

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, 2020

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: **77,013,411**

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 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.

Emerging Growth Company

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.

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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 SV*[®] and Trogarzo[®];
- our ability and capacity to grow the sales of *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*[®] and Trogarzo[®] 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 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 and successfully commercialize Trogarzo[®] in various countries of the European Union;
- the approval of a new formulation of tesamorelin, or F8 Formulation, by the United States Food and Drug Administration, or FDA;
- our capacity to develop a multi-dose pen injector, or Pen, for use with the F8 Formulation;
- our capacity to conduct a Phase 3 clinical trial using tesamorelin for the treatment of Non-alcoholic steatohepatitis, or NASH, in the general population;
- our capacity to conduct a Phase 1 clinical trial using our peptide-drug conjugate TH1902 in various types of cancers;
- our capacity to pursue the development of our other peptide-drug conjugates in the field of oncology;
- our capacity to acquire or in-license new products and/or compounds;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes;
- our estimates regarding our capital requirements; and
- our ability to meet the timelines set forth herein.

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:

- the current pandemic and the measures implemented to control it will have limited material adverse effect on our operations;
- the vaccines recently developed to thwart the coronavirus will be safe and effective at combatting the coronavirus in its current form and in any variant form thereof;
- sales of *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 where we commercialize our products 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 SV*® and Trogarzo® in countries where such products are commercialized;
- 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 biosimilar version of tesamorelin will be approved by the FDA;
- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;
- Trogarzo® will be added to the list of reimbursed drugs by countries of the European Union;
- the FDA will approve the F8 Formulation and the use of the Pen with the F8 Formulation;
- we will agree with the FDA on a final Phase 3 clinical trial design to begin studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting patients and in conducting our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting and in conducting our Phase 1 clinical trial studying TH1902 in various types of cancers;
- we will have the financial means to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population and a Phase 1 clinical trial studying TH1902 in various types of cancers;
- our research and development activities will yield positive results;
- the data obtained from our market research on the potential market for the treatment of NASH in the general population and on the potential market for Trogarzo® in the United States and in the European Union are accurate;
- our European infrastructure is adequate to successfully launch and commercialize Trogarzo® in key European countries;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise as of the date of this Annual Report; 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. 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, 2020, 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, 2020 and 2019, including the report 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, 2020 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, 2020, an evaluation was carried out by management, under the supervision and with the participation of our President and Chief Executive Officer, or CEO, and by our Senior Vice President and Chief Financial Officer, or CFO, who 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, management concluded that our disclosure controls and procedures was effective.

INTERNAL CONTROL OVER FINANCIAL REPORTING

Internal control over financial reporting, as defined by Rule 13a-15(f) and 15d-15(f) of the Exchange Act, is a process designed by, or under the supervision of the Company's principal executive and principal financial officers or persons performing similar functions and effected by the Board of Directors, management and other personnel, 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 control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with IFRS, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

In connection with the Company's reporting obligations in Canada and its obligations under Rule 13a-15(c) under the Exchange Act, management, under the supervision and with the participation of its CEO and CFO, conducted an evaluation of the effectiveness of the Company's internal control over financial reporting as of November 30, 2020, using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). Based on this evaluation, management concluded that its internal control over financial reporting were effective.

NO AUDITOR'S ATTESTATION REPORT

As an "emerging growth company" (as such term is defined in Rule 12b-2 under the Exchange Act), the Company is not required to include in this Annual Report an attestation report of the Company's independent registered public accounting firm relating to the Company's internal control over financial reporting. The Company will be required to provide an attestation report when it no longer qualifies as an emerging growth company.

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 four independent directors, namely: Paul Pommier, its Chair, Gary Littlejohn, Gérald A. Lacoste and Alain Trudeau.

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, 2020 filed as Exhibit 99.1, as set forth in the Exhibit Index attached hereto.

All four 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.

Alain Trudeau. Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal. From 1982 to 2019, Mr. Trudeau has had a distinguished career at Ernst & Young where he held the position of Managing Partner, Assurance Services, for Ernst & Young offices in the Province of Quebec, from 2008 to 2019. During his career, Mr. Trudeau was responsible for the audit of various publicly-traded companies.

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 that were billed or payable in respect of each of our fiscal years ended November 30, 2020 and 2019:

AUDITORS FEES

| Fees | Fiscal Year Ended November 30, 2020 (CAD) | Fiscal Year Ended November 30, 2019 (CAD) |
|-----------------------|--|--|
| Audit Fees(1) | \$497,667 | \$388,600 |
| Audit-Related Fees(2) | \$89,175 | \$71,310 |
| Tax Fees(3) | \$54,563 | \$158,092 |
| Total: | \$641,405 | \$618,002 |

- (1) Refers to the aggregate fees billed by our external auditors for audit services, including interim reviews 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 and accounting consultations, for which \$27,560 has been reclassified from audit to audit-related for the fiscal year ended November 30, 2019.
- (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, 2020, 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. 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. 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, 2020 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 |
|--|----------------------|----------------------|----------------------|---------------------|----------------------|
| Convertible unsecured senior notes, including interest | 67,419,000 | 3,306,000 | 64,113,000 | — | — |
| Lease Liabilities | 3,640,000 | 621,000 | 1,267,000 | 1,752,000 | — |
| Purchase Obligations (1) | 15,845,000 | 15,845,000 | — | — | — |
| Other Long-Term Liabilities (2) | 5,000,000 | 5,000,000 | — | — | — |
| Total | \$ 91,904,000 | \$ 24,772,000 | \$ 65,380,000 | \$ 1,752,000 | \$ — |

- (1) The Corporation has long-term procurement agreements with third party suppliers in connection with the commercialization of *EGRIFTA SV*® and Trogarzo®. As at November 30, 2020, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to \$14,042,000 for the manufacture of Trogarzo®, *EGRIFTA SV*® and for various services. The Corporation also had research commitments and outstanding clinical material purchase orders amounting to \$586,000 in connection with its oncology platform and \$1,217,000 in connection with the F8 Formulation and the Pen developed for the F8 Formulation.
- (2) Other Long-Term Liabilities comprise long-term obligations under commercialization rights agreement.

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, 2020 and 2019, the Corporation did not have any borrowings outstanding under this credit facility.

Licence agreement:

On February 4, 2020, the Corporation entered into an amended and restated licence agreement with the Massachusetts General Hospital, or MGH, as amended on April 15, 2020, in order to benefit from its assistance and knowledge for the development of tesamorelin for the potential treatment of NASH in the general 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 European Medicines Agency, or EMA. In consideration, we agreed to make certain milestone payments to the MGH related to the development of tesamorelin and to pay a low single-digit royalty on all sales of *EGRIFTA*® and *EGRIFTA SV*® 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 any fatty liver disease, including non-alcoholic fatty liver disease or NASH in the general population.

Post-Approval Commitments:

In connection with the approval of Trogarzo® in Europe, we are required to conduct a paediatric investigation plan, or PIP, and a post-authorisation efficacy study, or Registry. The PIP is comprised of two studies: the first one consists in evaluating the pharmacokinetics, pharmacodynamics, safety and tolerability of Trogarzo® in children from 6 to less than 18 years of age with HIV-1 infection in order to provide pharmacokinetics and pharmacodynamics data to support the extrapolation of efficacy from adults; and the second study is a modelling and simulation study to evaluate the use of Trogarzo® in the treatment of HIV-1 infection resistant to at least 1 agent in 3 different classes in children from 6 to less than 18 years of age. The Registry consists primarily in evaluating the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo® treatment *versus* matched patients not receiving Trogarzo®. The study comprising the Registry should be conducted over a five-year period. The cost of the Registry, estimated to be approximately 4,000,000 Euros, will be borne as to 52% by TaiMed and as to 48% by us.

Milestones:

Reference should be made to Note 12 (Intangible Assets) to the audited consolidated financial statements of the Registrant for the year ended November 30, 2020 for a description of all potential commercial milestones payable by the Registrant.

NOTICE PURSUANT TO REGULATION BTR

There were no notices required by Rule 104 of Regulation BTR during the fiscal year ended November 30, 2020, 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.

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/ Paul Lévesque
Name: Paul Lévesque
Title: President and
Chief Executive Officer

Date: February 25, 2021

EXHIBIT INDEX

| Exhibit | |
|---------|--|
| 99.1 | Annual Information Form dated February 24, 2021 for the financial year ended November 30, 2020 |
| 99.2 | Management's Discussion and Analysis for the year ended November 30, 2020 |
| 99.3 | Audited Consolidated Annual Financial Statements for the years ended November 30, 2020 and 2019 |
| 99.4 | Pre-Wholesaling Services Agreement entered into on June 23, 2020 between Theratechnologies Europe Limited and Loxxess Pharma GmbH |
| 99.5 | Master Services Agreement entered into on December 18, 2020 between Theratechnologies Inc. and Worldwide Clinical Trials, Inc. |
| 99.6 | Certificate of CEO dated February 25, 2021 pursuant to Rule 13a-14(a) of the Exchange Act |
| 99.7 | Certificate of CFO dated February 25, 2021 pursuant to Rule 13a-14(a) of the Exchange Act |
| 99.8 | Certificate of CEO dated February 25, 2021 pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 99.9 | Certificate of CFO dated February 25, 2021 pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 99.10 | Consent of KPMG LLP |
| 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, 2020



February 24, 2021

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*[®] (tesamorelin for injection) and *EGRIFTA SV*[®] (tesamorelin for injection) refer to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA* is our registered trademark in Canada and *EGRIFTA SV* is our registered trademark in the United States and these marks are 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 nonalcoholic steatohepatitis, or NASH, in the general population and for other diseases;
- Trogarzo[®] (Ibalizumab-uiyk) refers to the humanized monoclonal antibody ibalizumab indicated (i) in the United States, 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 and, (ii) in Europe, in combination with other antiretroviral(s), for the treatment of adults infected with multidrug resistant HIV-1 infection for whom it is otherwise not possible to construct a suppressive antiviral regimen. Trogarzo 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*[®] 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, 2021, 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 SV*[®] and Trogarzo[®];
- our ability and capacity to grow the sales of *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*[®] and Trogarzo[®] 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 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 and the United Kingdom;
- our ability and capacity to launch and successfully commercialize Trogarzo[®] in various countries of the European Union and the United Kingdom;
- the approval of a new formulation of tesamorelin, or F8 Formulation, by the United States Food and Drug Administration, or FDA;
- our capacity to develop a multi-dose pen injector, or Pen, for use with the F8 Formulation;
- our capacity to conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- our capacity to conduct a Phase 1 clinical trial using our peptide-drug conjugate TH1902 in various types of cancers;
- our capacity to pursue the development of our other peptide-drug conjugates in the field of oncology;
- our capacity to acquire or in-license new products and/or compounds;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes;
- our estimates regarding our capital requirements; and
- our ability to meet the timelines set forth herein.

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:

- the current pandemic and the measures implemented to control it will have limited material adverse effect on our operations;
- the vaccines recently developed to thwart the coronavirus will be safe and effective at combatting the coronavirus in its current form and in any variant form thereof;
- sales of *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 where we commercialize our products 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 countries where such products are commercialized;
- 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 biosimilar version of tesamorelin will be approved by the FDA;
- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;
- Trogarzo[®] will be added to the list of reimbursed drugs by countries of the European Union and the United Kingdom;
- the FDA will approve the F8 Formulation and the use of the Pen with the F8 Formulation;
- we will agree with the FDA on a final Phase 3 clinical trial design to begin studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting patients and in conducting our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting and in conducting our Phase 1 clinical trial studying TH1902 in various types of cancers;
- we will have the financial means to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population and a Phase 1 clinical trial studying TH1902 in various types of cancers;
- our research and development activities will yield positive results;
- the data obtained from our market research on the potential market for the treatment of NASH in the general population and on the potential market for Trogarzo[®] in the United States and in the European Union are accurate;
- our European infrastructure is adequate to successfully launch and commercialize Trogarzo[®] in key European countries;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise as of the date of this AIF; 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 2020 AND OUTLOOK

The following summary highlights selected events that occurred in the fiscal year 2020 up to the date of this AIF as well as our business objectives described elsewhere in this AIF for the fiscal year 2021. 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

- Record consolidated net revenues in a financial quarter (4th) and in a full fiscal year;
- Launch of Trogarzo® in Germany;
- Appointment of a new President and Chief Executive Officer; and
- Appointment of two (2) new independent directors to our board of directors.

Regulatory Events

- Filing of an investigational new drug, or IND, application with the FDA for a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- Receipt of “Study May Proceed” letter from the FDA for our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- Filing of an IND application with the FDA for a Phase 1 clinical trial studying TH1902 in various types of cancers;
- Receipt of “Study May Proceed” letter from the FDA for our Phase 1 clinical trial studying TH1902 in various types of cancers; and
- FDA’s grant of “Fast Track” designation to TH1902.

Research and Development Events

- Completion of bioequivalence study with the F8 Formulation; and
- Initiation of the development of the Pen for the F8 Formulation.

2021 Business Objectives

- We intend to continue growing our revenues in the United States from sales of *EGRIFTA SV*® and Trogarzo®;
- We intend to successfully obtain reimbursement for Trogarzo® in key European countries and launch Trogarzo® in some of these countries;
- We intend to initiate a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population by the end of the third quarter of calendar year 2021;
- We intend to initiate a Phase 1 clinical trial studying TH1902 in various types of cancers in the second quarter of calendar year 2021;

- We intend to continue pursuing potential product acquisitions, in-licensing transactions or other opportunities complementary to our business; and
- We plan on managing our financial position to ensure we can successfully execute on our 2021 business strategy and objectives.

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, 11th Floor, Montreal, Québec, Canada H3A 1T8. Our phone number is (514) 336-7800. Our website is www.theratech.com

1.2 SUBSIDIARIES

As at February 24, 2021, 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). Theratechnologies U.S., Inc. provides the services of personnel to Theratechnologies Inc. for some of its activities in the United States;
- **Theratechnologies Intercontinental Inc.¹**, 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.¹**, 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.¹**, a company governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.

¹ We plan on winding-up those wholly owned subsidiaries into Theratechnologies Inc. in 2021.

2.1 OVERVIEW

We are a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet 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 have two approved products: *EGRIFTA SV*[®] in the United States, and Trogarzo[®] in the United States, the European Union and the United Kingdom.

EGRIFTA SV[®] (tesamorelin for injection) is a new formulation of *EGRIFTA*[®] which was originally approved by the FDA in November 2010 and was launched in the United States in January 2011. *EGRIFTA SV*[®] was approved by the FDA in November 2018, was launched in 2019 and has now replaced *EGRIFTA*[®] in such country. *EGRIFTA SV*[®] can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration. *EGRIFTA SV*[®] 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.

EGRIFTA[®] (tesamorelin for injection) is the predecessor of *EGRIFTA SV*[®]. *EGRIFTA*[®] was approved by Health Canada in its 1 mg/vial presentation in March 2015 and was launched in Canada in June 2015. In Canada, *EGRIFTA*[®] is the only approved drug for the treatment of excess visceral adipose tissue, as assessed by waist circumference ³ 95 cm for men and ³ 94 cm for women, and confirmed by a visceral adipose tissue level of > 130 cm² by CT scan, in treatment-experienced adult HIV-infected patients. *EGRIFTA*[®] is marketed exclusively by us in Canada but sales of *EGRIFTA*[®] are not material to our business.

COFEPRIS, Mexico's health agency, also approved *EGRIFTA*[®] in its 1 mg/vial presentation in March 2016. We have not commercialized *EGRIFTA*[®] in this country and have abandoned our marketing authorization in this territory.

Trogarzo[®] (ibalizumab-uiyk) injection was approved by the FDA in March 2018 and was made commercially available in the United States in April 2018. Trogarzo[®] was also approved by the EMA in September 2019 and is commercially available in Germany and in other countries through early access programs. Trogarzo[®] is under licence to us following our entering into an amended and restated distribution and marketing agreement, as amended, 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. Trogarzo[®] was the first HIV treatment approved with a new mechanism of action in more than 10 years. The treatment is infused every two weeks. It is the first in a new class of antiretrovirals, or ARV, and is a long-acting ARV therapy that can lead to an undetectable viral load in combination with other ARVs.

In addition to the sale of our products, we are conducting research and development activities. We have a promising pipeline of investigational medicines in the areas of NASH and oncology. Tesamorelin, the active ingredient in *EGRIFTA SV*[®], is designed to increase endogenous growth hormone secretion and is the foundation for its potential use for the treatment of NASH in the general population. Tesamorelin has a well-established safety profile, with more than 10 years of product history in HIV lipodystrophy. TH1902, a peptide-drug conjugate derived from our licensed platform SORT1+ Technology[™] that attaches to docetaxel, is designed to specifically

target Sortilin, or SORT1, receptors expressed in cancer cells of various types of cancer. TH1904, another peptide-drug conjugate derived from the same licensed platform that combines to doxorubicin, is also designed to target SORT1 receptors.

We plan on initiating a Phase 3 clinical trial to study tesamorelin for the treatment of NASH in the general population by the end of the third quarter of calendar year 2021 and we also plan on initiating a Phase 1 clinical trial to study TH1902 in various types of cancers in the second quarter of calendar year 2021.

To date, we have completed the in-house bioequivalence study of the F8 Formulation and have begun the development of a multi-dose pen injector for use with the F8 Formulation. We intend to use the F8 Formulation in our Phase 3 clinical trial for NASH.

2.2 **THREE-YEAR HISTORY**

Current Fiscal Year

- *FDA's Grant of Fast track Designation to TH1902.* On February 4, 2021, we announced that the FDA granted fast track designation to TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy.
- *US\$46 Million Unit Offering.* On January 19, 2021, we announced the closing of a US\$46 million unit offering, or Offering, at a price of US\$ 2.75 per unit, each unit being comprised of one common share and one-half common share purchase warrant. Each whole warrant entitles the holders thereof to purchase one common share at a price of US\$ 3.18 until January 19, 2024. The Offering resulted in the sale of 16,727,900 units and included the full exercise of the over-allotment option to purchase an additional 2, 181,900 units. The announcement related to this Offering was made on January 11, 2021.
- *Preliminary Consolidated Annual Revenues and Update on Research and Development Activities.* On January 7, 2021, we announced consolidated net revenues estimates for our full fiscal year to be between US\$65.8 million and US\$66.1 million. We also announced the receipt of a "Study May Proceed Letter" from the FDA for our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population. Such letter contained a recommendation that we request a meeting with the FDA to discuss questions and comments received on certain aspects of the proposed trial design. We also announced the receipt of a "Study May Proceed" letter from the FDA for our Phase 1 clinical trial using TH1902.

2020

- *New Data on the Effect of Tesamorelin on Liver Fibrosis and NASH.* On November 16, 2020, we announced new data on tesamorelin further to a sub-study of the transcriptomic analysis of the liver biopsies resulting from the Phase 2 study evaluating the effect of tesamorelin in people living with HIV-associated NAFLD conducted at MGH. The data showed that the serum levels of three proteins associated with the development of NASH and fibrosis were reduced in tesamorelin patients compared to the placebo group.
- *Departure of Chief Commercial Officer.* On November 3, 2020, we announced the departure of Mr. Jovan Antunovic, our Senior Vice President and Chief Commercial Officer.
- *Appointment of New Directors.* On October 16, 2020, we announced the appointment of Mr. Andrew Molson and Mr. Alain Trudeau as new independent directors to our board of directors.

- *Issuance of U.S. Patent Directed to the Treatment of NASH and/or NAFLD Using Tesamorelin.* On October 13, 2020, we announced that the United States Patent and Trademark Office had issued U.S. patent No. 10,799,562 directed to the treatment of NASH and/or NAFLD in patients using tesamorelin. The patent is scheduled to expire in 2040 and we have an exclusive license with MGH to this patent.
- *Tesamorelin to Be Studied for the Treatment of NASH in General Population.* On September 10, 2020, we announced our plan to pursue the Phase 3 clinical development of tesamorelin for the treatment of NASH in the general population.
- *Commercialization of Trogarzo® in Germany.* On September 10, 2020, we announced that Trogarzo® would become commercially available in Germany as of September 11, 2020.
- *New Data on the Effects of Tesamorelin on Liver Fat.* On July 23, 2020, we announced new data derived from a sub-analysis of the Phase 2 study evaluating the effect of tesamorelin on the transcriptome of the liver biopsies in people living with HIV-associated nonalcoholic fatty liver disease conducted at MGH. The data showed that tesamorelin had a positive effect on gene expression related to oxidative phosphorylation and decreased gene expression related to inflammation, tissue repair and cell division. Treatment with tesamorelin also showed improvement of genes associated with hepatocellular carcinoma prognosis.
- *Bioequivalence of F8 Formulation with EGRIFTA®'s Formulation.* On July 7, 2020, we announced the successful completion of our bioequivalence study evaluating the F8 Formulation of tesamorelin against the formulation used for EGRIFTA®, or F1 Formulation.
- *Ibalizumab's Effects on HIV-2.* On July 6, 2020, we announced that data obtained from *in vitro* studies using ibalizumab could have some efficacy in patients infected with HIV-2.
- *New Positive Data for Investigational Peptide-Drug Conjugates Targeting Sortilin Positive Cancer.* On May 15, 2020, we announced *in vivo* results regarding TH1902 to assess its effect on triple-negative breast cancer compared to docetaxel alone. These results showed that docetaxel administered alone at one quarter of its maximum tolerated dose had no apparent effect on tumor burden whereas the administration of TH1902 at a comparable dose led to sustained tumor inhibition. TH1902 also showed a better safety profile than the administration of docetaxel alone. In addition, *in vitro* results obtained in ovarian cancer showed that TH1904 stopped the formation of vasculogenic mimicry at very low doses whereas doxorubicin alone had no effect. Inhibition of vasculogenic mimicry was also observed in a triple-negative breast cancer model with very low doses of TH1902 compared to docetaxel alone.
- *Positive results Announced for Two Investigational Peptide-Drug Conjugates Targeting Sortilin Positive Ovarian Cancer.* On April 27, 2020, we announced *in vivo* results obtained with TH1902 and TH1904. These results showed a high accumulation of both conjugates in ovarian tumors with low accumulation in healthy ovary tissue. TH1902 and TH1904 were found to have better efficacy in the animal model, at equivalent dose, than docetaxel and doxorubicin used alone. No weight loss or decreasing lymphocytes were induced using TH1902 and TH1904.
- *Feedback Received from FDA and EMA on Proposed Clinical Trial Using Tesamorelin for the Treatment of NASH in People Living with HIV.* On March 31, 2020, we announced that we had received feedback from both the FDA and the EMA on our proposed clinical trial seeking to develop tesamorelin for the treatment of NASH in people living with HIV and that further discussions were warranted with these regulatory agencies in order to harmonize their approaches with the aim of filing a common research

protocol.

