 7.

## 6. INFRINGEMENT

- 6.1 Company Right to Prosecute. Company shall have the first right to protect the Patent Rights from infringement and prosecute infringers; Institution shall have the second right. Company shall supply to Institution written evidence demonstrating to Institution's reasonable satisfaction prima facie infringement of a Patent Right by a Third Party which poses a material threat to Company's rights under this A&R Agreement. Company shall provide notice to Institution within **[REDACTED: Time Period]** after providing its written evidence notice above regarding its intent to prosecute the alleged infringement. Before commencing such action, however, Company shall consult with Institution and consider Institution's comments regarding the proposed action. Company shall indemnify and hold Institution harmless from all costs, expenses, and liabilities that

Institution incurs in connection with such action, regardless of whether Institution is a party-plaintiff, except for the expense of any independent counsel retained by Institution in accordance with Section 6.5 below.

- 6.2 Institution's Right to Prosecute. In the event Company notifies Institution that Company does not intend to prosecute infringement of the Patent Rights under Section 6.1, Institution may, upon notice to Company, initiate legal proceedings against the infringer at Institution's expense. Before commencing such action, Institution and, as applicable, any Affiliate, shall consult with Company, and shall consider Company's comments regarding the proposed action. Institution shall indemnify and hold Company harmless from all costs, expenses and liabilities that Company incurs in connection with such action, regardless of whether Company is a party-plaintiff, except for the expense of any independent counsel retained by Company in accordance with Section 6.5 below.
- 6.3 Assignment of Patent Right. If Company elects to commence an action as described in Section 6.1 above, Institution shall have the option to permit such action to be brought in its name and to be joined as a party-plaintiff if so required by Law, or to assign to Company all of Institution's right, title and interest in and to the Patent Right which is the subject of such action, subject to all of Institution's obligations to the Governmental Body under Law. If Institution makes such an assignment, such action by Company shall thereafter be brought or continued without Institution as a party; *provided however*, that Company shall continue to meet all of its obligations under this A&R Agreement as if the assigned Patent Rights were still licensed to Company hereunder.
- 6.4 Settlement. Neither Company nor Institution shall enter into any settlement, consent, judgment or other voluntary final disposition of any infringement action of the Patent Rights without the prior written consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned.
- 6.5 Cooperation. Each Party agrees to cooperate reasonably in any action under this Section 6 which is controlled by the other Party, provided that the controlling Party reimburses the cooperating Party for any costs and expenses incurred by the cooperating Party in connection with providing such assistance, except for the expense of any independent counsel retained by a cooperating Party in accordance with this Section 6.5. Such controlling Party shall keep the cooperating Party informed of the progress of such proceedings. The expense of independent counsel retained by the cooperating Party shall be the cooperating Party's responsibility. However, the expenses of the cooperating Party's independent counsel shall be offset against any damages received by the Party bringing suit in accordance with Section 6.6.
- 6.6 Recovery. Any award paid by Third Parties as the result of such proceedings (whether by way of settlement or otherwise) shall first be applied to reimbursement of the unreimbursed Third Party legal fees and expenses incurred by either Party and then the remainder shall be divided between the Parties in the order that follows:
- (a) Company shall receive an amount equal to its lost profits or a reasonable royalty on the infringing sales, or whichever measure of damages the court shall have applied;
  - (b) Institution shall receive an amount equal to the royalties and other amounts that Company would have paid to Institution if Company had Sold the infringing Products rather than the infringer; and

- (c) The balance, if any, shall be allocated to the Party that brought the lawsuit forward.

## 7. CONFIDENTIALITY

- 7.1 Confidential Information disclosed by one Party (each a “**Discloser**” as applicable) to the other Party (each a “**Recipient**” as applicable) in connection with the terms of this A&R Agreement shall be treated in accordance with this Section 7. Each Party agrees to safeguard the Confidential Information of the other Party with at least the degree of care normally afforded to its own Confidential Information.
- 7.2 Permitted Purpose. Recipient shall have the right to, and agrees that it will use Discloser’s Confidential Information solely for the purpose of executing and performing the obligations and undertakings contained herein (the “**Purpose**”).
- 7.3 Exclusions. Confidential Information shall not include any information to the extent that the information:
- (a) is published, in the public domain or becomes publicly available through no fault of any employee, agent or representative of either Party;
  - (b) was known by Recipient prior to disclosure by Discloser, as evidenced by written records maintained by the Recipient prior to disclosure of the information;
  - (c) becomes known to Recipient after disclosure from a Third Party that has a right to make such disclosure and did not obtain such information in violation of the confidentiality provisions of this Section 7;
  - (d) is independently developed or discovered by Recipient without use of Discloser’s Confidential Information, as evidenced by written records; and
  - (e) is required by Law for disclosure. If the Law requires disclosure, Recipient will notify the other Party immediately, if and to the extent permitted by Law, will give such other Party time and opportunity to file appropriate motions to protect the confidentiality of such information.
- 7.4 Restrictions. This Section 7 shall survive for the Term of the A&R Agreement and for a period of **[REDACTED: Time Period]** thereafter (and indefinitely with respect to any individually identifiable health information disclosed by Institution to Company, if any). Each Party agrees that:
- (a) it will not use the other Party’s Confidential Information for any purpose other than the Purpose, including without limitation for its own benefit or the benefit of any Third Party; and
  - (b) it will use reasonable efforts (but not less than the efforts used to protect its own confidential and/or proprietary information of a similar nature) not to disclose such Confidential Information to any Third Party, except as expressly permitted hereunder.

Recipient may, however, disclose Discloser’s Confidential Information only on a need to know basis to its and its Affiliates employees, staff members, and agents (“**Receiving Individuals**”) who are directly participating in the Purpose and who are informed of the

confidential nature of such information, and to its attorneys, accountants and other professional advisors (the “**Professional Recipients**”) who are under an obligation to keep such Confidential Information confidential, provided that Recipient shall be responsible for compliance by the Receiving Individuals and the Professional Recipients with the terms of this A&R Agreement and any breach thereof.

- 7.5 Right to Disclose. Discloser represents that, to the best of its knowledge, it has the right to disclose to Recipient all of Discloser’s Confidential Information that will be disclosed hereunder.
- 7.6 Ownership. All Confidential Information disclosed pursuant to the A&R Agreement, including without limitation all written and tangible forms thereof, shall be and remain the property of the Discloser. Upon termination of the A&R Agreement, if requested by Discloser, Recipient shall return or destroy at Discloser’s discretion all of Discloser’s Confidential Information, *provided however*, that Recipient shall be entitled to keep one copy of such Confidential Information in a secure location solely for the purpose of determining Recipient’s legal obligations hereunder and provided, further, that Recipient shall be entitled to keep one copy of the Confidential Information as part of its information technology back-up procedures in the normal course of its business.
- 7.7 Press Releases and Permitted Disclosure. The Parties hereby acknowledge and agree that within **[REDACTED: Time Period]** following execution of this A&R Agreement, Company may issue the press release attached as **Exhibit “D”** without further consent from Institution. Institution shall not make any press release or public announcements (including scientific publications) regarding the terms of this Agreement and the Technological Information solely and exclusively related to the Label Expansion without the prior written consent of Company. Notwithstanding the terms of Section 7.3(e), Institution acknowledges that Company may have to file this Agreement with U.S. and Canadian securities regulatory authorities for the purposes of complying with its continuous disclosure obligations under securities laws.