- *Appointment of New President and Chief Executive Officer.* On March 2, 2020, we announced the appointment of Mr. Paul Lévesque as our new president and chief executive officer in replacement of our retiring president and chief executive officer, Mr. Luc Tanguay.
- *Execution of Agreement with Massachusetts General Hospital and Dr. Steven Grinspoon.* On February 4, 2020, we announced the execution of two long-term agreements with Massachusetts General Hospital, or MGH, and Dr. Steve Grinspoon, regarding the assistance to be provided by MGH, through Dr. Steve Grinspoon, in connection with the study design, dosing, study duration and other matters in consideration of certain milestones and royalty payments related to the development of tesamorelin for the treatment of NAFLD and NASH in the HIV patient population. The agreements were subsequently amended to provide for the development of tesamorelin for the treatment of NAFLD and NASH in the general population.
- *In Vitro and In Vivo Data on our Investigational Oncology Peptide-Drug Conjugates Presented at Scientific Conference.* On December 13, 2019, we announced the results from *in vitro* and *in vivo* experiments using TH1902 at the San Antonio Breast Cancer Symposium. Results showed that treatment using TH1902, in combination with docetaxel, improved efficacy and had better tolerability over treatment with docetaxel alone.

2019

- *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 nonalcoholic 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”.
- *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.
- *Appointment of New Director.* On March 29, 2019, we announced the appointment of Ms. Sheila Frame as a new independent director 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 of 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 of EGRIFTA®, or F4 Formulation. The sNDA was filed in July 2018. The F4 Formulation is four times more concentrated than the 1mg/vial formulation that was then being commercialized. The F4 Formulation 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.
- *Appointment of New Director.* On October 15, 2018, we announced the appointment of Mr. Gary Littlejohn as a new independent director 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.
- *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 June 19, 2018, we announced the closing of a US\$57,500,000 5.75% convertible unsecured senior notes due June 30, 2023, or Notes, offering, or Note Offering. See “ITEM 9 – Material Contracts – Note Indenture” below.
- *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 with EMD Serono Inc. 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 Note 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 Nonalcoholic Liver Disease and Nonalcoholic 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.

2.3 OUR 2021 BUSINESS STRATEGY AND OBJECTIVES

Our business strategy in 2021 is focused on: increasing sales of EGRIFTA SV® and Trogarzo® in the United States; launch Trogarzo® in key countries of the European Union and obtain reimbursement for this product; beginning a Phase 3 clinical trial using tesamorelin for the potential treatment of NASH in the general population by the end of the third quarter of calendar year 2021; beginning a Phase 1 clinical trial using TH1902 in various types of cancers in the second quarter of calendar year 2021; pursuing potential product acquisitions, in-licensing transactions or other similar opportunities complementary to our business; and managing our financial position to ensure we can successfully execute on our 2021 business strategy and objectives.

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



2.4 PRODUCTS

Our Approved Products

EGRIFTA® and EGRIFTA SV® (tesamorelin for injection)

EGRIFTA® and *EGRIFTA SV®* (tesamorelin for injection) induce 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 Canada only 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® is a new formulation of *EGRIFTA®* and is available in the United States only. It was approved by the FDA in November 2018 and was made commercially available to patients in the United States in November 2019. *EGRIFTA SV®* comes in a single vial, can be stored at room temperature and has a higher concentration than the *EGRIFTA®* formulation, therefore resulting in a smaller volume of administration. No filing has been made in Canada to obtain the approval of *EGRIFTA SV®*. *EGRIFTA SV®* is injected under the skin into the abdomen once a day.

No filing has been made in Canada seeking the approval of *EGRIFTA SV®*.

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 growth hormone-releasing factor analogue, or GRF, 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 International Antiviral Society-United States and the treatment guidelines issued by the U.S. Department of Health and Human Services. In addition, since 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® 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.

In connection with the marketing authorization application of Trogarzo®, the EMA agreed with our proposed conduct of a paediatric investigation plan, or PIP, comprised of two studies: the first study is to evaluate pharmacokinetics, pharmacodynamics, safety and tolerability of Trogarzo® in children from 6 to less than 18 years of age with HIV-1 infection in order to provide pharmacokinetics and pharmacodynamics data to support the extrapolation of efficacy from adults, or PK/PD Study; and the second study is a modelling and simulation study to evaluate the use of Trogarzo® in the treatment of HIV-1 infection resistant to at least 1 agent in 3 different classes in children from 6 to less than 18 years of age, or Population PK Study. The Population PK Study will rely on the data generated from different clinical trials conducted with adults and those generated from the PK/PD Study conducted in children.

In August 2018, prior to the approval of Trogarzo® by the EMA, we obtained a deferral to conduct the PIP and a waiver to conduct the PK/PD Study and the Population PK Study in children who are less than 6 years old. The deferral required that we complete the PIP in children aged from 6 to less than 18 years of age by June 2022. In February 2021, we filed a request with the EMA seeking to defer the PK/PD Study to June 2023 from June 2022 and to defer the Population PK Study to June 2024 from June 2022. We expect receiving a decision from the EMA on this request by the end of the second quarter of calendar year 2021. Up to 24 patients will be enrolled in order to complete the PIP and each patient must be treated over a period of 24 weeks.

As part of the approval of Trogarzo®, the EMA requested that we conduct a post-authorisation efficacy study, or Registry, according to a protocol to be agreed with the EMA. In July 2020, we agreed on the final terms of this protocol. The Registry is aimed primarily at evaluating the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo® treatment *versus* matched patients not receiving Trogarzo®. The study comprising the Registry should be conducted over a five-year period and we expect initiating the enrollment of patients in late 2021. We expect the costs of the Registry to be approximately 4,000,000 euros. The costs are to be borne as to 52% by TaiMed and as to 48% by us.

Trogarzo® is currently commercially available in Germany. It is also available in certain other European countries through early access programs. We are working on obtaining reimbursement in key European countries and we anticipate launching Trogarzo® sequentially in countries where the product will be reimbursed.

Trogarzo® is available 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 developed by TaiMed and is under licence to us.

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+ 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 SV® - United States

General

We are responsible for the commercialization of *EGRIFTA SV®* (tesamorelin for injection) in the United States. Prior to November 2019, the date on which *EGRIFTA SV®* became commercially available in the United States, we were responsible for the commercialization of *EGRIFTA®* (tesamorelin for injection). *EGRIFTA®* is no longer offered for sale in the United States since being replaced by *EGRIFTA SV®* in the 2020 fiscal year.

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.

We currently manufacture *EGRIFTA SV®* in a 2 mg/vial formulation and one vial of *EGRIFTA SV®* is required to administer a dose of 1.4 mg which is bioequivalent to a 2 mg dose of the original formulation used for *EGRIFTA®*.

Active Pharmaceutical Ingredient

Our agreement with Bachem providing for the manufacture and supply of the active pharmaceutical ingredient of tesamorelin, or API, for *EGRIFTA SV®* for commercial sale in the United States (*EGRIFTA®* in Canada) as well as for clinical trials is currently terminated and under negotiations, or Bachem Agreement. However, despite the ongoing negotiations, Bachem has advised us that it would manufacture lots of API, if needed. We currently do not need Bachem to manufacture API. Bachem is our only validated supplier of raw materials. See “Item 9—Material Contracts – Bachem Agreement” below.

Finished Product

We have an agreement with Jubilant providing for the manufacture and supply of the finished form of *EGRIFTA SV®* for commercial sale in the United States (*EGRIFTA®* in Canada) and for tesamorelin in connection with clinical trials, or Jubilant Agreement. Under the Jubilant 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 – Jubilant Agreement” below.

Injection Tool Kit

In connection with the sale of *EGRIFTA SV®*, we provide patients with the necessary devices to administer *EGRIFTA SV®*. These devices are comprised of syringes, needles and water for injection. In the United States, we have an agreement with Hospira Worldwide, Inc., or Hospira, pursuant to which Hospira provides us with

sterile water for injection. The packaging of those devices is done through Sharp Clinical Services Inc., or Sharp, a third-party service provider. The packaging agreement with Sharp was entered into in August 2017, or Sharp Agreement. See “Item 9 - Material Contracts” below.

Distribution

In connection with the commercialization of *EGRIFTA SV*[®] 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 SV*[®] 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 SV*[®].

Logistic Service Provider and Distributor

On November 1st, 2017, we entered into an amended and restated master services agreement with RxC 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 over a certain period of time. RxCrossroads fulfills orders received from authorized wholesalers and certain authorized specialty pharmacies and, with respect to *EGRIFTA SV*[®], delivers it directly to that authorized wholesaler’s client, namely a specialty pharmacy forming part of our network of specialty pharmacies, or directly to those authorized specialty pharmacies. See “Item 9 - Material Contracts – RxCrossroads Agreements” below.

Wholesalers

Our supply chain of *EGRIFTA SV*[®] in the United States is comprised of a limited number of wholesalers through which specialty pharmacies we have contracted with can order *EGRIFTA SV*[®]. These wholesalers accept purchase orders from those specialty pharmacies, purchase *EGRIFTA SV*[®] from RxCrossroads, and resell this product to these specialty pharmacies. Our wholesalers do not handle the physical delivery of *EGRIFTA SV*[®]. The shipping and delivery of *EGRIFTA SV*[®] to those specialty pharmacies is handled by RxCrossroads. To date, we have agreements in place with the following wholesalers for *EGRIFTA SV*[®]: H.D. Smith, LLC., Cardinal Health, McKesson Corporation, Morris & Dickson Co., LLC, and Cesar Castillo, Inc. 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 SV*[®] from our authorized wholesalers and distribute *EGRIFTA SV*[®] to patients in the United States through their networks of local pharmacies.

In addition, a limited number of those specialty pharmacies are authorized to purchase *EGRIFTA SV*[®] 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. We have been commercializing *EGRIFTA*[®] in Canada since June 2015.

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. Sales of *EGRIFTA*[®] in Canada are not material to our business.

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 for 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.

EGRIFTA[®] is packaged in Canada using a third-party supplier. Under our agreement with such third-party supplier, 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. Our agreement with such third-party supplier renews automatically for one-year terms unless a party gives the other party written notice of its intent not to renew. 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.

Trogarzo[®]

General

Trogarzo[®] is under license to us from TaiMed. 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. TaiMed has kept all rights related to the further development of ibalizumab.

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.

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.

North American Territory - Terms and Conditions

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

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 made yet regarding a filing in Canada.

We are responsible for all regulatory activities, regulatory filings and communications with the FDA and with Health Canada, if and when applicable, 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 and the last one was paid in June 2020;
- 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. TaiMed and we must agree 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.

Manufacturing

TaiMed is responsible to manufacture and supply Trogarzo® to us for each country forming part of the North American Territory and European Territory. Since TaiMed has no manufacturing facility, TaiMed has subcontracted the manufacture of Trogarzo® to WuXi Apptec Biologics, Inc., or WuXi, in China.

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 for Trogarzo® in the United States under the RxCrossroads Agreements. Orders for Trogarzo® are being made directly by a limited number of specialty pharmacies and delivery of Trogarzo® is made directly to those specialty pharmacies by RxCrossroads.

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. Pursuant to the TaiMed Agreement, 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).

Manufacturing

The manufacture of Trogarzo® for the European Territory is made by WuXi, TaiMed's designee. In the European Territory, Trogarzo® is being supplied and delivered to us in brite stock form. We have agreed to take charge of quality testing and release of Trogarzo® in the European Territory as well as the packaging and labeling of the finished product. We have entered into various agreements with third party suppliers that assist us with those tasks.

Distribution

We are responsible for the importation of Trogarzo® into the European Territory.

On July 9, 2020, our European subsidiary, Theratechnologies Europe Limited, entered into a pre-whosaling services agreement with Loxxess Pharma GmbH, or Loxxess, pursuant to which Loxxess agreed to act as our third-party service logistic provider, or Loxxess Agreement, in certain key European countries, including Germany, France, Italy, Austria, The Netherlands, Portugal, Switzerland, the United Kingdom, Norway, Sweden, Finland and Denmark. Loxxess is also capable of serving other European countries, including Israel and Turkey. Pursuant to the Loxxess Agreement, Loxxess receives customers' orders, stores, packages and ships Trogarzo® to European hospitals and pharmacies. Loxxess is also responsible, on our behalf, to collect payments of the goods sold to those hospitals and pharmacies. The hospitals and pharmacies dispense Trogarzo® to patients. See "Item 9 – Material Contracts - Loxxess Agreement".

Marketing and Sales of Our Products

North American Territory

Our marketing and sales activities in the United States for *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, market access and medical 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 SV*® and Trogarzo® in the United States until November 30, 2021. 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 SV*[®] and Trogarzo[®], 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.

We have contracted with Asembia, LLC, or Asembia, for the provision of services related, amongst other things, to a call center. The call center, *THERA Patient Support*[®], 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*[®] also helps patients adhering to their treatment and answering questions about our products. See “Item 9 –Material Contracts” below

In Canada, we do not promote the sale of *EGRIFTA*[®] and sales of *EGRIFTA*[®] are not material to our business. McKesson Canada provides the services of a call center, *EGRIFTA Support*[®], which guides physicians and patients through the process of initiating treatment with *EGRIFTA*[®], which answers questions patients may have regarding *EGRIFTA*[®] and which helps patients with the reimbursement process with their private insurance providers.

Trogarzo[®] is not approved in Canada since no filing has been made with Health Canada to seek its approval and no decision has been made yet in regard to seeking its approval in Canada.

European Territory

EGRIFTA[®] and *EGRIFTA SV*[®]

EGRIFTA[®] and *EGRIFTA SV*[®] are not approved in Europe.

Trogarzo[®]

Trogarzo[®] became commercially available in Germany on September 11, 2020 following our dossier submission to German regulatory authorities to seek its reimbursement in such country. Our European subsidiary, Theratechnologies Europe Limited, has also retained the services of Syneos to assist us with the commercialization of Trogarzo[®]. In the European Territory, Syneos provides us with the services of a lead commercial responsible person, medical science liaison personnel for France, Germany, Italy and Spain, and one key account manager.

Although we cannot promote Trogarzo[®] in European countries located outside of Germany, Trogarzo[®] is available in other European countries, including France and Italy, through early access programs. We are continuing our efforts on obtaining reimbursement for Trogarzo[®] in other key European countries and it is anticipated that Trogarzo[®] will be launched sequentially as public reimbursement is obtained in those key European countries.

We have also filed a marketing authorization application seeking the approval of Trogarzo[®] in Israel and are currently negotiating the reimbursement of Trogarzo[®] with Norwegian regulatory authorities. No timeline has been set for the commercial availability of Trogarzo[®] in those two countries.

2.6 RESEARCH AND DEVELOPMENT ACTIVITIES

Below is a description of our research and development activities using our proprietary and licensed drugs and peptides.

Tesamorelin

F8 Formulation

We have completed the bioequivalence study of the F8 Formulation. The F8 Formulation is eight times more concentrated than the formulation used for *EGRIFTA*[®] and twice as concentrated as the current *EGRIFTA SV*[®] formulation. The F8 Formulation has a number of advantages for patients over the F1 Formulation: (1) it is intended to be presented in a multidose vial that will be reconstituted once per week; (2) it will be stable at room temperature, even once reconstituted; and (3) the volume of administration will be smaller, approximately 0.2 ml.

We intend to file a sBLA with the FDA to seek approval of the bioequivalence of the F8 Formulation in early 2022 for the treatment of lipodystrophy in people living with HIV.

We also intend to use the F8 Formulation in our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population.

Multi-Dose Pen Injector

In the last fiscal year, we began developing the Pen to be used in conjunction with the F8 Formulation. In connection with the development of the Pen, we have retained the services of various third parties.

One of those parties is responsible to provide the Pen and to modify it to our specifications whereas the other third party suppliers are responsible to develop the cartridge and needle that will allow the reconstitution and injection of the F8 Formulation at the proper dosage.

We intend to seek approval of the Pen from the FDA concurrently with the filing of the sBLA seeking the approval of the F8 Formulation.

We also intend to use the Pen in our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population.

Tesamorelin for NASH in the General Population

On September 10, 2020, we announced our intent to study tesamorelin for the potential treatment of NASH in the general population using the F8 Formulation. Previously, we had announced that we would move forward with the development of tesamorelin for the potential treatment of NASH in patients living with HIV. The change in the targeted patient population came from a review of the scientific evidence, including previously issued results of the study conducted by Dr. Steven Grinspoon of the MGH evaluating the safety and efficacy of tesamorelin in the treatment of HIV-infected patients suffering from NAFLD – NASH, or MGH Study, exchanges with the FDA and EMA regarding drug development for the treatment of NASH, and discussions with scientific advisors. In addition, the development of our intellectual property portfolio, the conclusion of our in-house bioequivalence study of the F8 Formulation and the ongoing development of the Pen played a key role in our decision to expand the potential indication of tesamorelin for the treatment of NASH.

The MGH 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 ³⁵%, 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 MGH 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 NAS 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 MGH Study were published in October 2019 in *The Lancet HIV Journal*. This publication followed prior data published in the *Journal of Clinical Endocrinology and Metabolism* in January 2011 showing that tesamorelin significantly reduced visceral (ectopic) adipose tissue in the non-HIV obese populations.

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.

The U.S. market is expected to represent a significant and growing opportunity in the general population suffering from NASH. The Corporation estimates that the number of NASH cases in this country is projected to increase by 63% from 16.5 million patients in 2015 to 27 million patients in 2030. Out of these numbers, it is projected that the number of patients with fibrosis scores of 2 and 3 was around 5.4 million in 2015 and will be around 10.6 million in 2030.

On November 18, 2020, we submitted an IND application to the FDA proposing the development of tesamorelin for the treatment of NASH in the general population in a Phase 3 clinical trial. The proposed Phase 3 clinical trial design will enroll participants with liver-biopsy confirmed NASH and stage 2 or 3 fibrosis. Participants will be randomized 1:1 to receive 2 mg of tesamorelin or placebo. A second liver biopsy will be performed after 18 months of treatment for the first 900 participants, approximately. These data will form the basis for filing a sBLA with the FDA to seek accelerated approval. The primary endpoint used to seek accelerated approval will be the percentage of participants achieving NASH resolution and no worsening of fibrosis compared to placebo. Participants will remain in the Phase 3 trial for a total of 60 months. Subject to further discussions with regulatory agencies, approximately 2,000 participants in total are expected to be enrolled, including a cohort of approximately 75 to 100 participants with HIV.

In late December 2020, the Corporation received a “Study May Proceed” letter from the FDA in connection with its IND application to develop tesamorelin for the treatment of NASH in the general population. The letter contained a recommendation that the Corporation requests a meeting to discuss the questions and comments contained in such letter to address certain aspects of the proposed trial design to ensure alignment with the agency’s expectations with NASH trials. The Corporation has followed up on the FDA’s recommendation and has requested a meeting with the agency. The Corporation is currently assessing its strategy regarding a filing with European agencies before initiating a Phase 3 clinical trial using tesamorelin for the treatment of NASH.

The Corporation’s goal is to initiate its Phase 3 trial by the end of the third quarter of calendar year 2021. The final timing of the trial initiation is dependent upon any adjustments to the protocol and trial design as recommended by the FDA and as may be recommended by European agencies. The Corporation has already entered into an agreement with Worldwide Clinical Trials, Inc., or WCT, a global large-scale contract research organization with experience in implementing large and late-stage clinical trials, to assist with the conduct of its Phase 3 clinical trial, or WCT Agreement. See “ITEM 9 – Material Contracts – WCT Agreement” below.

Ibalizumab

IV-Push Administration of Trogarzo®

Research and development activities around a new form of intravenous administration of Trogarzo®, known as the “IV-Push Administration”, is being conducted by TaiMed. To date, TaiMed has completed the recruitment of patients to test this 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 to administer the treatment benefitting both the person administering Trogarzo® and the patients. We expect TaiMed to file a sBLA with the FDA in relation to this new formulation in early 2022. Under the terms of the TaiMed Agreement, we are entitled to commercialize this new form of administration of Trogarzo® if, and when, approved.

Intra-Muscular Administration of Trogarzo®

In addition to the development of the “IV-Push Administration”, we intend to initiate enrollment of patients in the first half of calendar year 2021 to study the intra-muscular administration of Trogarzo®. The study will consist of assessing the safety and pharmacokinetic levels of Trogarzo® when administered intra-muscularly using a syringe. Under the terms of the TaiMed Agreement, we are entitled to commercialize this new form of administration of Trogarzo® if, and when, approved.

Post-Approval Requirements

In addition to the foregoing research and development work on new modes of administration of Trogarzo®, we intend to initiate the PK/PD Study comprising the PIP later this year and to initiate the enrollment of patients in the Registry in late 2021.

TH1902 and TH1904

Acquisition of SORT1+ Technology™

The research and development activities carried out on our peptide-drug conjugates TH1902 and TH1904 stem from our acquisition of all of the issued and outstanding common shares of Katana Biopharma Inc., or Katana, on February 25, 2019. Katana had the exclusive worldwide rights, through a royalty-bearing licence agreement, entered into with Transfert Plus, LP, or Transfert Plus, to a technology platform (*SORT1+ Technology™*) using

peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells, or Transfert Plus License Agreement. Katana was wound up into Theratechnologies in May 2019 and we are now a party to the Transfer Plus License Agreement.

Pursuant to the terms and conditions of the share purchase agreement dated February 25, 2019, as amended on August 12, 2019, the purchase price, or Purchase Price, for all of the issued and outstanding common shares of Katana was set at CAD 6,900,000 and was payable as to a maximum of CAD 2,600,000 in cash and through the issuance of common shares on the execution date of the agreement, or Up-Front Payment, 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 1 clinical trial is initiated using one of the peptides developed through the oncology platform and the second development milestone of up to CAD 2,300,000, or Third Installment, is payable upon our decision to pursue the development of the peptide studied in the Phase 1 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 Purchase Price was subject to an upward adjustment aggregating CAD 1,080,000 upon obtaining a subsidy, or Subsidy, from the *Consortium Québécois sur la Découverte du Médicament* and the Canadian Cancer Society to pursue the research and development work on the oncology platform. The Subsidy was 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 Transfert Plus Licence Agreement

Under the Transfert Plus License Agreement, we 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.

The annual maintenance fees payable to Transfert Plus amount to CAD 25,000 for the first five (5) years and to 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 Transfert Plus 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 pay amounts varying between 5% and 15% of the revenues received under such sublicense agreement. The percentage varies based on the timing of the execution of such 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 1 clinical trial;
- (ii) second milestone payment: CAD 100,000 upon the successful enrolment of the first patient in the first Phase 2 clinical trial;
- (iii) third milestone payment: CAD 200,000 upon the successful enrolment of the first patient in the first Phase 3 clinical trial.

Also, we must pay Transfert Plus 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. See “ITEM 9 – Material Contracts – Transfert Plus License Agreement” below.