## 8. INDEMNIFICATION AND INSURANCE

### 8.1 Indemnification.

- (a) At Company’s sole expense, Company shall indemnify, defend and hold harmless Institution and its owners, members and Affiliates and their respective trustees, directors, officers, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (the “**Institution Indemnitees**”), against any and all liability, damage, loss or expense (including reasonable attorney’s fees and expenses of litigation) (collectively, the “**Losses**”) incurred by or imposed upon the Institution Indemnitees or any one of them in connection with any Third Party claims, suits, actions, investigations, demands or judgments (collectively “**Demands**”) relating to or arising from, in whole or in part: (i) any theory of product liability (including, but not limited to, actions in the form of contract, tort, warranty, or strict liability) concerning the Product, Process, or service made, used or Sold or performed pursuant to any right or license granted under this A&R Agreement, or (ii) any claim by a Third Party that the Product, Process, or service made, used, or Sold or performed pursuant to any right or license granted under this A&R Agreement infringes any patent, copyright or trade secret, or (iii) Company breach of its obligations under Sections 2.2 and 8.2; except to the extent that Company can

demonstrate by clear and convincing evidence that any Losses as described in clause (i), (ii), or (iii) hereof directly results from the gross negligence or intentional misconduct of Institution Indemnitees.

- (b) Company agrees, at its own expense, to provide attorneys reasonably acceptable to the Institution on behalf of the Institution Indemnitees to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought; *provided however*, that any of the Institution Indemnitees shall have the right to retain its own counsel, at the expense of Company, if representation of such Institution Indemnitee by counsel retained by Company would be inappropriate because of conflict of interest of any such Institution Indemnitees and any other party represented by such counsel.
- (c) The indemnifying Party agrees to keep the indemnified Party informed of the progress in the defense and disposition of such claim and to consult with the indemnified Party prior to any proposed settlement.

## 8.2 Insurance.

- (a) Beginning at such time after Label Expansion when the Product or Process is being Sold, Company shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance in amounts not less than **[REDACTED: Amount]** per occurrence and **[REDACTED: Amount]** annual aggregate covering the obligations of Company under this Agreement, including contractual liability coverage for indemnification obligations under Section 8.1, if any, and shall maintain said insurance for the period that such Product or Process is being Sold. Such insurance shall include adequate tail coverage if the policy is on a claims-made basis.
- (b) Company shall contractually obligate any Sublicensees to the same insurance obligations as set forth for the Company in this Section 8.2.

## **9. DISCLAIMER OF WARRANTIES; LIMITATION OF LIABILITY**

- 9.1 Title to Patent Rights. Institution represents to the best of its knowledge that Institution is the owner of the Proprietary Rights, free and clear by assignment from the inventors of the of the Proprietary Rights and has the authority to enter into this A&R Agreement, license the Proprietary Rights and Technological Information to Company hereunder. Institution has not licensed the Proprietary Rights to any other Third Party, and undertakes to respect Company's license under this A&R Agreement, subject only to Institution's rights under Section 2.3.
- 9.2 No Warranties. INSTITUTION MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, CONCERNING THE PATENT RIGHTS, PROPRIETARY RIGHTS, AND THE RIGHTS GRANTED HEREUNDER, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, VALIDITY OF PATENT RIGHTS CLAIMS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS,

WHETHER OR NOT DISCOVERABLE, AND HEREBY DISCLAIMS THE SAME. SPECIFICALLY, AND NOT TO LIMIT THE FOREGOING, INSTITUTION MAKES NO WARRANTY OR REPRESENTATION (i) REGARDING THE VALIDITY OR SCOPE OF ANY OF THE CLAIM(S), WHETHER ISSUED OR PENDING, OF ANY OF THE PATENT RIGHTS OR PROPRIETARY RIGHTS, AND (ii) THAT THE EXPLOITATION OF THE PATENT RIGHTS, PROPRIETARY RIGHTS, OR ANY PRODUCT OR PROCESS WILL NOT INFRINGE ANY PATENTS OF ANY THIRD PARTY OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

- 9.3 Limitation of Liability. IN NO EVENT SHALL INSTITUTION OR ANY OF THEIR AFFILIATES OR ANY OF THEIR RESPECTIVE TRUSTEES, DIRECTORS, OFFICERS, MEDICAL OR PROFESSIONAL STAFF, EMPLOYEES, STUDENTS, VOLUNTEERS, AND AGENTS BE LIABLE TO COMPANY OR ANY OF ITS AFFILIATES, SUBLICENSEES OR DISTRIBUTORS FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS A&R AGREEMENT OR THE LICENSE OR RIGHTS GRANTED HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER INSTITUTION SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