Research and Development Activities

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.

The peptides derived from our oncology platform target SORT1 positive cancer cells by delivering commercially available anticancer drugs, like docetaxel, doxorubicin or tyrosine kinase inhibitors, within the tumor microenvironment and, more importantly, directly inside SORT1+ cancer cells.

We believe that the conjugation of 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.

To date, we have conducted pre-clinical work using two compounds derived from our *SORT1+ Technology™* platform: TH1902 (peptide-drug conjugated with docetaxel) and TH-1904 (peptide-drug conjugated with doxorubicin).

In preclinical data, the Corporation’s *SORT1+ Technology™* demonstrated that this new technology improved anti-tumor activity and reduced neutropenia and systemic toxicity. In addition, the Corporation’s *SORT1+ Technology™* was shown in preclinical models to bypass the multidrug resistance protein 1 (MDR1; also known as P-glycoprotein), one of the mechanisms of chemotherapy drug resistance. The Corporation’s *SORT1+ Technology™* demonstrated activity in preclinical models against the formation of vasculogenic mimicry, a mechanism also associated with cancer resistance.

When compared to the use of docetaxel alone, results obtained from preclinical *in vivo* research and development work using TH1902 showed similar tumor stabilization or regression in colorectal, pancreatic and endometrial cancers as that shown in triple-negative breast cancer and ovarian cancer. In addition, *in vivo* preclinical toxicity data have demonstrated that TH1902 could be administered at three times the maximum tolerated dose of docetaxel alone. The Corporation expects to present additional scientific data supporting these findings at scientific meetings to be held in 2021.

Based on the foregoing results, the Corporation filed an IND application with the FDA on December 6, 2020, proposing the development of TH1902 in a Phase 1 clinical trial. We received a “Study May Proceed” letter for our Phase 1 clinical trial in January 2021. The proposed Phase 1 clinical trial design includes a dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose, or MTD, and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Once the MTD is determined, it is expected that a total of 40 additional patients will be enrolled to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, colorectal, pancreatic and triple-negative breast cancers where it has been estimated that the sortilin receptor is expressed in 40% to 90% of cases.

The Phase 1 clinical trial is expected to be initiated in the second quarter of calendar year 2021 and is designed to identify a recommended dose for Phase 2 development.

The FDA has granted “Fast Track” designation to TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy. “Fast Track” designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose of “Fast Track” designation is to bring important new drugs to patients earlier. A drug that receives “Fast Track” designation is eligible for some or all of the following: (i) more frequent meetings with FDA to discuss the drug’s development plan and ensure collection of appropriate data needed to support drug approval; (ii) more frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers; (iii) eligibility for “Accelerated Approval” and “Priority Review”, if relevant criteria are met; and (iv) “Rolling Review”, which means that a sponsor can submit completed sections of its new drug application for review by FDA, rather than waiting until every section of the new drug application is completed before the entire application can be reviewed.

Preclinical research and development work is still ongoing in melanoma cancer using TH1902 whilst further preclinical development activities are being conducted using TH1904.

2.7 COMPETITION

EGRIFTA® and EGRIFTA SV®

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®* and *EGRIFTA SV®* 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®

Fostemsavir, which was approved by the FDA in July 2020 and by the EMA in February 2021, is a direct competitor to Trogarzo®. Contrary to Fostemsavir which is administered orally twice per day, Trogarzo® is a long-acting ARV that only needs to be administered intravenously twice per month. In addition, we are aware that dolutegravir and darunavir, for instance, are commonly used in regimens for the treatment of MDR HIV-1.

Tesamorelin for the Treatment of NASH in the General Population

There exists no approved medicine for the treatment of NASH. However, there are various compounds currently being studied for the treatment of this disease, some of which are already in Phase 3 clinical trials. These compounds have different mechanisms of action to treat different aspect of the disease, either fat accumulation or inflammation. Tesamorelin has a unique mechanism of action targeting liver fat. However, it has been shown that tesamorelin also improved inflammatory markers. Tesamorelin also benefits from a good safety profile based on more than ten (10) years of use. The development of tesamorelin for the treatment of NASH, if successful, may compete with many potential other drugs for this patient population and we expect strong competition among those companies that will have succeeded in developing and commercializing a medicine for this disease.

SORT1+ Technology™ Platform in Oncology

The development of novel treatments in oncology is competitive. Many companies are investing in the development of innovative cancer treatments or in finding a cure for cancer. Most of those companies have significant means and scientific experience. Some of those companies are at more advanced development stage of their drugs than us. In addition, there exists a variety of potential targets: some treatment will aim at focusing on one particular cancer type whereas others, like our peptide-drug conjugates, could be used in various types of cancers. Since we are only beginning our Phase 1 clinical trial, there can be no guarantee that TH1902 will yield positive results when administered into humans and, even if successful, by the time we enter the market, there may be approved medicines that would directly compete with our peptide-drug conjugates. Despite the potential competition in this field, we believe that cancer resistance will not be eradicated and that there will be patients in needs of our peptide-drug conjugates, if approved.

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*[®], *EGRIFTA SV*[®] and Trogarzo[®] 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 SV*[®] and Trogarzo[®] 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 SV*[®] and Trogarzo[®] 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 SV*[®] and Trogarzo[®] 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 and prescribing decisions.

The marketing of *EGRIFTA SV*[®] and Trogarzo[®] 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, imposition of a corporate integrity agreement, exclusion from U.S. federal and state healthcare programs (i.e., those programs will not provide reimbursement or payment coverage for *EGRIFTA SV*[®] and/or Trogarzo[®]), 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 certain individuals, including U.S.-licensed physicians, and certain teaching hospitals, otherwise known as the “Sunshine Act”. Any activities relating to the sale and marketing of *EGRIFTA SV*[®] and Trogarzo[®] 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 the states in the European Economic Area, or EEA, which consists of 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.

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*® and *EGRIFTA SV*®, as well as WuXi, the manufacturer of Trogarzo®, 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 FDA-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. In addition, importers are responsible to ensure that the third country manufacturer complies with GMP. 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. In the European Union, national competent authorities are responsible for inspecting manufacturing sites located within their own territories. Manufacturing sites outside the European Union are inspected by the national competent authority of the Member State where the European Union importer is located, unless a mutual recognition agreement, or MRA, is in place between the EU and the country concerned. If an MRA applies, the authorities mutually rely on each other's inspections. After inspecting a manufacturing site, EU competent authorities issue a GMP certificate or a non-compliance statement, which is entered in the EudraGMDP database. In the context of the Covid-19 pandemic, for sites in the EEA, GMP certificates and time-limited manufacturing and import authorizations are automatically extended until the end of 2021. This does not waive manufacturers' and importers' obligations to comply with GMP standards. For new sites and facilities within and outside the EEA that have not been inspected or where an inspection is required, a remote inspection by the relevant competent authorities may be carried out pending the resumption of onsite inspections.

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 (Regulation (EU) No 536/2014), which is due to come into application in 2021. The new EU Clinical Trials Regulation, which will replace the EU Clinical Trials Directive, including national legislation that was put

in place to implement the 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. This will be carried out via a Clinical Trials Information System, or CTIS. CTIS will contain the centralized EU portal and database for clinical trials envisaged by the Regulation and will be used by clinical trial sponsors as a single entry point in the EU to obtain approval for clinical trials based on applications and for monitoring clinical trials during their life cycle, including the submission of summary of results. The EMA will set up and maintain CTIS, in collaboration with the Member States and the European Commission. The timing of the Regulation's application is dependent on confirmation of full functionality of CTIS through an independent audit and it is anticipated that the CTIS will go live in December 2021. Once launched, CTIS will be immediately available for authorities and clinical trial sponsors, while a three-year phased transition period from the current Directive 2001/20/EC to the Regulation will apply. The authorization and oversight of clinical trials remains the responsibility of Member States, with the EMA managing CTIS and supervising content publication on the EMA's website.

2.9 PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and in other countries, sales of *EGRIFTA SV*[®] 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 SV*[®] and Trogarzo[®]. *EGRIFTA SV*[®] 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 SV*[®] 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 1st, 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, or CMS, 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. For example, CMS issued an interim final rule on November 27, 2020 designed to test whether a Most-Favored-Nation model will help control growth in spending for Medicare Part B drugs without adversely affecting quality of care. This followed an Executive Order issued in September 2020 that directed the Secretary of DHHS to implement new payment models under the Medicare Part B and Part D programs to curb “unfair” and high drug prices in the United States. Implementation of this interim final rule has been blocked by a temporary restraining order and preliminary injunctions through various court actions. Nonetheless, 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law. The Health Care Reform Law may be modified, amended or repealed at any time and may or may not be replaced with a different law or health care payment system. We are unable to predict the full impact of any such potential modification, amendment or repeal of the Health Care Reform Law.

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 INTELLECTUAL PROPERTY

As further described below, tesamorelin, the active ingredient comprising *EGRIFTA*® and *EGRIFTA SV*®, is protected by patents in both Canada and the United States.

Trogarzo® is not patent protected but benefits from twelve (12) years of market exclusivity in the United States and ten (10) years of market exclusivity in the European Territory. See “Regulatory Exclusivity” below.

Our Patent Portfolio

Tesamorelin in HIV

Our current patent portfolio is comprised of the following material patents for tesamorelin (*EGRIFTA*[®] and *EGRIFTA SV*[®]) in the field of HIV:

- In the United States, we own three patents relating to the use of tesamorelin in the treatment of HIV-associated lipodystrophy, which are scheduled to expire in 2023.
- 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 2024.

Formulation of Tesamorelin

- In the United States and in major European countries, we own patents relating to the F8 Formulation, which are scheduled to expire in 2023 and 2024, respectively; and
- We have also filed additional patent applications related to the bioequivalence of certain formulation of tesamorelin to the F1 Formulation.

Tesamorelin in NASH

- In the United States, we have the exclusive right to a patent that claims a method for the treatment of NAFLD or NASH in a patient via the administration of tesamorelin. This patent is scheduled to expire in 2040.

TH1902 and TH1904 – SORT1+ TechnologyTM

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 the *SORT1+ TechnologyTM* platform as well as the use thereof. A first patent was issued in Canada under number CA 3,006,313. This patent is scheduled to expire in 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 SV*[®] 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.

Trogarzo® benefits from twelve (12) years of market exclusivity in the United States.

In Europe, regulatory data exclusivity is independent of a product's patent position. Under the community code for medicinal products (*Directive 2001/83/EC (as amended) and Regulation (EC) 762/2004*), new medicinal products are entitled to eight years regulatory data exclusivity from the date on which the product is granted a marketing authorization in the European Union. During that period, generic applicants cannot file applications referring to the innovator's safety and efficacy data. At the end of that eight-year period, generic or biosimilar applicants may file and the competent authorities may review applications, however, the innovator is granted a further two years of market exclusivity before any approved generic or biosimilar product may be placed on the market. This period of market exclusivity can be extended by a further year if a new therapeutic indication that provides a significant clinical benefit is approved during the first eight years of data exclusivity.

Regulation (EC) No. 141/2000 (as amended), or Orphan Regulation, contains additional data exclusivity provisions for "orphan medicinal products". These are products intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union; or that without incentives is unlikely to generate sufficient return to justify the necessary investment needed for its development. An orphan designation can be granted only if there is no satisfactory method of diagnosis, prevention or treatment of the condition authorized in the European Union, or if the product will be of significant benefit.

If a medicine is approved as a designated orphan medicine, the product will benefit from 10 years' market exclusivity, from date of receipt of a marketing authorization from the European Commission, during which regulators cannot accept applications for similar medicinal products for the same indication, unless they offer a significant clinical benefit (i.e., in terms of safety or efficacy). To benefit from market exclusivity, a medicine must maintain its orphan designation at the time of marketing authorization. A medicine that has multiple orphan designations for different conditions will benefit from separate market exclusivity periods pertaining to its different orphan designations. To benefit from market exclusivity, a medicine must maintain its orphan designation at the time of marketing authorization. Article 8(2) of the Orphan Regulation establishes the possibility for Member States to request that the market exclusivity be reduced from ten to six years, under certain circumstances. Article 8(3) of the Orphan Regulation describes three types of derogations from the market exclusivity provided to orphan medicinal products where a marketing authorization may be granted, for the same therapeutic indication, to a similar medicinal product: (a) consent of the original marketing authorization holder; (b) inability of the original marketing authorization holder to supply sufficient quantities; and (c) the second medicinal product is safer, more effective or otherwise clinically superior.

The European Medicine Agency's CHMP may issue the marketing authorization/extension to the marketing authorization, in circumstances where the CHMP conclude that the marketing authorization application is not similar to an authorized orphan medicinal product or if similar, that one of the derogations provided for in the Orphan Regulation claimed by the applicant applies, provided that the marketing authorization applicant can

prove the quality, safety and efficacy of the medicinal product. However, if the CHMP conclude that the applicant product is similar to an authorized orphan medicinal product and none of the derogations apply, the CHMP will make a recommendation to refuse the marketing authorization /extension to the marketing authorization, irrespective of the quality, safety or efficacy of the medicinal product. The 10-year period of market exclusivity of an approved orphan product does not preclude a second, similar product, which has been authorized by way of derogation under Article 8(3) of the Orphan Regulation, to benefit from a new 10-year period of orphan market exclusivity, as long as it also fulfils the designation requirements set out in Article 3(1) of the Orphan Regulation. When the period of market exclusivity for an indication ends, the orphan designation for that indication expires and the European Commission removes it from the Community register of orphan medicinal products. Once all of the orphan designations associated with an approved medicine have expired or been withdrawn by the sponsor, the medicine ceases to be classified as an orphan medicine and no longer benefits from the orphan incentives.

The *Paediatric Regulation (EC) No. 1901/2006* also provides specific incentives for the development of products with paediatric indications. If a product is approved on the basis of a dossier that includes paediatric clinical trial data generated in accordance with an approved paediatric investigation plan, the applicant will benefit from one of two periods of exclusivity: (1) if the product is an orphan medicine, it will benefit from an additional two years of orphan drug exclusivity (i.e., a total of 12 years' orphan exclusivity); or (2) if the product is not an orphan medicine and is eligible for patent term extension (referred to as a supplementary protection certificate, or SPC) the patent term will be extended by six months. The paediatric-use marketing authorization, or PUMA, is a type of marketing authorization which applicants request for a medicinal product which is already authorized but is no longer covered by a patent or SPC and will be exclusively developed for use in children. This type of marketing authorization will cover the indication and appropriate formulation for the paediatric population and the development of this medicine in children will follow a paediatric investigation plan. Once issued, a PUMA will benefit from 10 years of market exclusivity (made up of 8 years data exclusivity and an additional two years marketing exclusivity) as an incentive for the development in children. The existing marketing authorization procedures including the centralised, Mutual Recognition Procedure, Decentralised Procedure, or national procedure are used for PUMA applications.

Trogarzo® benefits from ten (10) years of market exclusivity in the European Territory.

Our Trademark Portfolio

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

EGRIFTA SV® is our trademark in the United States and it is used in this country to commercialize a different 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® 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 SV*® and Trogarzo®.

EGRIFTA Support® 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*®.

SORT1+ Technology™ is our trademark and we have filed various trademark registration applications for this mark in trademark offices worldwide.

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.

2.11 EMPLOYEES

As at November 30, 2020, we had 47 employees in Canada and seven (7) employees in Ireland. All of our employees are engaged in administration, finance, legal, 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, 2020, we had an additional fifty (50) persons dedicated to the commercialization of *EGRIFTA SV*[®] and Trogarzo[®] in the United States and six (6) persons dedicated to the commercialization of Trogarzo[®] in the European Territory.

2.12 FACILITIES

Our head office is located at 2015 Peel Street, 11th 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, 4th 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

2.13 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

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 COVID-19 PANDEMIC

The COVID-19 pandemic could have a material adverse effect on our 2021 business strategy and objectives, the result of which could adversely impact the sales of our products, our revenues, results of operation and the conduct of our clinical trials and other research and development activities.

The outbreak of COVID-19, its recent variants and any other outbreaks of contagious diseases or other adverse public health developments, could have a material adverse effect on the successful implementation of our 2021 business strategy and objectives, the result of which could materially adversely impact the sales of our products, our revenues, results of operation and the conduct of our clinical trials and other research and development activities. The outbreak of COVID-19 has resulted in governmental authorities implementing numerous measures to try to contain the pandemic, such as travel bans and restrictions, quarantines, shelter in place orders, increased border and port controls and closures, and shutdowns. There is considerable uncertainty regarding such measures and potential future measures.

Since the onset of the COVID-19 pandemic, our office personnel have been working remotely, including our contractual sales force and medical science liaison personnel, and may continue to do so. The impact of working-from-home policies and other confinement measures have resulted in our sales force being unable to meet face-to-face with health care professionals to detail our products. In addition, patients have been unable to visit their physician as originally planned and receive a medicine such as Trogarzo® which requires intravenous infusion. Confinement measures could also slow down the recruitment of patients for our clinical trials and delay their completion.

The COVID-19 pandemic has significantly increased economic and demand uncertainty throughout North America and Europe. It is likely that the current pandemic or further spread of COVID-19 will continue to cause an economic slowdown, and it is possible that the COVID-19 pandemic could cause a global recession despite the introduction of vaccination campaigns. The COVID-19 pandemic has caused disruption and volatility in the global capital markets, which, depending on further developments, could impact our capital resources and liquidity in the future, including the availability of financing on attractive terms, if at all.

The extent to which COVID-19 could impact our operations, financial condition, liquidity, results of operations, and cash flows is still highly uncertain and will depend on future developments, including the safety and efficacy of the recently developed vaccines against the coronavirus and its variants, the access to those vaccines, success of mitigation measures effected by the Corporation to date and those which may be taken by it in the future.

3.2 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

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

Our success in generating sales revenue from *EGRIFTA SV*[®] and Trogarzo[®] in the United States and from Trogarzo[®] in European 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 SV*[®] and Trogarzo[®] by third-party payors;
- to obtain reimbursement coverage for Trogarzo[®] in major European countries;
- to maintain the registration of *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 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) and in Europe (Loxxess), as well as other specialized third parties; and
- to defend our intellectual property rights regarding tesamorelin 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 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 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 has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. We are also renegotiating some of the terms of our Jubilant Agreement. Although we are in discussions with Bachem and Jubilant, 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. If we fail to renegotiate the terms and conditions of the Bachem Agreement, we may no longer be able to rapidly manufacture tesamorelin for *EGRIFTA SV*[®] and for our Phase 3 clinical trial in NASH. If we fail to agree on revised terms of the Jubilant Agreement, our relationship with Jubilant may deteriorate and Jubilant could decide to terminate our agreement as per the current terms of the Jubilant Agreement governing termination. Despite our current level of inventory of *EGRIFTA SV*[®] and tesamorelin, we may incur a shortage of *EGRIFTA SV*[®] and tesamorelin by the time new manufacturers are qualified.

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 for Trogarzo[®] 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 SV*[®], Trogarzo[®] or any other product we may acquire or in-license 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 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 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.

In the European Territory, we hold a wholesale distribution authorization but do not have any warehouse and structure to store, pack and ship Trogarzo[®]. We do not currently intend to open a warehouse and do not have the infrastructure to carry out the activities set forth above. Therefore, we are relying on Loxxess to carry out these activities. We have not entered into a long-term commercial agreement with Loxxess. The Loxxess Agreement is a one-year term agreement that automatically renews at the end of its term unless a party provides the other with a prior written notice of its intent not to renew such agreement within a certain period of time. Although we have identified other third-party logistic service providers in the European Territory, if the Loxxess Agreement is terminated unilaterally by Loxxess, or if we decide to terminate such agreement, there can be no assurance that we would succeed in entering into agreements with those other third-party logistic service providers on terms satisfactory to us. Our failure to enter into long-term commercial agreements with those third-party logistic service providers would disrupt our supply and distribution chain and would delay the commercialization of Trogarzo[®] in the European Territory. All such events would result in a material adverse effect on our business, revenues and financial conditions.

The vast majority of our sales, medical service liaison and market access personnel in the United States and in the European Territory dedicated to the commercialization of our products in these territories is provided by Syneos. Syneos provides us with all of the services related to the commercialization of our products, namely sales personnel, medical science liaison personnel, market access 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.

Finally, we will be relying on the services of a contract research organization, or CRO, for the conduct of our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population and our Phase 1 clinical trial studying TH1902 in various types of cancer. These CROs will be tasked with the recruitment of patients, negotiations of clinical study agreements with various clinics and the monitoring of those clinics in connection with our clinical trials. If these CROs default on their covenants or are found, for instance, to be in violation of applicable laws, our clinical trials could be delayed and any timelines set forth in our public communications could be wrong. In addition, if these CROs are found to be in violation of applicable laws, any data generated in the course of our clinical trials could be questioned by regulatory agencies and this could lead to a rejection of any data submitted to those regulatory agencies at the time of submitting an sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers 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 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 SV*[®] and Trogarzo[®] in the United States, or of Trogarzo[®] in the European Territory, if:

- RxCrossroads or Loxxess becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws;
- RxCrossroads or Loxxess 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
- RxCrossroads or Loxxess 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 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 SV*[®] and Trogarzo[®] which could result in restrictions in *EGRIFTA SV*[®]'s or Trogarzo[®]'s label, product recall or withdrawal of any of our products from the market, any of which could materially adversely impact our business and our future business prospects.

New safety issues may arise as *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. 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.

We recently received a notification letter from the FDA requiring us to conduct a post-marketing requirement study to collect prospective data in individuals exposed to Trogarzo[®] during pregnancy to monitor maternal and pregnancy outcomes. This is based on findings from an enhanced pre- and post-natal development study conducted in cynomolgus monkeys administered Trogarzo[®] that had shown potential birth complications for newly born infant monkeys. We are currently in discussion with the FDA regarding the details of this request. It is possible that the request of the FDA may lead to a change in the Trogarzo[®] label resulting in the addition of further safety, contraindication and/or warnings and precautions information. Such warnings could also take the form of a “black box warning”.

Previously unknown safety problems could also result in product recalls, or withdrawal of the products from the territory(ies) where they are approved for commercialization. If new safety issues are discovered, sales of *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 SV® and Trogarzo®.

Market acceptance and sales of *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. Governmental 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 SV®* and *Trogarzo®*.

Sales of *EGRIFTA SV®* and *Trogarzo®* to patients benefitting from U.S. funded reimbursement programs represent the most important part of our sales. 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 few approved drug products competing directly with our approved products. However, with respect to Trogarzo[®], we face competition from the recent approval of fostemsavir in the United States and in the European Union. In addition, 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. With respect to *EGRIFTA SV*[®], we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching ARTs or liposuction.

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. We are also aware that a very low number of patients were cured from HIV. 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.