## 10. TERM AND TERMINATION

- 10.1 Term. The term of this A&R Agreement shall commence on the Effective Date and shall remain in effect until the later of:
- (a) The date on which all issued patents and filed patent applications within the Patent Rights have expired or been abandoned; and
  - (b) One (1) year after the last Sale for which a royalty is due under Section 3.2;

Unless this A&R Agreement is terminated earlier in accordance with any of the other provisions of this Section 10.

- 10.2 Termination for Failure to Pay by Company. If Company fails to make any payments due hereunder, Institution shall have the right to terminate this A&R Agreement upon **[REDACTED: Time Period]** written notice, unless Company makes such payments plus any interest due, as set forth in Section 3.4, within said **[REDACTED: Time Period]** period.
- 10.3 Termination for Termination of Consulting Agreement. In the event that the Consulting Agreement is terminated prior to November 30, 2023, Company may also terminate this A&R Agreement in parallel and effective upon termination of the Consulting Agreement. If the Consulting Agreement is terminated after November 23, 2023, or if the Initial Term is extended beyond November 30, 2023, then Company shall not have the right to terminate this A&R Agreement solely for termination of the Consulting Agreement.
- 10.4 Termination for Failure to Provide Technological Information. In the event that Institution, through its Principal Investigator, fails to provide the Technological Information that is necessary for Company to conduct the Pivotal Clinical Trial seeking

Label Expansion, Company may, upon giving **[REDACTED: Time Period]** written notice, terminate this A&R Agreement for such breach by Institution, provided Institution shall not have cured such breach within the aforementioned **[REDACTED: Time Period]** period. Company's ability to terminate the A&R Agreement pursuant to this Section 10.4 shall expire *upon the earlier of*: (i) achievement of Label Expansion of the Product or (ii) on December 31, 2023.

- 10.5 Termination for Lack of Label Expansion. Company shall seek Label Expansion of the Product by submitting a supplemental new drug application (or the equivalent thereof) to the FDA or EMA in accordance with Section 7.7. Label Expansion of the Product will be deemed to have occurred upon the first approval of such supplemental new drug application (or the equivalent thereof) by either the FDA or EMA, as applicable. If Company has sought Label Expansion of the Product by submitting a supplemental new drug application (or the equivalent thereof) to either of the FDA or EMA and (i) has not achieved Label Expansion of the Product, and (ii) is not seeking, and does not plan to seek, an appeal of such decision by either the FDA or EMA, then Company may terminate this A&R Agreement pursuant to Section 10.4 by providing **[REDACTED: Time Period]** written notice to Institution. In the event that Company, its Affiliate, or Sublicensee subsequently seeks an appeal of such decision regarding Label Expansion of the Product by the FDA or EMA, then termination of the A&R Agreement pursuant to this Section 10.5 shall be null and void and the A&R Agreement shall remain in full force and effect unless terminated by Company or Institution pursuant to another provision in Section 10.
- 10.6 Termination for Insolvency. Institution may terminate this A&R Agreement immediately upon written notice if Company shall become insolvent, shall make an assignment for the benefit of its creditors, or shall have a successful petition in bankruptcy filed for or against it.
- 10.7 Effect of Termination on Sublicenses. Any sublicenses granted by Company under this A&R Agreement shall provide for termination or assignment to Institution of Company's interest therein, at the option of Institution, upon termination of this A&R Agreement or upon termination of any license hereunder under which such sublicense has been granted
- 10.8 Effects of Termination of A&R Agreement. Upon termination of this A&R Agreement or any of the licenses hereunder for any reason, Company shall cease, and shall cause its Affiliates and Sublicensees to cease, to use the Patent Rights licensed hereunder, or those Proprietary Rights pertaining to a terminated license, as the case may be.
- 10.9 Inventory. Upon early termination of this A&R Agreement other than for Company default, Company, Company Affiliates and Sublicensees may complete and sell any work-in-progress and inventory of Products that exist as of the effective date of termination provided that (i) Company pays Institution the applicable running royalty or other amounts due on such Net Sales in accordance with the terms and conditions of this A&R Agreement, and (ii) Company, Company Affiliates and Sublicensees shall complete and sell the inventory of Products within **[REDACTED: Time Period]** after the effective date of termination. Upon expiration of this A&R Agreement, Company shall pay to Institution the royalties set forth in Section 3.2 for Sales of any Product that was in inventory on the date of expiration of the Agreement.