3.3 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. Therefore, there can be no assurance that any research and development plan on a product candidate or medical device will result in an approved drug or medical device.

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, a new mode of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology[™] platform, will end up generating positive results leading up to an approved formulation, label expansion, new medical device or a new product by a regulatory authority. The failure to develop a new formulation, a new method

of treatment, new mode of administration 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 development of tesamorelin for the treatment of NASH in the general population is subject to an agreement with the FDA on the final design of our Phase 3 clinical trial, the approval of the Corporation's proposed Phase 3 clinical trial design by European regulatory agencies, meeting of the Corporation's Phase 3 clinical trial endpoints and approval by those regulatory agencies of the Corporation's clinical study results. If the Corporation is unable to agree with the FDA on a final Phase 3 clinical trial design or with European regulatory agencies for such trial design, or if the Corporation is unable to meet the endpoints of its Phase 3 clinical trial or does not receive approval of tesamorelin for the treatment of NASH in the general population, its potential long-term revenues and prospects will be materially adversely affected.

Although the FDA has delivered to the Corporation a "Study May Proceed" letter for its Phase 3 clinical trial for the development of tesamorelin for the treatment of NASH, such letter included questions, comments and a recommendation that the Corporation requests a meeting to discuss those questions and comments on certain aspects of the proposed trial design. The Corporation has now requested such meeting. The European regulatory authorities have not approved the Corporation's Phase 3 clinical trial to develop tesamorelin for the treatment of NASH in the general population as the Corporation has not filed any documentation seeking such approval.

The Corporation's initial strategy is to have a Phase 3 clinical trial design that is accepted by both the FDA and the European regulatory agencies. However, there can be no guarantee that the Corporation's clinical trial design will be accepted by both agencies even if the FDA and the Corporation agreed on a trial design. The approval by the regulatory authority of one country does not guarantee that a similar approval will be obtained from regulatory authorities of other countries. If the Corporation is unable to come to an agreement on a similar clinical trial design with the FDA and European regulatory agencies, the Corporation may forego the conduct of its Phase 3 clinical trial in one of those jurisdictions and materially decrease the likelihood that the results obtained from the conduct of its Phase 3 clinical trial in one territory get recognized in the territory where no agreement was entered into with respect to such clinical trial design. As a result, even though there can be no guarantee that a regulatory authority will approve any sBLA, or the equivalent thereof, filed by the Corporation seeking approval of tesamorelin for the treatment of NASH, the Corporation may not obtain approval from the regulatory authority located in the territory where the Phase 3 clinical trial design was not approved and, therefore, limits its ability to expand sales of its product in such territory. If the Corporation is unable to maximize the number of territories in which it can sell its products, this would have a material adverse effects on its revenues, financial results and long-term growth prospects.

In addition, the timelines to initiate the Corporation's Phase 3 clinical trial will be dependent upon any adjustment the FDA may require the Corporation to make to its proposed clinical trial design and the negotiation, if any, to be had with European regulatory authorities once a proposed Phase 3 clinical trial design have been filed with such authorities to harmonize it to that agreed to with the FDA.

The beginning or completion of clinical studies may be delayed or prevented for several reasons, including, among others:

- Adjustments required to the proposed Phase 3 clinical trial design resulting from the meeting with the FDA may result in additional costs and/or delays in the anticipated timing for the initiation of the trial;
- The European regulatory authority may not approve the Corporation's Phase 3 clinical trial design or require that amendments be made thereto prior to approving such clinical trial;
- Negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its Phase 3 clinical trial;
- Delays in reaching or failing to reach agreement on acceptable terms with clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different study sites;

- Any breach of the terms of any contract research organization agreement by us or by our third-party suppliers that have responsibility to assist us for the conduct of our clinical trials;
- Inadequate quantity or quality of the F8 Formulation or other materials necessary to conduct the Corporation's Phase 3 clinical trial;
- Challenges in recruiting and enrolling patients to participate in the Corporation's Phase 3 clinical trial, such as the confinement measures adopted by regulatory authorities in the context of the COVID-19 pandemic, the proximity of patients to study sites, eligibility criteria to be included in the clinical trial, the nature of the clinical trial and the competition from other clinical study programs for the treatment of NASH in the general population;
- Severe or unexpected adverse tesamorelin-related drug effects experienced by patients using *EGRIFTA SV*[®] or patients using tesamorelin during the Phase 3 clinical trial;
- Regulatory agencies requiring the Corporation to conduct additional clinical studies prior to approving its sBLA after review of its Phase 3 clinical trial results;
- Regulatory agencies disagreeing with the Corporation's interpretation of the data resulting from its Phase 3 clinical trial, or changing the requirements for approval even after they have approved the Corporation's Phase 3 clinical trial design;
- Difficulties in retaining patients who have enrolled in the Corporation's Phase 3 clinical trial but who may be prone to withdraw due to rigours of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest; and
- Lack of funds or financing options to conduct a clinical trial such as the study of tesamorelin for the treatment of NASH in the general population.

In addition, clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. The Corporation may decide to suspend or terminate its Phase 3 clinical trial or regulatory agencies could order the Corporation to do so for several reasons, including, among others:

- Failure to conduct the clinical trial in accordance with the regulatory requirements of the Corporation's study protocol; and
- Inspections of the clinical study operations or study sites by regulatory agencies that would reveal deficiencies or violations requiring the Corporation to undertake corrective actions (to the extent any are available).

The Corporation's inability to obtain approval of its final Phase 3 clinical trial design, a delay in the conduct of its Phase 3 clinical trial or the suspension or termination of such trial could materially adversely affect our business prospects and our potential long-term revenues derived from the sale of tesamorelin for the treatment of NASH in the general population.

We will require substantial capital to pursue the development of our product pipeline, including the conduct of our Phase 3 clinical trial for the development of tesamorelin for the treatment of NASH in the general population and the development of TH1902 in various types of cancer. If we are unable to generate cash flow from our commercial operations or are unable to access capital if, and when, needed, we may have to delay, suspend or cancel our Phase 3 clinical trial, Phase 1 clinical trial or the development of any of our product candidates, the result of which would have a material adverse effect on our long-term growth, potential revenue growth and our business prospects.

The development of pharmaceutical products is very costly and capital intensive.

Our proposed Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population will require the enrollment of over 2,000 patients and our study will be conducted over many years. The costs associated with the enrollment of patients, the monitoring of a study and the monitoring of clinical sites are expensive and such costs are directly proportional to the number of patients enrolled in a study over the duration of such study. Therefore, we expect the Phase 3 clinical trial to cost multi-millions of dollars.

To the extent that the results obtained in our Phase 1 clinical trial are positive, the development of TH1902 could accelerate, especially as a result of the recent decision of the FDA to grant “Fast Track” designation to TH1902. The number of patients that we may have to enroll to move to a Phase 2 clinical trial would be based, among other things, on our development strategy. For instance, if we were to decide to study TH1902 concurrently, in various types of cancer, we could have to enroll a large number of patients. Such a Phase 2 clinical trial could be very expensive and require capital.

We intend to fund the development of our Phase 3 clinical trial, Phase 1 clinical trial and the development of other product candidates through cash flows resulting from the sales of our products and though the use of the net proceeds from the Offering. However, if our sales do not generate sufficient cash flows, or if we incur delays in recruiting patients or are faced with unexpected expenses in the conduct of our operations, we may not have enough cash to fund our research and development activities. In addition, market conditions may not be favorable to resort to public financing and, even if favorable, the terms of such financing may not be attractive to us. If we are unable to generate sufficient cash flows from our operations or do not have access to public or private financing to fund our research and development activities, we may have to delay, suspend or cancel the conduct of our clinical trials and the development of our product candidates. Any delay, suspension or cancellation of the development of our product candidates would have a material adverse effect on our long-term growth, potential revenue growth and business prospects.

The development of TH1902 for the potential treatment of various types of cancer is still uncertain since results obtained from preclinical in vivo development work may not be replicated into human subjects. The goal of the Phase 1 clinical trial using TH1902 is to determine the MTD that can be administered to human subjects and various serious adverse side effects are expected to be discovered from the injection of TH1902 in human subjects. If the Corporation is unable to replicate results obtained from its preclinical work or if patients enrolled in the clinical trial are subject to serious adverse side effects, the Corporation may have to discontinue its Phase 1 clinical trial. Any interruption or halt in the Corporation’s Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology™ platform, reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

Clinical failure can occur at any stage of clinical development. The Corporation’s Phase 1 clinical trial may not replicate results obtained from its preclinical *in vivo* work and we may not be able to determine the MTD into human subjects as a result of difficulty in enrolling patients, patients’ responsiveness to TH1902’s serious adverse side effects or patients death.

TH1902 is being developed as a potential treatment for severe, various life-threatening types of cancer. The Phase 1 clinical trial will be conducted with patients that will be more prone than the general population to exhibit certain diseases state or adverse events. Some of those patients face a life-threatening situation and may die during our Phase 1 clinical trial. Although the Corporation expects patients to have serious adverse side effects from the administration of TH1902, it may become difficult to discern whether certain events or symptoms observed in certain patients are directly related to TH1902. In the event of the death of a patient, the Corporation may have to suspend its Phase 1 clinical trial to determine whether such patient’s death is associated with the administration of TH1902. The suspension period could be lengthy since an investigation will be conducted to determine its causation. In the event the death of a patient is found not to be associated with TH1902, which would lead to the continuity of the Corporation’s Phase 1 clinical trial, the FDA may nonetheless require that the Corporation amend its Phase 1 clinical trial design by imposing various safety measures, the effect of which would be to increase its costs. In addition, the Corporation may have difficulty enrolling additional patients to resume the trial as a result of such death. The amendment of a Phase 1 clinical trial design, the obligation to add additional safety measures or the difficulty in enrolling additional patients would cause delays and increase the costs to complete the Corporation’s Phase 1 clinical trial. If the death of a patient is found to be related to TH1902, the Corporation may have to halt or completely cease its Phase 1 clinical trial which could lead to the abandonment of the development of our SORT1+ Technology™ platform. The abandonment of the development of the Corporation’s SORT1+

Technology™ platform would reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

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 the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology™ 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 the confinement measures adopted by regulatory authorities in the context of the COVID-19 pandemic, 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 candidates tested in those clinical trials and have a material adverse effect on our long-term growth and prospects.

Regulatory agencies have not approved the F8 Formulation as being bioequivalent to the Corporation's F1 Formulation. Under such circumstances, the Corporation may have to conduct additional clinical studies to prove the bioequivalence of the F8 Formulation against the F1 Formulation, resulting in additional capital expenditures and delays in the use of the F8 Formulation.

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the F1 Formulation. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not filed a sBLA with the FDA seeking the approval of the F8 Formulation for commercial use and does not contemplate making such filing before 2022.

In addition, the Corporation has not manufactured validation batches of the F8 Formulation and is therefore currently unable to determine whether the manufacturing process will be stable and allow the commercial use of the F8 Formulation, even if approved by the FDA as being bioequivalent to the F1 Formulation.

If the FDA does not approve the F8 Formulation as being bioequivalent to the F1 Formulation, the Corporation would have to conduct additional testing using the F8 Formulation which would delay the time by which the Corporation could commercialize the F8 Formulation and which would require the Corporation to incur additional expenses, all of which could adversely affect the Corporation's financial condition or results of operations. Furthermore, the non-approval of the F8 Formulation would prevent the Corporation from using the Pen currently under development.

The development of a multi-dose pen injector for the F8 Formulation is risky, and its commercial use is subject to the approval of regulatory agencies. There can be no guarantee that the development of the multi-dose pen injector will be successful or, even if successful, that it will be approved for commercial use by regulatory agencies. The failure to obtain approval of the multi-dose pen injector using the F8 Formulation could reduce our competitive advantage vis-à-vis other potential medicine for the treatment of NASH in the general population and also result in lower sales of tesamorelin approved for the treatment of lipodystrophy in patients living with HIV.

The Corporation has undertaken through third-party service providers the development of the Pen for the F8 Formulation. Although the Pen is already used with other drugs, some development is required to adapt its delivery system to the F8 Formulation dosing. The development of a device is complex, subject to failure, and there can be no guarantee that it will result in an approved drug-device for commercial use. Any issues encountered in

developing the Pen could delay its use in the development of tesamorelin for the treatment of NASH in the general population and reduce the likelihood of such device being approved for use in the treatment of NASH in the general population. Consequently, the Corporation could have to conduct additional clinical trials using the device and incur unplanned capital expenditures, thereby affecting its financial condition.

The Corporation could lose its competitive advantage *vis-à-vis* other potential medicine for the treatment of NASH in the general population if it is unable to develop or obtain approval of the Pen for its F8 Formulation. The Corporation could also reduce the potential growth of its tesamorelin-related franchise for the treatment of HIV-associated lipodystrophy if it is unable to introduce a Pen using the F8 Formulation for the treatment of such disease. Any delays in getting the Pen approved, or the non-approval thereof, will have a material adverse effect on the Corporation's sales growth, financial results and business prospects.

Finally, the development of the Pen relies on agreements with single third-party service providers and exposes the Corporation to the risks faced by these third-party service providers, such as failure by these third parties to comply with applicable laws, the loss of their operating licenses, the loss of key personnel, a shutdown of their facilities as a result of financial condition, COVID-19 or other *force majeure* issues, as well as their failure to perform their contractual obligations under the agreements with the Corporation. The occurrence of any of those instances would have a material adverse effect on the Corporation's business, results of operations and financial condition.

3.4 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 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. For instance, the fact that we own patents 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.

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 license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property and to compete with us.

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.

3.5 **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 EGRIFTA SV® and Trogarzo® in Canada since none of those products have 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 on 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 SV*[®], Trogarzo[®] or their respective manufacturing processes, withdrawal of *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.

3.6 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 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 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 the damages resulting from 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.

3.7 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 commercialization plan for Trogarzo® in the United Kingdom, the cost associated with such commercialization and the potential conduct of clinical trials in this country has been impacted as a result of Brexit.

On December 31, 2020, the United Kingdom completed the transition period for its exit from the European Union, or Brexit. This has brought about changes in the registration and regulation of medicinal products intended for sale in the UK and the EU. The UK's regime for regulating the manufacture, sale, licensing and distribution of medicinal products has changed since the end of the Brexit transition period. There is now a developing pathway towards achieving marketing authorization for the sale of medicinal products in both the UK and the EU, and this will increase the overall regulatory burden on us in respect of Trogarzo®. These changes to the regulatory environment may also require us to revamp certain pharmacovigilance protocols for Trogarzo®. Overall, we may incur additional costs that may adversely impact our business, operating results and financial condition. This will require time from the management team to ensure that the appropriate authorization procedures are followed to obtain market access across the relevant regions.

In addition, from January 1, 2021, in order for results obtained from the conduct of clinical trials in EU countries to be acceptable to The Medicines and Healthcare Products Regulatory Agency, or MHRA, either the sponsor or the legal representative of that clinical trial must be established in the UK or in a country on an approved list – this list, which is subject to review every three years, currently includes all countries in the EU. In terms of the data obtained from such clinical trials, the MHRA will accept Qualified Person, or QP, certified products from EU countries if they have been checked by a Responsible Person (Import). However, if the QP for the oversight process is not a UK resident, they will only be able to perform the duties required in respect of the oversight process and will not be authorized to certify products within the UK. Therefore, if we decide to seek approval in the UK, we may need to put in place additional arrangements to achieve certification which 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.

3.8 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 commercialization of our products and with the conduct of clinical trials, we must comply with privacy laws of various countries. For instance, 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 personal 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 continue to build our infrastructure in Europe, we will continue to optimize our systems 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, 2020. Our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*[®] and Trogarzo[®] successfully in the United States and Trogarzo[®] in the European Territory 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 SV*[®] and Trogarzo[®] under U.S. Medicare and Medicaid programs and under private-health insurers programs in the United States. The obtaining of reimbursement of Trogarzo[®] in key European countries will also impact our capacity to be profitable.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*[®] and Trogarzo[®] in the United States. In addition, there is no guarantee that we will be able to successfully launch, commercialize and obtain reimbursement of Trogarzo[®] in key European countries. 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, 2020, we had negative operating cash flow of \$5,906,000. 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, including our Phase 3 clinical trial studying tesamorelin for the treatment of NASH and our Phase 1 clinical trial studying TH1902 for various types of cancers, 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 SV*[®] and Trogarzo[®] in the United States. Syneos has also hired, amongst others, 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 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 actual future payments for allowances for discounts, returns, rebates and chargebacks exceed the estimates the Corporation made at the time of the sale of its products, its financial position, results of operations, and cash flows may be negatively impacted.

Pursuant to the Corporation's accounts and revenue recognition policies, the product revenue recognized quarter over quarter by the Corporation is net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates require subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including the Corporation, have liberal return policies, sometimes making it difficult to estimate the timing and amount of expected revenues.

A chargeback is the difference between the price the wholesaler pays the Corporation (wholesale acquisition cost) and the price that the wholesaler's customer pays for the Corporation's product (contracted customer). The Corporation's products were subject to certain programs with federal government qualified entities whereby pricing on products is discounted to such entities and results in a chargeback claim to the Corporation, or for the Corporation to bill certain qualifying Public Health Service end-users at government-mandated pricing. To the extent that the Corporation's sales to discount purchasers, such as federal government qualified entities, increases, chargeback claims will also increase. There may be significant lag time between the Corporation's original sale to the wholesaler and the Corporation's receipt of the corresponding government chargeback claims from the Corporation's wholesalers.

The Corporation's products are subject to state government-managed Medicaid programs, whereby rebates for purchases are issued to participating state governments. These rebates arise when the patient treated with the Corporation's products is covered under Medicaid. The Corporation's calculations require the Corporation to estimate end-user and patient mix to determine which of its sales will likely be subject to these rebates. There is a significant time lag in the Corporation receiving these rebate notices (generally several months after its sale is made). The Corporation's estimates are based on its historical claims from participating state governments, as supplemented by management's judgment.

Although the Corporation believes that it has sufficient allowances, actual results may differ significantly from its estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on its financial condition, results of operations and cash flows. Such changes to estimates will be made to the financial statements in the period in which the estimate is changed. In addition, the Corporation's financial position, results of operations and cash flows may be negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates the Corporation made at the time of the sale of its products

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.

3.9 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. Any decline in value or fluctuation in the market price of our common shares could also affect the market price of the Notes and the value of the warrants issued in the Offering.

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 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 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, 2021: 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>Sheila M. Frame Age: 59 Naples, Florida, USA</p> <p>Independent</p> <p>Director since: March 29, 2019</p> <p>Areas of Expertise:</p> <ul style="list-style-type: none"> - Pharmaceutical Industry - Sales and Marketing - Strategy - Government Relations - Leadership <p>Other Directorship: None</p> | Principal Occupation | | Vice President and Head of Biopharmaceuticals, North America Sandoz Inc. | |
| | 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. | | | |
| | 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. | | | |
| | Securities Held or Controlled | | | |
| | Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| | 6,000 | 20,043 | 10,600 | Nil |
| Committees of the Board of Directors | | | | |
| Member of Compensation Committee | | | | |



Gérald A. Lacoste

Age: 77
Rivière-Rouge,
Québec, Canada

Independent

Director since:
February 8, 2006

Areas of Expertise:

- Securities and Market Regulations
- Corporate Governance
- Mergers & Acquisitions

Other Directorship:

None

| Principal Occupation | | 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. | | | |
| Securities Held or Controlled | | | |
| Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 100,000 | 21,936 | 66,746 | 45,000 |
| Committees of the Board of Directors | | | |
| Chair of Nominating and Corporate Governance Committee Member of Audit Committee | | | |



Paul Lévesque

Age: 57
Westmount, Québec,
Canada

Non-independent

Director since:

April 6, 2020

Areas of Expertise:

- Pharmaceutical Industry
- Sales and Marketing
- Management
- Human Resources

Other Directorship:

None

| Principal Occupation | | President and Chief Executive Officer of the Corporation | |
|---|--------------------|--|-------------------------|
| <p>Paul Lévesque has built an enviable reputation in the pharmaceutical industry both here and abroad. He is recognized for his track record at delivering growth.</p> <p>Paul has worked in the research-based pharmaceutical industry since 1985. He started with Upjohn Canada and then joined Pfizer Canada in 1992. He went on to occupy increasingly senior positions within the organization including as Vice President of Marketing in Canada and in France, Country Manager for Canada, Chief Marketing Officer for the U.S. in Primary Care and as Regional President in Asia-Pacific for the innovative division of Pfizer.</p> <p>He also assumed the role of Global President and General Manager for the Rare Disease Unit until he joined Theratechnologies on April 6, 2020.</p> <p>Paul carries a passion for bringing to patients therapies in areas of unmet medical needs and will put to contribution his learnings from his 35 years in the pharmaceutical industry.</p> <p>Paul holds a BSc in biochemistry from Laval University and a Diploma in Management from McGill University. Paul is married and has three children.</p> | | | |
| Securities Held or Controlled | | | |
| Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 111,200 | Nil | 487,421 | Nil |
| | | | |



Gary Littlejohn
 Age: 65
 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

| Principal Occupation | | 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> | | | |
| Securities Held or Controlled | | | |
| Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 19,060 | Nil | 19,500 | Nil |
| Committees of the Board of Directors | | | |
| <p>Chair of Compensation Committee Member of Audit Committee</p> | | | |



Dale MacCandlish Weil

Age: 65
 Baie d'Urfé,
 Québec, Canada

Independent

Director since:
 May 16, 2017

Areas of Expertise:

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

Other Directorship:
 Tetra Bio-Pharma Inc.

| Principal Occupation | | 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 Teresa Dellar Palliative Care Residence) and, in January 2020, she became Executive Director of the Teresa Dellar 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 is a member of the board of directors of Tetra Bio-Pharma Inc. in Ontario. 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> | | | |
| Securities Held or Controlled | | | |
| Common Shares | DSU | Options | Notes |
| (#) | (#) | (#) | (US\$) |
| 16,700 | 5,531 | 41,746 | 2,000 |
| Committees of the Board of Directors | | | |
| Member of Nominating and Corporate Governance Committee | | | |



Andrew Molson
 Age: 53
 Westmount, Québec,
 Canada

Independent

Director since:
 October 15, 2020

Areas of Expertise:
 - Communications
 - Governance

Other Directorship:
 Molson Coors Beverage
 Company;
 Dundee Corporation

| Principal Occupation | |
|--|---------------|
| Corporate Director | |
| <p>Andrew Molson serves as chairman of AVENIR GLOBAL, an organization uniting seven strategic communications firms across Canada, the U.S., Europe and the Middle East. He is also chairman of Molson Coors Beverage Company and a member of the board of directors of Groupe Deschênes Inc., Dundee Corporation and the CH Group Limited Partnership, owner of evenko and the Montreal Canadiens.</p> <p>He previously served as a director of The Group Jean Coutu PJC Inc. from 2014 to 2018, as Chair of Molson Coors from May 2011 to May 2013 and as its Vice Chair from May 2009 to May 2011.</p> <p>He was called to the Quebec Bar in 1995 after studying law at Laval University in Quebec City. He also holds a Bachelor of Arts from Princeton University and a Master of Science in corporate governance and ethics from University of London (Birkbeck College). Mr. Molson serves on several non-profit boards, including the Institute for Governance of Private and Public Organizations, Concordia University Foundation, the Québec Blue Cross, the evenko foundation for emerging talent, the Montreal General Hospital Foundation and the Molson Foundation, a family foundation dedicated to the betterment of Canadian society.</p> | |
| Securities Held or Controlled | |
| Common Shares | DSU |
| (#) | (#) |
| 30,000 | Nil |
| Options | Notes |
| (#) | (US\$) |
| Nil | Nil |



Paul Pommier
 Age: 78
 Laval, Québec,
 Canada

Independent

Director since:
 January 6, 1997

Areas of Expertise:
 - Corporate Finance
 - Securities
 - Mergers &
 Acquisitions

Other Directorship:
 None

| Principal Occupation | | 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. | | | |
| Securities Held or Controlled | | | |
| Common Shares | DSU | Options | Notes |
| (#) | (#) | (#) | (US\$) |
| 420,100 | 122,208 | 56,146 | Nil |
| Committees of the Board of Directors | | | |
| Chair of the Audit Committee Member of Compensation Committee | | | |



Dawn Svoronos

Age: 67
 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.;
 Adverum Biotechnologies, Inc.

| | | | |
|---|------------|--|---------------|
| Principal Occupation | | 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 four other public companies: Xenon Pharmaceuticals Inc. in British Columbia, Canada, PTC Therapeutics, Inc. in New Jersey, U.S.A., Global Blood Therapeutics, Inc. in San Francisco, California, and Adverum Biotechnologies, Inc. in Redwood City, California. | | | |
| Securities Held or Controlled | | | |
| Common Shares | DSU | Options | Notes |
| (#) | (#) | (#) | (US\$) |
| 273,600 | 855 | 106,746 | Nil |
| Committees of the Board of Directors | | | |
| Member of Compensation Committee Member of Nominating and Corporate Governance Committee | | | |

| | | | | |
|---|---|----------------|--------------------|---------------------|
|  <p>Alain Trudeau Age: 61 Montréal, Québec, Canada</p> <p>Independent</p> <p>Director since: October 15, 2020</p> <p>Areas of Expertise:</p> <ul style="list-style-type: none"> - Accounting - Finance governance <p>Other Directorship: None</p> | Principal Occupation | | Corporate Director | |
| | <p>A fellow of the Quebec CPA Order, Alain Trudeau has had a distinguished career at Ernst & Young from 1982 to 2019 where he held the position of Managing Partner, Assurance Services, for EY offices in the Province of Quebec from 2008 to 2019. He was also responsible for the audit of many publicly-traded companies.</p> <p>He currently serves on the board of directors of the <i>Montréal Inc.</i> Foundation, the <i>Institut de médiation et d'arbitrage du Québec</i> (IMAQ) and Blue Bridge Trust Company Inc.</p> <p>From 2008 to 2019, Mr. Trudeau was a lecturer at the Collège des administrateurs de sociétés de l'université Laval in Quebec City.</p> <p>Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal.</p> | | | |
| | Securities Held or Controlled | | | |
| | Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| | 11,300 | Nil | Nil | Nil |
| Member of Audit Committee | | | | |

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, 2020, the Audit Committee was composed of four members: Paul Pommier, its Chair, Gary Littlejohn, Gérald A. Lacoste and Alain Trudeau. All four 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.

Alain Trudeau. Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal. From 1982 to 2019, Mr. Trudeau has had a distinguished career at Ernst & Young where he held the position of Managing Partner, Assurance Services, for Ernst & Young offices in the Province of Quebec, from 2008 to 2019. During his career, Mr. Trudeau was responsible for the audit of various publicly-traded companies.

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, 2021: 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. Paul Lévesque, the President and Chief Executive Officer of the Corporation, is found in the table above regarding information about our directors.



Denis Boucher
Age: 55
Montreal, Québec,
Canada

| | | | |
|--|----------------|--|---------------------|
| Principal Occupation | | 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. | | | |
| Securities Held or Controlled | | | |
| Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 5,980 | Nil | 68,122 | 40,000 |




Marie-Noël Colussi
Age: 52
Laval, Québec,
Canada


| | | | |
|--|----------------|-------------------------|---------------------|
| Principal Occupation | | 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. | | | |
| Securities Held or Controlled | | | |
| Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 11,075 | 3,182 | 105,193 | 10,000 |




Philippe Dubuc
Age: 54
Montreal, Québec,
Canada

| | | | |
|--|----------------|---|---------------------|
| Principal Occupation | | 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. | | | |
| Securities Held or Controlled | | | |
| Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 31,000 | Nil | 327,286 | 25,000 |

| | | | | |
|---|---|----------------|--|---------------------|
|  <p>Jocelyn Lafond Age: 53 Montreal, Québec, Canada</p> | Principal Occupation | | Vice President, Legal Affairs, and Corporate Secretary | |
| | 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. | | | |
| | Securities Held or Controlled | | | |
| | Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 18,000 | 5,000 | 260,193 | 8,000 | |

| | | | | |
|--|--|----------------|---|---------------------|
|  <p>Christian Marsolais Age: 58 Town of Mount Royal, Québec, Canada</p> | Principal Occupation | | Senior Vice President and Chief Medical Officer | |
| | 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. 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. Dr. Marsolais holds a Ph.D. in biochemistry from the Université de Montréal | | | |
| | Securities Held or Controlled | | | |
| | Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| 59,297 | 6,312 | 427,286 | 15,000 | |

| | | | | |
|---|--|----------------|---|---------------------|
|  <p>Conor Walshe Age: 47 Rathmines, Ireland</p> | Principal Occupation | | General Manager, Theratechnologies Europe Limited | |
| | Mr. Walshe is based at the Theratechnologies European head office in Dublin, Ireland. Prior to joining our European subsidiary, Mr. Walshe was General Manager and Vice President, Operations and Commercial, at Aralez Plc. Prior to Aralez Plc, Mr. Walshe spent more than 15 years in the pharmaceutical industry including at Perrigo Plc, Elan Plc and Venn Life Sciences where he was called upon to serve, among others, as CFO, Senior Vice President Commercial and Financial Operations and in product management. Mr. Walshe is a Chartered Accountant. He holds a Bachelor of Commerce and a Master in Business Studies from the University College in Dublin. He also obtained a diploma in IFRS from the Institute of Chartered Accountants and in Advanced International Corporate Finance from INSEAD. | | | |
| | Securities Held or Controlled | | | |
| | Common Shares (#) | DSU (#) | Options (#) | Notes (US\$) |
| Nil | Nil | 90,000 | Nil | |

4.4 CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

To our knowledge, no director and executive officer (a) is, as at February 24, 2021, or has been within the ten (10) years before February 24, 2021, 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, 2021, 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.

4.5 SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS

As at February 24, 2021, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 1,113,312, which represented 1.19% of our outstanding common shares.

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 that were billed or payable in respect of each of our fiscal years ended November 30, 2020 and 2019:

| Fees | Fiscal Year Ended November 30, 2020 (CA\$) | Fiscal Year Ended November 30, 2019 (CA\$) |
|-----------------------|---|---|
| Audit Fees(1) | 497,667 | 388,600 |
| Audit-Related Fees(2) | 89,175 | 71,310 |
| Tax Fees(3) | 54,563 | 158,092 |
| Total: | 641,405 | 618,002 |

- (1) Refers to the aggregate fees billed by our external auditors for audit services, including interim reviews 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 and accounting consultations, for which \$27,560 has been reclassified from audit to audit-related for the fiscal year ended November 30, 2019.
- (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.

| <u>Period(1)</u> | <u>TSX</u> | | | <u>NASDAQ(2)</u> | | |
|------------------------------|---------------------|--------------------|---------------|--------------------|-------------------|---------------|
| | <u>High (Cdn\$)</u> | <u>Low (Cdn\$)</u> | <u>Volume</u> | <u>High (US\$)</u> | <u>Low (US\$)</u> | <u>Volume</u> |
| 2019 | | | | | | |
| December | 4.31 | 3.44 | 3,543,600 | 3.32 | 2.61 | 3,861,300 |
| 2020 | | | | | | |
| January | 4.30 | 3.38 | 1,797,900 | 3.31 | 2.05 | 1,262,500 |
| February | 4.11 | 2.84 | 1,763,000 | 3.09 | 2.09 | 1,345,425 |
| March | 4.38 | 1.93 | 4,328,000 | 3.24 | 1.33 | 3,164,400 |
| April | 4.17 | 2.19 | 2,619,600 | 2.96 | 1.56 | 2,245,100 |
| May | 3.51 | 2.47 | 3,321,000 | 2.63 | 1.79 | 1,768,000 |
| June | 3.71 | 2.30 | 4,096,700 | 2.75 | 1.68 | 10,000,000 |
| July | 3.75 | 2.61 | 2,636,900 | 2.81 | 1.93 | 7,401,200 |
| August | 3.99 | 3.14 | 2,946,000 | 3.02 | 2.34 | 2,024,700 |
| September | 3.55 | 2.86 | 2,257,000 | 2.72 | 2.13 | 2,993,700 |
| October | 3.16 | 2.43 | 2,235,200 | 2.40 | 1.83 | 1,935,400 |
| November | 3.15 | 2.47 | 1,636,000 | 2.41 | 1.86 | 1,674,900 |
| December | 3.23 | 2.68 | 1,778,455 | 2.54 | 2.09 | 2,812,100 |
| 2021 | | | | | | |
| January | 4.16 | 2.72 | 4,907,187 | 3.25 | 2.13 | 7,878,300 |
| February (to February 23) | 3.95 | 2.82 | 5,313,800 | 3.17 | 2.20 | 22,574,900 |

(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 Yahoo Finance.

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) | | Volume |
|---------------------------|---------------------|------------|---------|
| | High (US\$) | Low (US\$) | |
| 2019 | | | |
| December | 79.00 | 70.31 | 875,000 |
| 2020 | | | |
| January | 80.00 | 80.00 | 21,000 |
| February | 86.00 | 74.85 | 246,000 |
| March | 75.00 | 60.00 | 374,000 |
| April | 80.00 | 78.00 | 7,000 |
| May | 76.00 | 75.00 | 26,000 |
| June | 78.00 | 70.00 | 308,000 |
| July | 76.00 | 70.00 | 21,000 |
| August | 74.00 | 72.50 | 61,000 |
| September | 90.00 | 72.00 | 31,000 |
| October | 84.00 | 70.00 | 22,000 |
| November | 75.00 | 70.00 | 38,000 |
| December | 75.00 | 61.10 | 223,000 |
| 2021 | | | |
| January | 83.00 | 80.00 | 51,000 |
| February (to February 23) | 87.00 | 81.00 | 40,100 |

- (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, 2020 | Stock Options | CA \$3.22 | 577,800 |
| April 15, 2020 | Deferred Stock Units(1) | CA \$2.58 | 5,814 |
| April 15, 2020 | Stock Options | CA \$2.87 | 499,921 |
| November 19, 2020 | Deferred Stock Units | CA \$3.00 | 10,000 |
| November 27, 2020 | Stock Options | CA \$2.35 | 12,500 |

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

ITEM 8 LEGAL PROCEEDINGS

In the last financial year, we were not subject to any legal proceedings and, as at February 24, 2021, we are not subject to any such proceedings.

ITEM 9 MATERIAL CONTRACTS

Note Indenture

On June 19, 2018, we entered into a trust indenture with Computershare Trust Company of Canada, or Trustee, providing for the issue of the Notes and governing the terms and conditions of the Notes as well as our rights and obligations and those of the Trustee. The Notes were issued under a final prospectus dated June 12, 2018. The Notes bear interest at a rate of 5.75% per annum, which will be payable in US dollars in equal instalments semi-annually in arrears on June 30 and December 31 of each year, commencing on December 31, 2018, computed on the basis of a 360-day year composed of twelve 30-day months. The Notes will mature at 5:00 pm (Eastern Time) on June 30, 2023. The Notes are our direct, senior obligations and are not secured by any mortgage, pledge, hypothec or other charge and rank equally and *pari passu* to all of our existing and future senior unsecured and unsubordinated indebtedness. The Note Indenture does not restrict us from incurring additional indebtedness, whether senior secured, *pari passu* or subordinated, for borrowed money or from mortgaging, pledging or charging our assets to secure any indebtedness.

The Notes are convertible at the holder's option into fully-paid, non-assessable and freely-tradeable common shares at any time prior to the close of business on the earliest of (i) the business day immediately preceding the June 30, 2020; (ii) the business day immediately preceding the date specified by us for redemption of the Notes; and (iii) the business day immediately preceding the payment date in the event we are required to offer to repurchase the Notes in connection with a change of control, at a conversion price of US\$14.85 per common share, representing a conversion rate of approximately 67.3401 common shares per US\$1,000 principal amount of Notes. Holders converting their Notes will receive, as the case may be, accrued and unpaid interest thereon for the period from the last interest payment date prior to the date of conversion up to but excluding the date of conversion. Holders converting their Notes will become holders of record of common shares on the business day immediately following the date of conversion. Notwithstanding the foregoing, no Notes may be converted during the five business days preceding June 30 and December 31 of each year.

The Notes may not be redeemed by us before June 30, 2021 (except in certain limited circumstances following a change of control). On or after June 30, 2021 and prior to June 30, 2023, the Notes may be redeemed by us in whole or in part from time to time at our option on not more than 60 days' and not less than 40 days' prior written notice at a redemption price equal to their principal amount plus accrued and unpaid interest thereon, up to, but excluding, the date set for redemption; provided that, as of the date of the notice for redemption, the market price of our common shares is at least 130% of the conversion price of the Notes.

Bachem Agreement

We are currently renegotiating the terms of our agreement with Bachem which has now expired. This agreement provides for the manufacturing and supply of the active pharmaceutical ingredient of tesamorelin for *EGRIFTA SV*[®] and for the conduct of clinical trials. Bachem is our only validated supplier of raw materials. Despite the ongoing renegotiation of this agreement, Bachem has indicated to us that it could manufacture lots of tesamorelin, if needed.

Jubilant Agreement

On December 23, 2009, we entered into a supply and manufacturing agreement with Jubilant. This agreement provides for the manufacture and supply of the finished form of *EGRIFTA SV*[®]. Under the agreement, Jubilant must fill vials with tesamorelin, lyophilize it, label and package those vials and deliver them to locations in accordance with our instructions. The agreement contains customary representations and warranties, indemnity provisions and was originally 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 Jubilant Agreement contains a renewal provision providing for automatic successive one-year term renewals unless a party gives the other a written notice within a certain period of time of its intent not to renew the agreement. We are currently renegotiating some of the terms of the Jubilant Agreement.

Hospira Agreement

Effective March 19, 2015, we entered into a supply agreement with Hospira. Under this agreement, Hospira is responsible for manufacturing and supplying us with sterile water for injection, filled and finished in plastic vials, in connection with the sale of *EGRIFTA SV*[®] in the United States only. This agreement contains customary representations and warranties, indemnity provisions and was scheduled to expire in December 2016. The agreement has been renewed since for one-year terms pursuant to an automatic one-year term renewal provision. A party is entitled not to renew the term of this agreement by providing the other with a written notice within a certain period of time prior to the renewal term.

Sharp Agreement

On August 10, 2017, we entered into a packaging agreement with Sharp to package and ship injection tool kits for *EGRIFTA SV*[®] to our third-party logistic service provider in the United States, RxCrossroads. The agreement contains customary covenants and undertakings for the activities carried out by Sharp, allocation of risk provisions in relation to the packaging of the injection tool kits and indemnity provisions.

RxCrossroads Agreements

On November 1st, 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*[®] and Trogarzo[®] in the United States. Effective November 1st, 2019, we amended the amended and restated statement of work agreements to add *EGRIFTA SV*[®] 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 1st, 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*[®] 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*[®] 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 1st, 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.

TaiMed Agreement

See “ITEM 2.5. Commercialization Activities – Trogarzo” above for a description of the TaiMed Agreement.

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.

Loxxess Agreement

On July 9, 2020, our European subsidiary, Theratechnologies Europe Limited, entered into the Loxxess Agreement pursuant to which Loxxess agreed to act as our third-party service logistic provider for Trogarzo® in certain key European countries, including Germany, France, Italy, Austria, The Netherlands, Portugal, Switzerland, the United Kingdom, Norway, Sweden, Finland and Denmark. Loxxess has also indicated to us that it is capable of serving various additional countries, including Israel and Turkey. Pursuant to the Loxxess Agreement, Loxxess receives customers' orders, stores, packages and ships Trogarzo® to European hospitals and pharmacies. Loxxess is also responsible, on our behalf, to collect payments of the goods sold to those hospitals and pharmacies. The Loxxess Agreement contain customary representations and warranties, covenants, risk allocation provisions in respect of the activities carried out by Loxxes and indemnity provisions. The Loxxess Agreement has a one-year term and is scheduled to expire in July 2021 but renews automatically for additional one-year terms unless a party provides the other with a written notice within a certain period of time preceding the expiry of the term of its intent not to renew. Unless a party is in default under the terms of the Loxxess Agreement before the end of the term and such default is not cured within the period set forth in the Loxxess Agreement, or unless the parties decide not to renew the Loxxess Agreement, this agreement will be automatically renewed in July 2021 for an additional one-year term.

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 SV*[®] (*EGRIFTA*[®] at the time) and Trogarzo[®] in the United States and Trogarzo[®] in Europe. 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 and community liaison 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.

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*[®], 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.

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 SV*[®] 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 regardless of the patient 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.

WCT Agreement

On December 18, 2020, we entered into a master services agreement with WCT to define the terms and conditions pursuant to which we would retain the services of WCT to assist us with the conduct of our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population. The agreement provides for the entering of the entering of statements of work whenever services would be required from WCT. The agreement contains provisions relating to the quality of the services to be provided, covenants and undertakings of the parties in relation to services to be performed, customary representations and warranties, confidentiality, ownership of intellectual property and indemnification. The agreement has a three-year term and is scheduled to expire on December 18, 2023, subject to automatic renewal for one-year terms, unless a party provides the other with a written notice within a certain period of time preceding the expiry of the term of its intent not to renew.

Transfert Plus 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 License 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.

ITEM 10 ADDITIONAL INFORMATION

Additional information with respect to our Company, including directors' and officers' compensation, principal holders of our securities and securities authorized for issuance under equity compensation plans, where applicable, is contained in our Management Proxy Circular. Our financial information is provided in our comparative financial statements and Management Discussion & Analysis for our financial year ended November 30, 2020.

Additional information regarding our Company is available on SEDAR at www.sedar.com, or upon written request addressed to Jocelyn Lafond, Vice President, Legal Affairs, and Corporate Secretary, at 2015 Peel Street, 11th 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.

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.



MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE YEAR ENDED NOVEMBER 30, 2020

The following Management's Discussion and Analysis, or MD&A, provides Management's point of view on the financial position and results of operations of Theratechnologies Inc., on a consolidated basis, for the twelve-month period ended November 30, 2020, or Fiscal 2020, compared to the twelve-month period ended November 30, 2019, or Fiscal 2019. 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, 2021, was approved by our Board of Directors on February 24, 2021 and should be read in conjunction with our audited annual consolidated financial statements and the notes thereto as at November 30, 2020, or Audited Financial Statements.

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 Company's functional and reporting 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 this MD&A, the use of *EGRIFTA SV*[®] (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and the use of Trogarzo[®] (ibalizumab-uiyk) injection refers to ibalizumab for the treatment of multidrug resistant HIV-1 infected patients. The use of tesamorelin refers to the use of our tesamorelin compound for the potential treatment of nonalcoholic steatohepatitis, or NASH, in the general population.

Forward-Looking Information

This MD&A 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:

Theratechnologies Inc.
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Montreal, Québec H3A 1T8

- our expectations regarding the commercialization of *EGRIFTA SV*[®] and Trogarzo[®];
- our ability and capacity to grow the sales of *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*[®] and Trogarzo[®] 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 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 and the United Kingdom;
- our ability and capacity to launch and successfully commercialize Trogarzo[®] in various countries of the European Union and the United Kingdom;
- the approval of a new formulation of tesamorelin, or F8 Formulation, by the United States Food and Drug Administration, or FDA;
- our capacity to develop a multi-dose pen injector, or Pen, for use with the F8 Formulation;
- our capacity to conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- our capacity to conduct a Phase 1 clinical trial using our peptide-drug conjugate TH1902 in various types of cancers;
- our capacity to pursue the development of our other peptide-drug conjugates in the field of oncology;
- our capacity to acquire or in-license new products and/or compounds;
- our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes;
- our estimates regarding our capital requirements; and
- our ability to meet the timelines set forth herein.

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:

- the current pandemic and the measures implemented to control it will have limited material adverse effect on the Company's operations;
- the vaccines recently developed to thwart the coronavirus will be safe and effective at combatting the coronavirus in its current form and in any variant form thereof;
- sales of *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 where we commercialize our products 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 SV*[®] and Trogarzo[®] in countries where such products are commercialized;
- 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 biosimilar version of tesamorelin will be approved by the FDA;
- our intellectual property will prevent companies from commercializing biosimilar versions of tesamorelin in the United States;
- Trogarzo[®] will be added to the list of reimbursed drugs by countries of the European Union and the United Kingdom;
- the FDA will approve the F8 Formulation and the use of the Pen with the F8 Formulation;
- we will agree with the FDA on a final Phase 3 clinical trial design to begin studying tesamorelin for the treatment of NASH in the general population;
- we will succeed in recruiting patients and in conducting our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;

- we will succeed in recruiting and in conducting our Phase 1 clinical trial studying TH1902 in various types of cancers;
- we will have the financial means to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population and a Phase 1 clinical trial studying TH1902 in various types of cancers;
- our research and development activities will yield positive results;
- the data obtained from our market research on the potential market for the treatment of NASH in the general population and on the potential market for Trogarzo® in the United States and in the European Union are accurate;
- our European infrastructure is adequate to successfully launch and commercialize Trogarzo® in key European countries;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise as of the date of this MD&A; 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 MD&A 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 “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 MD&A. 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 MD&A, and particularly our forward-looking statements, with these cautionary statements.

BUSINESS OVERVIEW

Theratechnologies is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. We have two approved medicines (*EGRIFTA SV*® and Trogarzo®) for people living with HIV and a promising pipeline of investigational medicines in other areas of high unmet need, including NASH and oncology. The Company has a sales and marketing infrastructure to commercialize its products in the United States and Europe, and we continue to assess the market for potential product acquisitions or in-licensing transactions that would be complementary to our business.