## 11. COMPLIANCE WITH LAW

- 11.1 Compliance. Company shall have the sole obligation for compliance with, and shall ensure that any Affiliates and Sublicensees comply with, all Laws that relate to Products and Processes, including, but not limited to, those of the FDA, and any applicable Laws and regulations of any other country in the License Territory where the Product benefitting from the Label Expansion is Sold. Company agrees that it shall be solely responsible for obtaining any necessary licenses to export, re-export, or import Products or Processes or materials covered by Patent Rights or Confidential Information.

## 12. MISCELLANEOUS

- 12.1 Entire Agreement. This A&R Agreement constitutes the entire understanding between the Parties with respect to the subject matter hereof and replaces and supersedes the Original Agreement, but for greater certainty, does not replace and supersede the MTA.
- 12.2 Notices. Any written notices, reports, waivers, correspondences or other communications required under or pertaining to this A&R Agreement, and including all payments required hereunder, shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other Party, as follows:

*If to Institution:*

[REDACTED: Address]

*If to Company:*

[REDACTED: Address]

*With a copy to:*

[REDACTED: Addressee]

Notices and payments shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by legibly dated U.S. Postal Service postmark or dated receipt from a commercial carrier. Notices shall be deemed given on the date received if delivered as indicated by the carrier receipt if sent to the addressees set forth above.

- 12.3 Amendment; Waiver. This A&R Agreement may be amended and any of its terms or conditions may be waived only by a written instrument executed by an authorized signatory of the Parties or, in the case of a waiver, by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition of term shall be deemed as a further or continuing waiver of such condition or term or of any other condition or term.
- 12.4 Binding Effect. This A&R Agreement shall be binding upon and inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and



assigns.

- 12.5 Assignment. Company shall be entitled to assign this A&R Agreement or any of its rights or obligations under this Agreement without the prior written consent of Institution in the context of a bona fide corporate reorganization, corporate arrangement, amalgamation, merger, take-over or in the context of the sale of all or substantially all of its assets. Any successor, purchaser, or resulting merged entity shall agree in writing to be bound by all of the terms and conditions hereof prior or concurrently to such assignment. Company shall notify Institution in writing of any such assignment and provide a copy of all assignment documents to Institution within **[REDACTED: Time Period]** after such assignment. Failure of an assignee to agree to be bound by the terms hereof or failure of Company to notify Institution and provide copies of assignment documentation shall be grounds for termination of this A&R Agreement for default. Further, neither any rights granted under this A&R Agreement nor any sublicense may be assigned by any Sublicensee without the prior written consent of Institution.
- 12.6 Force Majeure. Neither Party shall be responsible for delays resulting from causes beyond the reasonable control of such Party, including without limitation fire, explosion, flood, war, sabotage, strike or riot, provided that the nonperforming Party uses commercially reasonable efforts to avoid or remove such causes of nonperformance and continues performance under this A&R Agreement with reasonable dispatch whenever such causes are removed.
- 12.7 Use of Name. Neither Party shall use the name of the other Party or of any trustee, director, officer, staff member, employee, student or agent of the other Party or any adaptation thereof in any advertising, promotional or sales literature, publicity or in any document employed to obtain funds or financing without the prior written approval of the Party or individual whose name is to be used. For Institution, such approval shall be obtained from Institution's Public Affairs Office.
- 12.8 Governing Law. This A&R Agreement shall be governed by and construed and interpreted in accordance with the laws of the State of New York, excluding any conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted.
- 12.9 Severability. If any provision(s) of this A&R Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable law from time to time in effect during the term hereof, it is the intention of the Parties that the remainder of this A&R Agreement shall not be effected thereby. It is further the intention of the Parties that in lieu of each such provision which is invalid, illegal or unenforceable, there be substituted or added as part of this A&R Agreement a provision which shall be as similar as possible in economic and business objectives as intended by the Parties to such invalid, illegal or enforceable provision, but shall be valid, legal and enforceable.
- 12.10 Survival. Company's obligations to pay all monies due and owed to Institution under this A&R Agreement shall survive the termination or expiration of this A&R Agreement. In addition to any specific survival references in this A&R Agreement, Sections 1, 4.2, 4.3, 8.1, 8.2, 10.6, 10.7, 10.8, 12.7, 12.8, 12.9 and 12.11 shall also survive termination or expiration of this A&R Agreement upon the term contained therein, failing which they