FY2020 AND RECENT HIGHLIGHTS

- In July 2020, the Company completed the evaluation and development of the F8 Formulation of tesamorelin.
- In August 2020, the Company completed the transition to *EGRIFTA SV*® from the original formulation of *EGRIFTA*®.
- In September 2020, the Company announced its intent to develop tesamorelin for the treatment of NASH in the general population.

- In November 2020, the Company filed an investigational new drug application, or IND with the FDA for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH.
- In December 2020, the Company received a “Study May Proceed” letter from the FDA for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH. The Company intends to initiate the Phase 3 clinical trial by the end of the third quarter of calendar year 2021.
- In December 2020, the Company filed an IND application with the FDA for the Phase 1 first-in-human clinical trial evaluating TH1902 for the treatment of various cancers.
- In January 2021, the Company received a “Study May Proceed” letter from the FDA for the Phase 1 clinical trial of TH1902. The Phase 1 clinical trial is expected to be initiated in the second quarter of calendar year 2021.
- In February 2021, Theratechnologies received fast track designation from the FDA for TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy.

OUR MEDICINES

The Company has two approved medicines for people living with HIV, namely Trogarzo® in the United States, European Union, and United Kingdom, and *EGRIFTA SV*® in the United States. *EGRIFTA*® is commercially available in Canada. Sales of *EGRIFTA*® in Canada are not material to our business.

EGRIFTA SV® is a new formulation of *EGRIFTA*® that was approved by the FDA for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and launched in the United States in November 2019. Unlike *EGRIFTA*®, *EGRIFTA SV*® can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration.

Trogarzo® was the first HIV treatment approved with a new mechanism of action in more than 10 years. It is the first in a new class of antiretrovirals, or ARV, and is a long-acting ARV therapy that can lead to an undetectable viral load in heavily treatment-experienced adult HIV-infected patients when used in combination with other ARVs. The treatment is infused once every two weeks.

Trogarzo® was approved by the FDA in March 2018 for the treatment of human immunodeficiency virus type 1, or HIV-1, infection in heavily treatment-experienced adults with multidrug resistant, or MDR, HIV-1 infection failing their current antiretroviral regimen. Trogarzo® was also approved 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® is currently commercially available in Germany and the Company expects to launch Trogarzo® in key additional European countries later in 2021 and in 2022. A number of patients are also being treated with Trogarzo® in some European countries through early access programs. Trogarzo® will be launched on a country-by-country basis across Europe as it gains public reimbursement in each such country. In addition, the Company has filed a marketing authorization application, or MAA, in Israel for Trogarzo®.

In March 2016, we obtained the rights to commercialize Trogarzo® in the United States and Canada pursuant to a distribution and licensing agreement with TaiMed Biologics, Inc., or TaiMed. In March 2017, the agreement was amended to include the commercial rights to Trogarzo® in the European Union and in other countries such as Israel, Norway, Russia and Switzerland, or TaiMed Agreement.

The Company's commercial product strategy for the 2021 fiscal year is to generate revenue growth through increased sales of our medicines in the United States while working on securing an appropriate price and widespread reimbursement for Trogarzo® in key European countries and launch Trogarzo® in those key European countries.

IMPACT OF THE COVID-19 PANDEMIC

As of November 2020, a novel strain of coronavirus, or COVID-19, continued to spread globally. Efforts to contain the spread of COVID-19 have intensified and North America, Europe and Asia have implemented severe travel restrictions, social distancing requirements, and stay-at-home orders, among other restrictions. As a result, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies.

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of employees, and their families and to reduce the spread of COVID-19. We have established, and maintained without interruption, a work-from-home policy for all employees.

Throughout 2020, face-to-face interactions in clinics, hospitals, AIDS services organizations and other offices were reduced and patient treatment initiations were delayed due to restrictions implemented to stop the spread of COVID-19. In order to adapt to the pandemic environment, we transitioned to offering virtual interactions to continue to provide education and support for people in need of our medications, people living with HIV, case managers, healthcare providers and their staff, on how to manage HIV during the COVID-19 pandemic. On September 21, 2020, we announced a change to our U.S. sales infrastructure and a reallocation of resources to adapt to this new business environment and increase our presence in the healthcare community. We anticipate these measures will support our efforts to increase U.S. sales of Trogarzo® and *EGRIFTA SV*® going forward. In the European Union, sales of Trogarzo® and the review of regulatory dossiers were adversely impacted by COVID-19 due to strict lockdown measures imposed in many European countries.

We have and continue to impose measures to address and mitigate the impact of the COVID-19 pandemic on our employees and customers and to continue to progress our research and development programs. To date, preparations for our upcoming Phase 1 clinical trial of TH1902 for the treatment of various cancers and our Phase 3 clinical trial of tesamorelin for the treatment of NASH have not been materially adversely impacted by the COVID-19 pandemic.

OUR PIPELINE

Theratechnologies has established a promising pipeline of investigational medicines in areas of high unmet need, including NASH, oncology and HIV.

Tesamorelin

During fiscal year 2020, the Company completed the evaluation and development of the F8 Formulation, which based on internal studies, is bioequivalent to the original commercialized formulation of tesamorelin, or F1 Formulation. The F8 Formulation has a number of advantages over the current formulation of *EGRIFTA SV*[®]. Specifically, it is two times more concentrated resulting in a smaller volume of administration and is intended to be presented in a multi-dose vial that can be reconstituted once per week. Similar to the current formulation of *EGRIFTA SV*[®], the F8 Formulation is stable at room temperature, even once reconstituted.

The F8 Formulation is patent protected in the United States until 2033 and until 2034 in major European countries. Furthermore, the United States Patent and Trademark Office recently issued U.S. Patent 10,799,562 to Massachusetts General Hospital, or MGH, relating to the treatment of hepatic disease using growth hormone related hormone, or GHRH, or analogues thereof which is scheduled to expire in 2040. This patent application claims, among other things, a method for the treatment of NAFLD or NASH in a patient via the administration of tesamorelin. We have an exclusive worldwide license with MGH for this patent.

The Company is currently working on the development of a multi-dose pen injector to be used in conjunction with the F8 Formulation and we intend to seek marketing approval of the pen in the same supplemental Biologics License Application, or sBLA, as that for the F8 Formulation. We plan to file an sBLA for the F8 Formulation and multi-dose pen injector in early 2022 for the treatment of lipodystrophy in people living with HIV.

In September 2020, we announced our intent to develop tesamorelin for the treatment of NASH in the general population. This decision was largely based on positive scientific evidence in addition to discussions with scientific advisors and the FDA and European regulatory agencies regarding drug development for the treatment of NASH.

In conjunction with The Liver Meeting[®] 2020 of the American Association for the Study of Liver Diseases, or AASLD, in November 2020, Lindsay T. Fourman, M.D., of the Metabolism Unit, Department of Medicine, Massachusetts General Hospital presented results from a new proteomics sub-analysis that demonstrated that serum levels of three proteins associated with the development of NASH and fibrosis, Vascular Endothelial Growth Factor A (VEGFA), Transforming Growth Factor Beta 1 (TGF β 1) and Colony Stimulating Factor 1 (CSF1), were significantly reduced in tesamorelin patients compared to a placebo group. These results help to understand how tesamorelin may induce key metabolic pathways that could have a direct effect on liver inflammation, fat and fibrosis and support the Company's plan to develop tesamorelin for the treatment of NASH.

In November 2020, the Company filed an IND with the FDA for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH.

The proposed Phase 3 clinical trial design will enroll participants with liver-biopsy confirmed NASH and stage 2 or 3 fibrosis. Participants will be randomized 1:1 to receive 2 mg of tesamorelin or placebo. A second liver biopsy will be performed after 18 months of treatment for the first 900 participants, approximately. These data will form the basis for filing an sBLA with the FDA to seek accelerated approval. The primary endpoint used to

seek accelerated approval will be the percentage of participants achieving NASH resolution and no worsening of fibrosis compared to placebo. Participants will remain in the Phase 3 trial for a total of 60 months. Subject to additional discussions with regulatory agencies, approximately 2,000 participants in total are expected to be enrolled, including a cohort of approximately 75 to 100 participants with HIV.

Theratechnologies intends to use the F8 Formulation for the Phase 3 clinical trial in NASH. The Phase 3 trial in NASH will compare the F8 Formulation to a placebo.

In late December 2020, we received a “Study May Proceed” letter for the Phase 3 trial from the FDA with a recommendation that the Company requests a meeting to discuss questions and comments provided on certain aspects of the proposed trial design. We have formally requested a meeting with the FDA to ensure alignment with current regulatory expectations for the late-stage development of treatments for NASH. The Company is assessing its strategy regarding a filing with the EMA to initiate a Phase 3 clinical trial of tesamorelin for the treatment of NASH in the European Union.

Our goal is to initiate the Phase 3 clinical trial by the end of the third quarter of calendar year 2021. The timing of the trial initiation and the final number of patients enrolled are dependent upon any adjustments to the protocol and trial design as recommended by the FDA and EMA. The Company has retained the services of a global, large-scale contract research organization, or CRO, with experience in implementing large and late-stage clinical trials to assist with the execution of its Phase 3 clinical trial in NASH.

SORT1+ Technology™

The Company is currently developing a platform of new proprietary peptides for cancer drug development targeting the sortilin, or SORT1, receptor. SORT1 is expressed in ovarian, triple-negative breast, skin, lung, colorectal and pancreatic cancers, among others. SORT1 plays a significant role in protein internalization, sorting and trafficking, and therefore, is an attractive target for anticancer drug development. Our innovative peptide-drug conjugates, or PDCs, generated through our SORT1+ Technology™ embody distinct pharmacodynamic and pharmacokinetic properties that differentiate them from traditional chemotherapy. In contrast to traditional chemotherapy, our proprietary PDCs are designed to enable selective delivery of certain anticancer drugs within the tumor microenvironment, and more importantly, directly inside sortilin positive cancer cells.

Our SORT1+ Technology™ was acquired in February 2019 as part of the acquisition of Katana Biopharma, Inc., or Katana. Through the acquisition, Theratechnologies obtained the worldwide rights to this platform based on an exclusive royalty-bearing license entered into between Katana and Transfer Plus L.P.

Preclinical *in vivo* data demonstrated that our SORT1+ Technology™ improved anti-tumor activity and reduced neutropenia and systemic toxicity. It also was shown in preclinical models to bypass the multidrug resistance protein 1, or MDR1; also known as P-glycoprotein, one of the mechanisms of chemotherapy drug resistance. In addition, our SORT1+ Technology™ demonstrated activity in preclinical models against the formation of vasculogenic mimicry, or VM, a mechanism also associated with cancer resistance. *In vivo* preclinical toxicity data have also demonstrated that TH1902, our lead PDC

(docetaxel conjugate), could be administered at three times the maximum tolerated dose, or MTD, of docetaxel alone. The Company expects to present additional scientific data supporting these findings at scientific meetings to be held in 2021.

In December 2020, the Company filed an IND application with the FDA for the Phase 1 first-in-human clinical trial evaluating TH1902 for the treatment of various cancers. The proposed Phase 1 clinical trial design includes a dose escalation study to evaluate the safety, pharmacokinetics, MTD and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Once the MTD is determined, we expect a total of 40 additional patients will be enrolled to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers where it has been estimated that the sortilin receptor is expressed in 40% to 90% of cases.

In January 2021, we received a “Study May Proceed” letter from the FDA for the Phase 1 trial of TH1902. The Phase 1 trial is expected to be initiated in the second quarter of calendar year 2021 and is designed to identify a recommended dose for Phase 2 development. The Company plans to retain the services of a global, large-scale CRO to assist with the conduct of our Phase 1 clinical trial. The detailed study protocol is available at ClinicalTrials.gov under the identifier number: NCT04706962.

In February 2021, we received fast track designation from the FDA for TH1902 as a single agent for the treatment of patients with sortilin positive recurrent advanced solid tumors that are refractory to standard therapy.

Preclinical research is ongoing in melanoma using TH1902. In addition, further preclinical research activities are being conducted using TH1904, our second investigational PDC (doxorubicin conjugate). *In vitro* and *in vivo* experiments using TH1904 have demonstrated results similar to those obtained with TH1902 and support the development of additional investigational compounds using our SORT1+ Technology™ that may help in the fight against cancer.

Ibalizumab for HIV

A study evaluating an intravenous, or IV, push formulation of Trogarzo® is currently being conducted by TaiMed. Enrollment in this study is now complete and TaiMed expects to complete the trial in the third quarter of 2021. Theratechnologies and TaiMed are also planning to evaluate an intramuscular, or IM, method of administration of Trogarzo®. Enrollment for the IM study is expected to begin in the first half of 2021. Under the terms of the TaiMed Agreement, we are entitled to commercialize the new methods of administration of Trogarzo® if, and when, approved.

In connection with the September 2019 approval of Trogarzo® in Europe, the EMA has requested a post-authorization efficacy study, or Registry, to be conducted to evaluate the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals. The enrollment of patients in this study is expected to begin in late 2021. The Company is also required to conduct a pediatric investigation plan, or PIP, to evaluate Trogarzo® in children aged 6 to <18 years old. The PIP will be comprised of two studies with the first study expected to begin in the second half of 2021.

2021 BUSINESS STRATEGY AND OBJECTIVES

Our 2021 Business Strategies and Objectives are as follows:

- Continue to grow our revenues in the United States from increased sales of *EGRIFTA SV*® and Trogarzo®
- Successfully obtain reimbursement for Trogarzo® in key European countries and launch Trogarzo® in some of these countries
- Initiate a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH by the end of the third quarter of calendar year 2021
- Initiate a Phase 1 clinical trial evaluating TH1902 for the treatment of various cancer types in the second quarter of calendar year 2021
- Seek and pursue potential product acquisitions, in-licensing transactions or other opportunities complementary to our business
- Manage our financial position to ensure we can successfully execute on our 2021 business strategy and objectives

Fourth-Quarter and Fiscal 2020 Revenue Highlights

(in thousands of dollars)

| | Three-month periods ended November 30, | | % change | Twelve-month periods ended November 30, | | % change |
|---|--|-----------------|--------------|---|-----------------|-------------|
| | 2020 | 2019 | | 2020 | 2019 | |
| <i>EGRIFTA</i> ®, <i>EGRIFTA SV</i> ® net sales | 10,751 | 8,731 | 23.1% | 35,399 | 35,520 | -- |
| Trogarzo® net sales | 8,372 | 7,669 | 9.2% | 30,654 | 27,696 | 10.7% |
| Revenue | \$19,123 | \$16,400 | 16.6% | \$66,053 | \$63,216 | 4.5% |

Fourth-Quarter Fiscal 2020 Financial Results

Consolidated revenue for the three months ended November 30, 2020 amounted to \$19,123,000 compared to \$16,400,000 for the same period last year, representing an increase of 16.6%.

For the fourth quarter of Fiscal 2020, sales of *EGRIFTA SV*® reached \$10,751,000 compared to \$8,731,000 in the fourth quarter of the prior year, representing an increase of 23.1%.

In the fourth quarter of Fiscal 2020, Trogarzo® sales amounted to \$8,372,000 compared to \$7,669,000 for the same quarter of 2019, representing an increase of 9.2%.

Cost of Sales

For the three-month period ended November 30, 2020, cost of sales was \$6,650,000 compared to \$6,989,000 in the comparable period of Fiscal 2019. Cost of goods sold was \$5,190,000 compared to \$5,754,000 for the same period last year. The decrease in cost of goods sold was mainly due to lower cost of goods for *EGRIFTA SV*® compared to *EGRIFTA*® and a lower transfer price for Trogarzo® given the achievement of a predetermined of net sales of the product on the U.S. market.

Cost of sales included an amortization of \$1,220,000 in the fourth quarter of 2020 and 2019 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, 2020 amounted to \$6,795,000 compared to \$3,877,000 in the comparable period of Fiscal 2019. The increase during the fourth quarter of Fiscal 2020 was largely due to the development of our oncology platform, the F8 Formulation and multi-dose pen injector, and spending related to the development of tesamorelin for the treatment of NASH in the general

population as well as regulatory expenses and increased medical education initiatives in Europe in preparation for the Trogarzo® launch.

Selling Expenses

Selling expenses in the three-month period ended November 30, 2020 amounted to \$6,532,000 compared to \$7,673,000 in the comparable period of Fiscal 2019.

The decrease in selling expenses is largely associated with lower spending in Europe given a shift to spending related to medical affairs, lower Trogarzo® promotion spending as well as lower headcount in our field sales force.

The amortization of the intangible asset value established for the *EGRIFTA*®, *EGRIFTA SV*® and Trogarzo® commercialization rights in North America was also included in selling expenses. We recorded an expense of \$795,000 in the fourth quarter of Fiscal 2020 compared to \$642,000 for the same period of Fiscal 2019.

General and Administrative Expenses

General and administrative expenses in the fourth quarter of Fiscal 2020 amounted to \$3,255,000, which was relatively in line with \$3,258,000 reported in the same period of Fiscal 2019.

Finance Income

Finance income, consisting of interest income, for the three-month period ended November 30, 2020 was \$21,000 compared to \$217,000 in the comparable quarter of Fiscal 2019. Lower finance income was a reflection of our lower liquidity position during the fourth quarter of Fiscal 2020 compared to the same period of Fiscal 2019.

Finance Costs

Finance costs for the fourth quarter of Fiscal 2020 were \$1,445,000 compared to \$1,275,000 for the same quarter of Fiscal 2019. As previously stated, finance costs are mostly comprised of interest on the 5.75% convertible unsecured senior notes, or Notes, issued on June 19, 2018.

Finance costs also included accretion expense, which was \$548,000 for the fourth quarter of Fiscal 2020 compared to \$440,000 for the same period last year. Accretion expense was mainly associated with the Notes.

Adjusted EBITDA

Adjusted EBITDA for the fourth quarter of Fiscal 2020 was \$(1,417,000) compared to \$(3,217,000) in same period of Fiscal 2019. See “Non-IFRS Financial Measures” below.

The variation from Q4 2019 to Q4 2020 was mainly due to higher net sales, higher gross margins and lower selling expenses, which was offset by higher spending on research and development activities in the fourth quarter of 2020.

Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$5,549,000, or \$0.07 per share, in the fourth quarter of Fiscal 2020 compared to \$6,445,000, or \$0.08 per share, in the fourth quarter of Fiscal 2019.

Financial Position

We ended the fourth quarter of Fiscal 2020 with \$20,768,000 in cash, bonds and money market funds.

For the three-month period ended November 30, 2020, operating activities used \$5,906,000 compared to generating \$2,760,000 in the comparable period of Fiscal 2019.

In the fourth quarter of Fiscal 2020, changes in operating assets and liabilities had a negative impact on cash flow of \$4,402,000. These changes included an increase of \$4,149,000 in accounts receivable, an increase in prepaid expenses of \$2,739,000, which were offset by an increase in accounts payable of \$3,210,000. 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 three-month periods ended November 30, 2020 and November 30, 2019

(in thousands of dollars, except per share amounts)

| | 2020 ¹ | | | | 2019 | | | |
|---|-------------------|---------|---------|---------|---------|---------|---------|---------|
| | Q4 | Q3 | Q2 | Q1 | Q4 | Q3 | Q2 | Q1 |
| Revenue | 19,123 | 14,049 | 17,162 | 15,719 | 16,400 | 16,111 | 15,609 | 15,096 |
| Operating expenses | | | | | | | | |
| Cost of sales | | | | | | | | |
| Cost of goods sold | 5,190 | 4,611 | 5,769 | 5,400 | 5,754 | 5,215 | 5,346 | 4,810 |
| Other production-related costs | 240 | 280 | 391 | 140 | 14 | 1 | 18 | 34 |
| Amortization of other asset | 1,220 | 1,220 | 1,220 | 1,221 | 1,221 | 1,221 | 1,221 | 1,221 |
| R&D | 6,795 | 4,183 | 3,622 | 3,419 | 3,877 | 2,152 | 2,285 | 2,527 |
| Selling | 6,532 | 7,025 | 6,941 | 6,361 | 7,673 | 6,389 | 6,972 | 5,448 |
| General and administrative | 3,255 | 2,699 | 3,706 | 2,570 | 3,258 | 1,772 | 1,784 | 1,516 |
| Total operating expenses | 23,232 | 20,018 | 21,649 | 19,111 | 21,797 | 16,750 | 17,626 | 15,556 |
| Finance income | 21 | 32 | 80 | 166 | 217 | 253 | 292 | 335 |
| Finance costs | (1,445) | (831) | (1,399) | (1,318) | (1,275) | (1,253) | (1,449) | (1,103) |
| Income taxes | (16) | - | - | - | - | - | - | - |
| Net loss | (5,549) | (6,768) | (5,806) | (4,544) | (6,455) | (1,639) | (3,174) | (1,228) |
| Basic and diluted loss per share | (0.07) | (0.09) | (0.08) | (0.06) | (0.08) | (0.02) | (0.04) | (0.02) |

1 The Company adopted IFRS 16 – Leases, using the modified retrospective approach, effective for Fiscal 2020, beginning on December 1, 2019. Accordingly, comparative figures for Fiscal 2019 have not been restated and continue to be reported under IAS 17-. See note 1 in the Audited Financial Statements.

Factors Affecting the Variability of Financial Results

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 research and development expenses in 2020 were associated with the development of our product pipeline.

Fiscal Year 2020 Financial Results

Consolidated revenue for fiscal year ended November 30, 2020 was \$66,053,000 compared to \$63,216,000 for the same period last year, representing an increase of 4.5%.

For the fiscal year ended November 30, 2020, sales of *EGRIFTA*® and *EGRIFTA SV*® reached \$35,399,000 compared to \$35,520,000 for the same period last year.

In the fiscal year ended November 30, 2020, Trogarzo® sales were \$30,654,000 compared to \$27,696,000 for the same period last year, representing an increase of 10.7%.

Cost of Sales

For the year ended November 30, 2020, cost of sales was \$26,902,000 compared to \$26,076,000 in the comparable period of Fiscal 2019. Cost of sales included cost of goods sold that amounted to \$20,970,000 in Fiscal 2020 compared to \$21,125,000 in Fiscal 2019. The decrease in cost of goods sold was mainly due to lower cost of goods for *EGRIFTA SV*® compared to *EGRIFTA*® and a lower transfer price for Trogarzo® in the fourth quarter of Fiscal 2020 given the achievement of a predetermined amount of net sales of the product on the U.S. market.

R&D Expenses

R&D expenses were \$18,019,000 for Fiscal 2020 compared to \$10,841,000 for Fiscal 2019. The increase in R&D expenses was largely due to the development of our oncology platform, the F8 Formulation and multi-dose pen injector, spending related to the development of tesamorelin for the treatment of NASH in the general population as well as regulatory expenses and increased medical education initiatives in Europe in preparation for the Trogarzo® launch.

Selling Expenses

Selling expenses for the fiscal year ended November 30, 2020 were \$26,859,000 compared to \$26,482,000 for the same period in Fiscal 2019.

General and Administrative Expenses

General and administrative expenses for the fiscal year ended November 30, 2020 were \$12,230,000 compared to \$8,330,000 for the same period in Fiscal 2019. The increase over the same period last year was due to the transition to a new President and Chief Executive Officer, additional expenses incurred in Fiscal 2020 as a result of the listing of our common shares on the NASDAQ and a ramp up of administrative activities in Europe in preparation for the Trogarzo® launch.

Finance Income

Finance income, consisting of interest income, for the fiscal year ended November 30, 2020 was \$299,000 compared to \$1,097,000 in Fiscal 2019. Lower finance income during Fiscal year 2020 was primarily related to a lower average liquidity position.

Finance Costs

Finance costs for the fiscal year ended November 30, 2020 were \$4,993,000 compared to \$5,080,000 in Fiscal 2019. Finance costs in Fiscal 2020 mostly represented interest of \$3,306,000 on the Notes, compared to \$3,317,000 in Fiscal 2019.

Finance costs also included an accretion expense, which amounted to \$2,056,000 during Fiscal 2020 compared to \$1,673,000 during Fiscal 2019.

Adjusted EBITDA

Adjusted EBITDA for Fiscal 2020 was \$(7,093,000) compared to \$323,000 in Fiscal 2019, reflecting increased investments towards building our infrastructure in Europe, increased R&D expenses and higher general and administrative expenses. 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 \$22,667,000, or \$0.29 per share, in Fiscal 2020 compared to \$12,496,000, or \$0.16 per share, in Fiscal 2019.

Selected Annual Information

(in thousands of dollars, except per share amounts)

| Years ended November 30 | 2020 | 2019 | 2018 |
|---|----------|----------|---------|
| Revenue | 66,053 | 63,216 | 45,217 |
| Selling expenses | 26,859 | 26,482 | 21,693 |
| Research and development expenses | 18,019 | 10,841 | 7,994 |
| General and administrative expenses | 12,230 | 8,330 | 5,828 |
| Adjusted EBITDA ¹ | (7,093) | 323 | 1,664 |
| Net loss | (22,667) | (12,496) | (4,700) |
| Loss per share: Basic and diluted | (0.29) | (0.16) | (0.06) |
| Cash, bonds and money market funds | 20,768 | 41,244 | 53,888 |
| Total assets | 100,142 | 117,555 | 111,116 |
| Long-term obligations (including current portion) | 4,666 | 7,987 | — |
| Lease liabilities | 2,980 | — | — |
| Convertible unsecured senior notes | 52,403 | 50,741 | 49,233 |

1 See "Non-IFRS Financial Measures" below.

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 SV*[®] 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 2020, cash flow used in operating activities was \$13,554,000 compared to \$3,391,000 in Fiscal 2019.

In Fiscal 2020, changes in operating assets and liabilities negatively affected cash flow by \$6,274,000 compared to \$3,662,000 in Fiscal 2019. Those changes are directly related to an increase in our commercial and R&D activities.

During Fiscal 2020, we paid \$3,306,000 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 first payment of \$3,500,000 was made in July 2019 and the second payment was made in June 2020.

As at November 30, 2020, cash, bonds and money market funds amounted to \$20,768,000 compared to \$41,244,000 at November 30, 2019. Available cash is invested in highly liquid fixed income instruments including governmental, municipal and paragonovernmental organizations, high-grade corporate bonds and money market funds.

On January 19, 2021, the Company completed a public offering for the sale and issuance of 16,727,900 units of the Company for a gross cash consideration of \$46,002,000 including the full exercise of the over-allotment option. Share issue costs are estimated at \$3,334,000 resulting in net proceeds of \$42,668,000.

Each unit is comprised of one common share of the Company and one-half of one common share purchase warrant of the Company (each whole warrant, a "Warrant"). Each Warrant entitles the holder to purchase one common share of the Company at an exercise price of \$3.18 until January 19, 2024.

Our current cash, bond and money market funds will be sufficient to fund the Company's operations for at least the next twelve months from the balance sheet date.

Commitments

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Contractual obligations

The following table lists as of November 30, 2020 information with respect to the Company's known contractual obligations.

(in thousands of dollars)

| Contractual Obligations | Total | Less than 1 Year | 1 to 3 Years | 3 to 5 Years | More than 5 years |
|--|------------------|---------------------|------------------|-----------------|----------------------|
| Convertible unsecured senior notes, including interest | 67,419 | 3,306 | 64,113 | — | — |
| Lease Liabilities | 3,640 | 621 | 1,267 | 1,752 | — |
| Purchase Obligations (1) | 15,845 | 15,845 | — | — | — |
| Other Long-Term Liabilities (2) | 5,000 | 5,000 | — | — | — |
| Total | \$ 91,904 | \$ 24,772 | \$ 65,380 | \$ 1,752 | \$ — |

(1) The Company has long-term procurement agreements with third party suppliers in connection with the commercialization of *EGRIFTA SV*[®] and Trogarzo[®]. As at November 30, 2020, the Company had outstanding purchase orders and minimum payments under these agreements amounting to \$14,042,000 for the manufacture of Trogarzo[®], *EGRIFTA SV*[®] and for various services. The Company also had research commitments and outstanding clinical material purchase orders amounting to \$586,000 in connection with its oncology platform and \$1,217,000 in connection with the F8 Formulation and the Pen developed for the F8 Formulation.

(2) Other Long-Term Liabilities comprise long-term obligations under commercialization rights agreement.

Credit facility

The Company 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 Company.

As at November 30, 2020 and 2019, the Company did not have any borrowings outstanding under this credit facility.

License agreement

On February 4, 2020, the Company entered into an amended and restated license agreement with MGH as amended on April 15, 2020, in order to benefit from its assistance and knowledge for the development of tesamorelin for the potential treatment of NASH in the general population. Under the terms of the amended agreement, 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 MGH related to the development of tesamorelin and to pay a low single-digit royalty on all sales of *EGRIFTA*[®] and *EGRIFTA SV*[®] 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 any fatty liver disease, including NASH in the general population.

Post-Approval Commitments

In connection with the approval of Trogarzo[®] in Europe, we are required to conduct a PIP and a Registry. The PIP is comprised of two studies: the first one consists in evaluating the pharmacokinetics, pharmacodynamics, safety and tolerability of Trogarzo[®] in children from 6 to less than 18 years of age with HIV-1 infection in order to provide pharmacokinetics and pharmacodynamics data to support the extrapolation of efficacy

from adults; and the second study is a modelling and simulation study to evaluate the use of Trogarzo® in the treatment of HIV-1 infection resistant to at least 1 agent in 3 different classes in children from 6 to less than 18 years of age. The Registry consists primarily in evaluating the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo® treatment *versus* matched patients not receiving Trogarzo®. The study comprising the Registry should be conducted over a five-year period. The cost of the Registry, estimated to be approximately 4,000,000 Euros, will be borne as to 52% by TaiMed and as to 48% by us.

Milestones

Reference should be made to Note 12 (Intangible Assets) to the Audited Financial Statements for a description of all potential commercial milestones payable by the Company.

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 27 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 \$10,947,000 (2019: \$9,538,000), all of which were aged under 60 days. There was nil recorded as bad debt expense for the years ended November 30, 2020 and 2019. 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 (2020: \$8,031,000; 2019: \$12,583,000). As at November 30, 2020, 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 24, 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 US\$, primarily cash, sale of goods and expenses incurred in CA\$ and Euro.

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 US\$ 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 CA\$ or Euro denominated obligations.

The following table presents the significant items in the original currencies exposed to currency risk as at November 30, 2020 and 2019.

(in thousands)

| | 2020 | | 2019 | |
|---|----------------|----------------|--------------|------------|
| | CA\$ | EURO | CA\$ | EURO |
| Cash | 871 | 36 | 740 | 533 |
| Bonds and money market funds | 821 | - | 6,982 | - |
| Trade and other receivables | 522 | 1,052 | 328 | 447 |
| Tax credits and grants receivable | 942 | 25 | - | - |
| Accounts payables and accrued liabilities | (4,937) | (4,496) | (5,101) | (793) |
| Lease liabilities | (2,109) | (1,138) | - | - |
| Total exposure | (3,890) | (4,521) | 2,949 | 187 |

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The following exchange rates are those applicable as at November 30, 2020 and 2019 to:

| | Average rate | 2020 | | 2019 | |
|-------------|-----------------|------------------------|-----------------|------------------------|-----------------|
| | | Reporting date rate | Average rate | Reporting date rate | Average rate |
| CA\$ – US\$ | 0.7445 | 0.7695 | 0.7524 | 0.7530 | |
| Euro – US\$ | 1.1325 | 1.1928 | 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 CA\$ or the Euro would have a positive impact on net earnings as follows, assuming that all other variables remained constant.

(in thousands)

| | 2020 | | 2019 | |
|-----------------|-------|-------|------|------|
| | CA\$ | EURO | CA\$ | EURO |
| Positive impact | (195) | (226) | 147 | 9 |

An assumed 5% weakening of the CA\$ 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 (loss).

Based on the value of the Company's short and long term bonds as at November 30, 2020, an assumed 0.5% decrease in market interest rates would have increased the fair value of these bonds and the accumulated other comprehensive income (loss) by

approximately nil (2019: \$14,000); 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, 2020 of \$28,124,000 (2019: \$39,032,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately \$141,000 (2019: \$195,000); 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 and long-term obligations approximate their fair value because of their relatively short period to maturity.

Bonds and money market funds and derivative financial assets and financial 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 senior notes, including the equity portion, as at November 30, 2020 was approximately \$43,125,000 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 28 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. 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.

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 allowances

Management uses judgment in estimating provisions for sale allowances such as cash discounts, returns, rebates and chargebacks. The product revenue we recognize quarter over quarter is net of these estimated allowances. Such estimates require the need to make estimates about matters that are inherently uncertain. The Company's estimates are based on our historical claims, as supplemented by management's judgment (see Notes 2 (Revenue recognition) and 3 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.

Recent Changes in Accounting Standards

Initial application of new or amended accounting standards

(a) Leases

In January 2016, the IASB issued IFRS 16, *Leases*, which replaced IAS 17, *Leases*. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract, the customer (lessee) and the

supplier (lessor). IFRS 16 eliminates the classification of leases as either operating leases or finance leases, 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.

The Company has adopted IFRS 16 using the modified retrospective transition approach, with the effect of initially applying this standard recognized at the date of initial application, i.e. December 1, 2019. Under this method, the Company elected to measure right-of-use of asset as equal to lease liability, adjusted for amounts previously recorded for deferred lease inducements or prepaid rent as at the date of adoption. Accordingly, the cumulative effect of initially applying IFRS 16 is nil on the opening balance of deficit as at December 1, 2019. The comparative information has not been restated, i.e. it is presented, as previously reported, under IAS 17 and related interpretations.

Transition options and practical expedients

The Company has elected to apply the following transition options and practical expedients available under IFRS 16:

- Lease definition: to grandfather the assessment of which transactions are leases on the date of initial application. Accordingly, the Company applied IFRS 16 only to contracts that were previously identified as leases under IAS 17 and IFRIC 4, *Determining whether an Arrangement Contains a Lease*, and applied the definition of leases under IFRS 16 only to contracts entered on or after the date of initial application; and
- Short-term leases and leases of low-value items recognition exemptions: related lease payments are recognized as an expense on a straight-line basis or another basis if that basis is more representative.

Impact of adopting IFRS 16

The most significant impact as a result of adopting IFRS 16 related to the accounting for the Company's operating leases, since the nature of expenses related to most of the Company's leases changed as IFRS 16 replaced the straight-line operating lease expense with an amortization charge for right-of-use assets and interest expense on lease liabilities.

Under IAS 17, the Company classified each of its leases at the inception date as either a finance lease or an operating lease, based on the extent to which risks and rewards of ownership were transferred to the Company. The Company's leases were classified as operating leases as they did not transfer substantially all the risks and rewards of ownership to the Company. Lease payments related to the Company's operating leases were recognized as rent expense in general and administrative expenses, selling expenses and research and development expenses in the consolidated statements of net loss and comprehensive loss on a straight-line basis over the lease term and presented as part of cash flows from operating activities in the consolidated statements of cash flows. Deferred lease inducements were recognized under other liabilities, in the consolidated statement of financial position as at November 30, 2019.

Upon adoption of IFRS 16, the Company recognized right-of-use assets for leases previously classified as operating leases. Right-of-use assets were measured for an amount equal to the lease liability adjusted for deferred lease inducements. Lease liabilities were measured at the present value of the remaining lease payments on a discounted basis, using the incremental borrowing rate at the date of initial application.

The following table summarizes the impacts of adopting IFRS 16 on the Company's consolidated statement of financial position as at December 1, 2019:

(in thousands of dollars)

| Impact of adopting IFRS 16 as at December 1, 2019 | Increase (decrease) |
|--|--------------------------------|
| Assets | |
| Non-current assets: | |
| Right-of-use of assets | \$ 2,954 |
| Total assets | \$ 2,954 |
| Liabilities | |
| Non-current liabilities: | |
| Lease liabilities | \$ 3,192 |
| Other liabilities | (238) |
| Total liabilities | \$ 2,954 |

(i) Lease liabilities of \$3,192 and related right-of-use assets of \$2,954 were recognized and presented separately on the consolidated statement of financial position. There was no adjustment from the adoption of IFRS 16 on the opening deficit as at December 1, 2019 due to the Company's choice of transition method.

(ii) Deferred lease inducements related to previous operating leases were derecognized.

Reconciliation of operating lease commitments to lease liabilities recognized

When measuring lease liabilities, the Company discounted lease payments using its incremental borrowing rate as at December 1, 2019. The weighted average incremental borrowing rate applied as at December 1, 2019 was 7.1%. The lease liabilities as at December 1, 2019 can be reconciled to the operating lease commitments as at November 30, 2019 as follows:

(in thousands of dollars)

| Reconciliation of operating lease commitment to operating lease liabilities | |
|---|----------|
| Operating lease commitments as at November 30, 2019 | \$ 4,035 |
| Effect of discounting | (843) |
| Discounted lease liabilities as at December 1, 2019 | \$ 3,192 |

Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after December 1, 2020 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these consolidated financial statements.

The following amended standards and interpretations are not expected to have a significant impact on the Company's consolidated financial statements:

- Amendments to References to Conceptual Framework in IFRS, and;
- Definition of Material (Amendments to IAS 1, *Presentation of Financial Statements*, and IAS 8, *Accounting Policies, Changes in Accounting Estimates and Errors*).

Outstanding Securities Data

As at February 24, 2021, the number of common shares issued and outstanding was 93,841,311 while outstanding options granted under our stock option plan were 3,206,193. We also had \$57,500,000 aggregate principal amount of Notes due June 30, 2023 issued and outstanding as a result of the public offering of those notes closed on June 19, 2018. 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, 2020. 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, 2020, 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 2020 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, 2020, our internal controls over financial reporting were appropriately designed and operating effectively.

Changes in Internal Control over Financial Reporting

There was no change in our internal controls over financial reporting that occurred during the period from September 1st, 2020 to November 30, 2020 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 prior to the adoption of IFRS-16, 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 | | |
|--|--|----------------|---------------------------|------------|--------------|
| | 2020 | 2019 | 2020 ¹ | 2019 | 2018 |
| Net loss | (5,549) | (6,455) | (22,667) | (12,496) | (4,700) |
| Add (deduct): | | | | | |
| Depreciation and amortization | 2,192 | 1,930 | 8,520 | 7,495 | 4,230 |
| Lease inducement and amortization | - | 5 | - | 238 | - |
| Finance costs | 1,445 | 1,275 | 4,993 | 5,080 | 3,016 |
| Finance income | (21) | (217) | (299) | (1,097) | (608) |
| Income taxes (recovery) | 16 | - | 16 | - | (1,269) |
| Share-based compensation for stock option plan | 259 | 232 | 1,427 | 1,087 | 851 |
| Write-down of inventories | 241 | 13 | 917 | 16 | 144 |
| Adjusted EBITDA | (1,417) | (3,217) | (7,093) | 323 | 1,664 |

¹ The Company adopted IFRS-16 – Leases, using the modified retrospective approach, effective for Fiscal 2020, beginning on December 1, 2019. Accordingly, comparative figures for Fiscal 2019 have not been restated. As a result, adjusted EBITDA includes adjustments for additional amortization related to the right-of-use asset of \$112,000 and an accretion expense on lease liabilities, included in finance costs, of \$53,000 for the three-months ended November 30, 2020. In addition, adjusted EBITDA includes adjustments for additional amortization related to the right-to-use asset of \$441,000 for the year ended November 30, 2020.

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 COVID-19 PANDEMIC

The COVID-19 pandemic could have a material adverse effect on our 2021 business strategy and objectives, the result of which could adversely impact the sales of our products, our revenues, results of operation and the conduct of our clinical trials and other research and development activities.

The outbreak of COVID-19, its recent variants and any other outbreaks of contagious diseases or other adverse public health developments, could have a material adverse effect on the successful implementation of our 2021 business strategy and objectives, the result of which could materially adversely impact the sales of our products, our revenues, results of operation and the conduct of our clinical trials and other research and development activities. The outbreak of COVID-19 has resulted in governmental authorities implementing numerous measures to try to contain the pandemic, such as travel bans and restrictions, quarantines, shelter in place orders, increased border and port controls and closures, and shutdowns. There is considerable uncertainty regarding such measures and potential future measures.

Since the onset of the COVID-19 pandemic, our office personnel have been working remotely, including our contractual sales force and medical science liaison personnel, and may continue to do so. The impact of working-from-home policies and other confinement measures have resulted in our sales force being unable to meet face-to-face with health care professionals to detail our products. In addition, patients have been unable to visit their physician as originally planned and receive a medicine such as Trogarzo® which requires intravenous infusion. Confinement measures could also slow down the recruitment of patients for our clinical trials and delay their completion.

The COVID-19 pandemic has significantly increased economic and demand uncertainty throughout North America and Europe. It is likely that the current pandemic or further spread of COVID-19 will continue to cause an economic slowdown, and it is possible that the COVID-19 pandemic could cause a global recession despite the introduction of vaccination campaigns. The COVID-19 pandemic has caused disruption and volatility in the global capital markets, which, depending on further developments, could impact our capital resources and liquidity in the future, including the availability of financing on attractive terms, if at all.

The extent to which COVID-19 could impact our operations, financial condition, liquidity, results of operations, and cash flows is still highly uncertain and will depend on future developments, including the safety and efficacy of the recently developed vaccines against the coronavirus and its variants, the access to those vaccines, success of mitigation measures effected by the Company to date and those which may be taken by it in the future.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

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

Our success in generating sales revenue from *EGRIFTA SV*[®] and Trogarzo[®] in the United States and from Trogarzo[®] in European 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 SV*[®] and Trogarzo[®] by third-party payors;
- to obtain reimbursement coverage for Trogarzo[®] in major European countries;
- to maintain the registration of *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 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) and in Europe (Loxess), as well as other specialized third parties; and
- to defend our intellectual property rights regarding tesamorelin 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 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 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 has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. We are also renegotiating some of the terms of our agreement with Jubilant. Although we are in discussions with Bachem and Jubilant, 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. If we fail to renegotiate the terms and conditions of our manufacturing agreement with Bachem, we may no longer be able to rapidly manufacture tesamorelin for *EGRIFTA SV*[®] and for the conduct of our Phase 3 clinical trial in NASH. If we fail to agree on revised terms of our manufacturing agreement with Jubilant, our relationship with Jubilant may deteriorate and Jubilant could decide to terminate our agreement as per the current terms of this agreement governing termination. Despite our current level of inventory of *EGRIFTA SV*[®] and tesamorelin, we may incur a shortage of *EGRIFTA SV*[®] and tesamorelin by the time new manufacturers are qualified.

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 for Trogarzo[®] 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 SV*[®], Trogarzo[®] or any other product we may acquire or in-license 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 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 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.

In the European Territory, we hold a wholesale distribution authorization but do not have any warehouse and structure to store, pack and ship Trogarzo[®]. We do not currently intend to open a warehouse and do not have the infrastructure to carry out the activities set forth above. Therefore, we are relying on Loxxess to carry out these activities. We have not entered into a long-term commercial agreement with Loxxess. The Loxxess Agreement is a one-year term agreement that automatically renews at the end of its term unless a party provides the other with a prior written notice of its intent not to renew such agreement within a certain period of time. Although we have identified other third-party logistic service providers in the European Territory, if the Loxxess Agreement is terminated unilaterally by Loxxess, or if we decide to terminate such agreement, there can be no assurance that we would succeed in entering into agreements with those other third-party logistic service providers on terms satisfactory to us. Our failure to enter into long-term commercial agreements with those third-party logistic service providers would disrupt our supply and distribution chain and would delay the commercialization of Trogarzo[®] in the European

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

The vast majority of our sales, medical service liaison and market access personnel in the United States and in the European Territory dedicated to the commercialization of our products in these territories is provided by Syneos. Syneos provides us with all of the services related to the commercialization of our products, namely sales personnel, medical science liaison personnel, market access 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.

Finally, we will be relying on the services of a CRO for the conduct of our Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population and our Phase 1 clinical trial studying TH1902 in various types of cancer. These CROs will be tasked with the recruitment of patients, negotiations of clinical study agreements with various clinics and the monitoring of those clinics in connection with our clinical trials. If these CROs default on their covenants or are found, for instance, to be in violation of applicable laws, our clinical trials could be delayed and any timelines set forth in our public communications could be wrong. In addition, if these CROs are found to be in violation of applicable laws, any data generated in the course of our clinical trials could be questioned by regulatory agencies and this could lead to a rejection of any data submitted to those regulatory agencies at the time of submitting an sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers 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 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 SV*[®] and Trogarzo[®] in the United States or of Trogarzo[®] in the European Territory if:

- RxCrossroads or Loxxess becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws;
- RxCrossroads or Loxxess 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
- RxCrossroads or Loxxess 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 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 SV[®] and Trogarzo[®] which could result in restrictions in EGRIFTA SV[®]'s or Trogarzo[®]'s label, product recall or withdrawal of any of our products from the market, any of which could materially adversely impact our business and our future business prospects.

New safety issues may arise as *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. 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.

We recently received a notification letter from the FDA requiring us to conduct a post-marketing requirement study to collect prospective data in individuals exposed to Trogarzo[®] during pregnancy to monitor maternal and pregnancy outcomes. This is based on findings from an enhanced pre- and post-natal development study conducted in cynomolgus monkeys administered Trogarzo[®] that had shown potential birth complications for newly born infant monkeys. We are currently in discussion with the FDA regarding the details of this request. It is possible that the request of the FDA may lead to a change in the Trogarzo[®] label resulting in the addition of further safety, contraindication and/or warnings and precautions information. Such warnings could also take the form of a "black box warning".