shall survive for an indefinite period.

- 12.11 Interpretation. The Parties hereto are sophisticated, have had the opportunity to consult legal counsel with respect to this transaction and hereby waive any presumptions of any statutory or common law rule relating to the interpretation of contracts against the drafter.
- 12.12 Headings. All headings are for convenience only and shall not affect the meaning of any provision of this A&R Agreement.
- 12.13 Counterparts. For the convenience of the Parties, this A&R Agreement may be executed electronically by email or facsimile transmission of signature pages, and in counterparts, each of which shall be deemed to be an original, and both of which taken together, shall constitute an agreement binding on both Parties.

*[The remainder of this page is intentionally left blank.]*

**IN WITNESS WHEREOF**, the Parties have caused this A&R Agreement to be executed by their duly authorized representatives as of the Effective Date.

**THERATECHNOLOGIES INC.**

**THE GENERAL HOSPITAL CORPORATION**

By: (signed) Luc Tanguay  
Name: Luc Tanguay  
Title: President and Chief Executive Officer  
Date: February 3, 2020

By: (signed) Jeannette Fiala  
Name: Jeannette Fiala, PhD  
Title: Associate Director, Licensing  
Date: February 3, 2020

By: (signed) Christian Marsolais  
Name: Christian Marsolais  
Title: Senior Vice President and Chief Medical  
Officer  
Date: February 3, 2020

**EXHIBIT "A"**  
**Patent Rights**

**[REDACTED: List of Patents/Patent Applications]**

**EXHIBIT "B"**  
**Technological Information**

**[REDACTED: Description of Technological Information]**

EXHIBIT "C"  
Sales Report

[REDACTED: Form of Sales Report]

**EXHIBIT "D"**  
**Press Release**

**[REDACTED: Form of Press Release]**

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Theratechnologies Inc.

We, KPMG LLP, consent to the incorporation by reference in the Registration Statement (No. 333-234172) on Form F-10 of Theratechnologies Inc. of:

- our report dated February 24, 2020, on the consolidated financial statements which comprise the consolidated statement of financial position as of November 30, 2019, the related consolidated statements of net loss and comprehensive loss, changes in equity and cash flows for the year ended November 30, 2019, and the related notes; and
- our report dated February 20, 2019, on the consolidated financial statements which comprise the consolidated statements of financial position as of November 30, 2018 and December 1, 2017, the consolidated statements of net loss and comprehensive loss, changes in equity and cash flows for the year ended November 30, 2018, and notes, comprising a summary of significant accounting policies and other explanatory information,

which reports refer to a change in presentation currency to the United States dollar in fiscal 2019 on a retrospective basis, and which reports appear in the annual report on Form 40-F of Theratechnologies Inc. for the fiscal year ended November 30, 2019, and further consent to the use of such reports in such annual report on Form 40-F.

(signed) KPMG LLP\*

February 25, 2020  
Montreal, Canada

\*CPA auditor, CA, public accountancy permit No. A110592