Previously unknown safety problems could also result in product recalls, or withdrawal of the products from the territory(ies) where they are approved for commercialization. If new

safety issues are discovered, sales of *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 SV® and Trogarzo®.

Market acceptance and sales of *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 SV*® and Trogarzo®.

Sales of *EGRIFTA SV*® and Trogarzo® to patients benefitting from U.S. funded reimbursement programs represent the most important part of our sales. 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 few approved drug products competing directly with our approved products. However, with respect to Trogarzo®, we face competition from the recent approval of fostemsavir in the United States and in the European Union. In addition, 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. With respect to EGRIFTA SV®, we face competition from companies selling human growth hormone, testosterone, insulin sensitizing agents, GLP-1 receptor agonists and sermorelin as those products may be prescribed by physicians. In addition, other approaches to reduce visceral adipose tissue in the abdominal area include coping mechanisms such as lifestyle modification (diet and exercise), switching ARTs or liposuction.

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. We are also aware that a very low number of patients were cured from HIV. 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.

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. Therefore, there can be no assurance that any research and development plan on a product candidate or medical device will result in an approved drug or medical device.

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, a new mode of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our PDCs resulting from our SORT1+ Technology™ platform, will end up generating positive results leading up to an approved formulation, label expansion, new medical device or a new product by a regulatory authority. The failure to develop a new formulation, a new method of treatment, new mode of administration 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 development of tesamorelin for the treatment of NASH in the general population is subject to an agreement with the FDA on the final design of our Phase 3 clinical trial, the approval of the Company's proposed Phase 3 clinical trial design by European regulatory agencies, meeting of the Company's Phase 3 clinical trial endpoints and approval by those regulatory agencies of the Company's clinical study results. If the Company is unable to agree with the FDA on a final Phase 3 clinical trial design or with European regulatory agencies for such trial design, or if the Company is unable to meet the endpoints of its Phase 3 clinical trial or does not receive approval of tesamorelin for the treatment of NASH in the general population, its potential long-term revenues and prospects will be materially adversely affected.

Although the FDA has delivered to the Company a "Study May Proceed" letter for its Phase 3 clinical trial for the development of tesamorelin for the treatment of NASH, such letter included questions, comments and a recommendation that the Company requests a meeting to discuss those questions and comments on certain aspects of the proposed trial design. The Company has now requested such meeting. The European regulatory authorities have not approved the Company's Phase 3 clinical trial to develop tesamorelin for the treatment of NASH in the general population as the Company has not filed any documentation seeking such approval.

The Company's initial strategy is to have a Phase 3 clinical trial design that is accepted by both the FDA and the European regulatory agencies. However, there can be no guarantee that the Company's clinical trial design will be accepted by both agencies even if the FDA and the Company agreed on a trial design. The approval by the regulatory authority of one country does not guarantee that a similar approval will be obtained from regulatory authorities of other countries. If the Company is unable to come to an agreement on a similar clinical trial design with the FDA and European regulatory agencies, the Company may forego the conduct of its Phase 3 clinical trial in one of those jurisdictions and materially decrease the likelihood that the results obtained from the conduct of its Phase 3 clinical trial in one territory get recognized in the territory where no agreement was entered into with respect to such clinical trial design. As a result, even though there can be no guarantee that a regulatory authority will approve any sBLA, or the equivalent thereof, filed by the Company seeking approval of tesamorelin for the treatment of NASH, the Company may not obtain approval from the regulatory authority located in the territory where the Phase 3 clinical trial design was not approved and, therefore, limits its ability to expand sales of its product in such territory. If the Company is unable to maximize the number of territories in which it can sell its products, this would have a material adverse effects on its revenues, financial results and long-term growth prospects.

In addition, the timelines to initiate the Company's Phase 3 clinical trial will be dependent upon any adjustment the FDA may require the Company to make to its proposed clinical trial design and the negotiation, if any, to be had with European regulatory authorities once a proposed Phase 3 clinical trial design have been filed with such authorities to harmonize it to that agreed to with the FDA.

The beginning or completion of clinical studies may be delayed or prevented for several reasons, including, among others:

- Adjustments required to the proposed Phase 3 clinical trial design resulting from the meeting with the FDA may result in additional costs and/or delays in the anticipated timing for the initiation of the trial;
- The European regulatory authority may not approve the Company's Phase 3 clinical trial design or require that amendments be made thereto prior to approving such clinical trial;
- Negative results from the Company's clinical trial resulting in a failure to meet the endpoints of its Phase 3 clinical trial;
- Delays in reaching or failing to reach agreement on acceptable terms with clinical study sites, the terms of which can be subject to considerable negotiation and may vary significantly among different study sites;
- Any breach of the terms of any contract research organization agreement by us or by our third-party suppliers that have responsibility to assist us for the conduct of our clinical trials;
- Inadequate quantity or quality of the F8 Formulation or other materials necessary to conduct the Company's Phase 3 clinical trial;
- Challenges in recruiting and enrolling patients to participate in the Company's Phase 3 clinical trial, such as the confinement measures adopted by regulatory authorities in the context of the COVID-19 pandemic, the proximity of patients to study sites, eligibility criteria to be included in the clinical trial, the nature of the

clinical trial and the competition from other clinical study programs for the treatment of NASH in the general population;

- Severe or unexpected adverse tesamorelin-related drug effects experienced by patients using *EGRIFTA SV*[®] or patients using tesamorelin during the Phase 3 clinical trial;
- Regulatory agencies requiring the Company to conduct additional clinical studies prior to approving its sBLA after review of its Phase 3 clinical trial results;
- Regulatory agencies disagreeing with the Company's interpretation of the data resulting from its Phase 3 clinical trial, or changing the requirements for approval even after they have approved the Company's Phase 3 clinical trial design;
- Difficulties in retaining patients who have enrolled in the Company's Phase 3 clinical trial but who may be prone to withdraw due to rigours of the clinical trial, lack of efficacy, side effects, personal issues or loss of interest; and
- Lack of funds or financing options to conduct a clinical trial such as the study of tesamorelin for the treatment of NASH in the general population.

In addition, clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. The Company may decide to suspend or terminate its Phase 3 clinical trial or regulatory agencies could order the Company to do so for several reasons, including, among others:

- Failure to conduct the clinical trial in accordance with the regulatory requirements of the Company's study protocol; and
- Inspections of the clinical study operations or study sites by regulatory agencies that would reveal deficiencies or violations requiring the Company to undertake corrective actions (to the extent any are available).

The Company's inability to obtain approval of its final Phase 3 clinical trial design, a delay in the conduct of its Phase 3 clinical trial or the suspension or termination of such trial could materially adversely affect our business prospects and our potential long-term revenues derived from the sale of tesamorelin for the treatment of NASH in the general population.

We will require substantial capital to pursue the development of our product pipeline, including the conduct of our Phase 3 clinical trial for the development of tesamorelin for the treatment of NASH in the general population and the development of TH1902 in various types of cancer. If we are unable to generate cash flow from our commercial operations or are unable to access capital if, and when, needed, we may have to delay, suspend or cancel our Phase 3 clinical trial, Phase 1 clinical trial or the development of any of our product candidates, the result of which would have a material adverse effect on our long-term growth, potential revenue growth and our business prospects.

The development of pharmaceutical products is very costly and capital intensive.

Our proposed Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population will require the enrollment of over 2,000 patients and our study will be conducted over many years. The costs associated with the enrollment of patients, the monitoring of a study and the monitoring of clinical sites are expensive and such costs are

directly proportional to the number of patients enrolled in a study over the duration of such study. Therefore, we expect the Phase 3 clinical trial to cost multi-millions of dollars.

To the extent that the results obtained in our Phase 1 clinical trial are positive, the development of TH1902 could accelerate, especially as a result of the recent decision of the FDA to grant fast track designation to TH1902. The number of patients that we may have to enroll to move to a Phase 2 clinical trial would be based, among other things, on our development strategy. For instance, if we were to decide to study TH1902 concurrently, in various types of cancer, we could have to enroll a large number of patients. Such a Phase 2 clinical trial could be very expensive and require capital.

We intend to fund the development of our Phase 3 clinical trial, Phase 1 clinical trial and the development of other product candidates through cash flows resulting from the sales of our products and through the use of the net proceeds from the Offering. However, if our sales do not generate sufficient cash flows, or if we incur delays in recruiting patients or are faced with unexpected expenses in the conduct of our operations, we may not have enough cash to fund our research and development activities. In addition, market conditions may not be favorable to resort to public financing and, even if favorable, the terms of such financing may not be attractive to us. If we are unable to generate sufficient cash flows from our operations or do not have access to public or private financing to fund our research and development activities, we may have to delay, suspend or cancel the conduct of our clinical trials and the development of our product candidates. Any delay, suspension or cancellation of the development of our product candidates would have a material adverse effect on our long-term growth, potential revenue growth and business prospects.

The development of TH1902 for the potential treatment of various types of cancer is still uncertain since results obtained from preclinical in vivo development work may not be replicated into human subjects. The goal of the Phase 1 clinical trial using TH1902 is to determine the MTD that can be administered to human subjects and various serious adverse side effects are expected to be discovered from the injection of TH1902 in human subjects. If the Company is unable to replicate results obtained from its preclinical work or if patients enrolled in the clinical trial are subject to serious adverse side effects, the Company may have to discontinue its Phase 1 clinical trial. Any interruption or halt in the Company's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology™ platform, reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

Clinical failure can occur at any stage of clinical development. The Company's Phase 1 clinical trial may not replicate results obtained from its preclinical *in vivo* work and we may not be able to determine the MTD into human subjects as a result of difficulty in enrolling patients, patients' responsiveness to TH1902's serious adverse side effects or patients death.

TH1902 is being developed as a potential treatment for severe, various life-threatening types of cancer. The Phase 1 clinical trial will be conducted with patients that will be more prone than the general population to exhibit certain diseases state or adverse events. Some of those patients face a life-threatening situation and may die during our Phase 1

clinical trial. Although the Company expects patients to have serious adverse side effects from the administration of TH1902, it may become difficult to discern whether certain events or symptoms observed in certain patients are directly related to TH1902. In the event of the death of a patient, the Company may have to suspend its Phase 1 clinical trial to determine whether such patient's death is associated with the administration of TH1902. The suspension period could be lengthy since an investigation will be conducted to determine its causation. In the event the death of a patient is found not to be associated with TH1902, which would lead to the continuity of the Company's Phase 1 clinical trial, the FDA may nonetheless require that the Company amend its Phase 1 clinical trial design by imposing various safety measures, the effect of which would be to increase its costs. In addition, the Company may have difficulty enrolling additional patients to resume the trial as a result of such death. The amendment of a Phase 1 clinical trial design, the obligation to add additional safety measures or the difficulty in enrolling additional patients would cause delays and increase the costs to complete the Company's Phase 1 clinical trial. If the death of a patient is found to be related to TH1902, the Company may have to halt or completely cease its Phase 1 clinical trial which could lead to the abandonment of the development of our SORT1+ Technology™ platform. The abandonment of the development of the Company's SORT1+ Technology™ platform would reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

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 the general population and the development of our PDCs resulting from our SORT1+ Technology™ 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 the confinement measures adopted by regulatory authorities in the context of the COVID-19 pandemic, 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 candidates tested in those clinical trials and have a material adverse effect on our long-term growth and prospects.

Regulatory agencies have not approved the F8 Formulation as being bioequivalent to the Company's F1 Formulation. Under such circumstances, the Company may have to conduct additional clinical studies to prove the bioequivalence of the F8 Formulation against the F1 Formulation, resulting in additional capital expenditures and delays in the use of the F8 Formulation.

The Company has conducted studies to assess the bioequivalence of the F8 Formulation against the F1 Formulation. These studies were conducted based on the current FDA

regulation to show the bioequivalence of formulations. The Company has not filed an sBLA with the FDA seeking the approval of the F8 Formulation for commercial use and does not contemplate making such filing before 2022.

In addition, the Company has not manufactured validation batches of the F8 Formulation and is therefore currently unable to determine whether the manufacturing process will be stable and allow the commercial use of the F8 Formulation, even if approved by the FDA as being bioequivalent to the F1 Formulation.

If the FDA does not approve the F8 Formulation as being bioequivalent to the F1 Formulation, the Company would have to conduct additional testing using the F8 Formulation which would delay the time by which the Company could commercialize the F8 Formulation and which would require the Company to incur additional expenses, all of which could adversely affect the Company's financial condition or results of operations. Furthermore, the non-approval of the F8 Formulation would prevent the Company from using the Pen currently under development.

The development of a multi-dose pen injector for the F8 Formulation is risky, and its commercial use is subject to the approval of regulatory agencies. There can be no guarantee that the development of the multi-dose pen injector will be successful or, even if successful, that it will be approved for commercial use by regulatory agencies. The failure to obtain approval of the multi-dose pen injector using the F8 Formulation could reduce our competitive advantage vis-à-vis other potential medicine for the treatment of NASH in the general population and also result in lower sales of tesamorelin approved for the treatment of lipodystrophy in patients living with HIV.

The Company has undertaken through third-party service providers the development of the Pen for the F8 Formulation. Although the Pen is already used with other drugs, some development is required to adapt its delivery system to the F8 Formulation dosing. The development of a device is complex, subject to failure, and there can be no guarantee that it will result in an approved drug-device for commercial use. Any issues encountered in developing the Pen could delay its use in the development of tesamorelin for the treatment of NASH in the general population and reduce the likelihood of such device being approved for use in the treatment of NASH in the general population. Consequently, the Company could have to conduct additional clinical trials using the device and incur unplanned capital expenditures, thereby affecting its financial condition.

The Company could lose its competitive advantage vis-à-vis other potential medicine for the treatment of NASH in the general population if it is unable to develop or obtain approval of the Pen for its F8 Formulation. The Company could also reduce the potential growth of its tesamorelin-related franchise for the treatment of HIV-associated lipodystrophy if it is unable to introduce a Pen using the F8 Formulation for the treatment of such disease. Any delays in getting the Pen approved, or the non-approval thereof, will have a material adverse effect on the Company's sales growth, financial results and business prospects.

Finally, the development of the Pen relies on agreements with single third-party service providers and exposes the Company to the risks faced by these third-party service providers, such as failure by these third parties to comply with applicable laws, the loss of

their operating licenses, the loss of key personnel, a shutdown of their facilities as a result of financial condition, COVID-19 or other *force majeure* issues, as well as their failure to perform their contractual obligations under the agreements with the Company. The occurrence of any of those instances would have a material adverse effect on the Company's business, results of operations and financial condition.

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 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. For instance, the fact that we own patents 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.

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 license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property and to compete with us.

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 FFDCFA, 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 FFDCFA 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 *EGRIFTA SV*[®] and Trogarzo[®] in Canada since none of those products have 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 FFDCRA 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 on 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 SV*[®], Trogarzo[®] or their respective manufacturing processes, withdrawal of *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 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 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 the damages resulting from 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.

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 commercialization plan for Trogarzo® in the United Kingdom, the cost associated with such commercialization and the potential conduct of clinical trials in this country has been impacted as a result of Brexit.

On December 31, 2020, the United Kingdom completed the transition period for its exit from the European Union, or Brexit. This has brought about changes in the registration and regulation of medicinal products intended for sale in the UK and the EU. The UK's regime for regulating the manufacture, sale, licensing and distribution of medicinal products has changed since the end of the Brexit transition period. There is now a developing pathway towards achieving marketing authorization for the sale of medicinal products in both the UK and the EU, and this will increase the overall regulatory burden on us in respect of Trogarzo®. These changes to the regulatory environment may also require us to revamp certain pharmacovigilance protocols for Trogarzo®. Overall, we may incur additional costs that may adversely impact our business, operating results and financial condition. This will require time from the management team to ensure that the appropriate authorization procedures are followed to obtain market access across the relevant regions.

In addition, from January 1, 2021, in order for results obtained from the conduct of clinical trials in EU countries to be acceptable to The Medicines and Healthcare Products Regulatory Agency, or MHRA, either the sponsor or the legal representative of that clinical trial must be established in the UK or in a country on an approved list – this list, which is subject to review every three years, currently includes all countries in the EU. In terms of the data obtained from such clinical trials, the MHRA will accept Qualified Person, or QP, certified products from EU countries if they have been checked by a Responsible Person (Import). However, if the QP for the oversight process is not a UK resident, they will only be able to perform the duties required in respect of the oversight process and will not be authorized to certify products within the UK. Therefore, if we decide to seek approval in the UK, we may need to put in place additional arrangements to achieve certification which 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 commercialization of our products and with the conduct of clinical trials, we must comply with privacy laws of various countries. For instance, 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 continue to build our infrastructure in Europe, we will continue to optimize our systems 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, 2020. Our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*® and Trogarzo® successfully in the United States and Trogarzo® in the European Territory 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 SV*® and Trogarzo® under U.S. Medicare and Medicaid programs and under private-health insurers programs in the

United States. The obtaining of reimbursement of Trogarzo® in key European countries will also impact our capacity to be profitable.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*® and Trogarzo® in the United States. In addition, there is no guarantee that we will be able to successfully launch, commercialize and obtain reimbursement of Trogarzo® in key European countries. 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, 2020, we had negative operating cash flow of \$5,906,000. 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, including our Phase 3 clinical trial studying tesamorelin for the treatment of NASH and our Phase 1 clinical trial studying TH1902 for various types of cancers, 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 SV*[®] and *Trogarzo*[®] in the United States. Syneos has also hired, amongst others, 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 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 actual future payments for allowances for discounts, returns, rebates and chargebacks exceed the estimates the Company made at the time of the sale of its products, its financial position, results of operations, and cash flows may be negatively impacted.

Pursuant to the Company's accounts and revenue recognition policies, the product revenue recognized quarter over quarter by the Company is net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates require subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including the Company, have liberal return policies, sometimes making it difficult to estimate the timing and amount of expected revenues.

A chargeback is the difference between the price the wholesaler pays the Company (wholesale acquisition cost) and the price that the wholesaler's customer pays for the Company's product (contracted customer). The Company's products were subject to certain programs with federal government qualified entities whereby pricing on products is discounted to such entities and results in a chargeback claim to the Company, or for the Company to bill certain qualifying Public Health Service end-users at government-mandated pricing. To the extent that the Company's sales to discount purchasers, such as federal government qualified entities, increases, chargeback claims will also increase. There may be significant lag time between the Company's original sale to the wholesaler and the Company's receipt of the corresponding government chargeback claims from the Company's wholesalers.

The Company's products are subject to state government-managed Medicaid programs, whereby rebates for purchases are issued to participating state governments. These rebates arise when the patient treated with the Company's products is covered under Medicaid. The Company's calculations require the Company to estimate end-user and patient mix to determine which of its sales will likely be subject to these rebates. There is a significant time lag in the Company receiving these rebate notices (generally several

months after its sale is made). The Company's estimates are based on its historical claims from participating state governments, as supplemented by management's judgment.

Although the Company believes that it has sufficient allowances, actual results may differ significantly from its estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on its financial condition, results of operations and cash flows. Such changes to estimates will be made to the financial statements in the period in which the estimate is changed. In addition, the Company's financial position, results of operations and cash flows may be negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates the Company made at the time of the sale of its products

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. Any decline in value or fluctuation in the market price of our common shares could also affect the market price of the Notes and the value of the warrants issued in the Offering.

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 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 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 analysts 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.

Consolidated Financial Statements
(In thousands of United States dollars)

THERATECHNOLOGIES INC.

November 30, 2020 and 2019

THERATECHNOLOGIES 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 statements of financial position of Theratechnologies Inc. (the "Company") as of November 30, 2020 and 2019, the related consolidated statements of net loss and comprehensive loss, changes in equity, and cash flows for the years ended November 30, 2020 and 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, 2020 and 2019, and the financial performance and its cash flows for the years ended November 30, 2020 and 2019, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Change in Accounting Principle

As discussed in Note 1(a) to the consolidated financial statements, the Company has changed its method of accounting for leases as of December 1, 2019, due to the adoption of IFRS 16, *Leases*, using a modified retrospective transition approach.

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 audits. 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 audits 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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 audits 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 audits provide a reasonable basis for our opinion.

A handwritten signature in black ink that reads 'KPMG LLP' with a horizontal line underneath.

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

Montréal, Canada

February 24, 2021

THERATECHNOLOGIES INC.

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

As at November 30, 2020 and 2019

| | Note | November 30, 2020 | November 30, 2019 |
|--|-------|----------------------|----------------------|
| Assets | | | |
| Current assets | | | |
| Cash | | \$ 12,737 | \$ 28,661 |
| Bonds and money market funds | 6 | 8,031 | 11,964 |
| Trade and other receivables | 7 | 12,430 | 10,116 |
| Tax credits and grants receivable | 8 | 755 | - |
| Inventories | 9 | 25,145 | 20,929 |
| Prepaid expenses and deposits | | 5,189 | 3,874 |
| Derivative financial assets | 20(b) | 520 | 637 |
| Total current assets | | 64,807 | 76,181 |
| Non-current assets | | | |
| Bonds and money market funds | 6 | - | 619 |
| Property and equipment | 10 | 865 | 1,071 |
| Right-of-use-assets | 11 | 2,618 | - |
| Intangible assets | 12 | 24,529 | 27,480 |
| Other asset | 13 | 7,323 | 12,204 |
| Total non-current assets | | 35,335 | 41,374 |
| Total assets | | \$ 100,142 | \$ 117,555 |
| Liabilities | | | |
| Current liabilities | | | |
| Accounts payable and accrued liabilities | 14 | \$ 34,815 | \$ 31,173 |
| Provisions | 15 | 1,947 | 2,484 |
| Current portion of long-term obligations | 16 | 4,666 | 3,417 |
| Current portion of lease liabilities | 18 | 425 | - |
| Income taxes payable | | 16 | - |
| Deferred revenue | | 50 | 70 |
| Total current liabilities | | 41,919 | 37,144 |
| Non-current liabilities | | | |
| Long-term obligations | 16 | - | 4,570 |
| Convertible unsecured senior notes | 17 | 52,403 | 50,741 |
| Lease liabilities | 18 | 2,555 | - |
| Other liabilities | 19 | 41 | 266 |
| Total non-current liabilities | | 54,999 | 55,577 |
| Total liabilities | | 96,918 | 92,721 |
| Equity | | | |
| Share capital | 20 | 287,312 | 287,035 |
| Equity component of convertible unsecured senior notes | | 4,457 | 4,457 |
| Contributed surplus | | 12,065 | 10,783 |
| Deficit | | (300,129) | (277,462) |
| Accumulated other comprehensive income (loss) | 20(g) | (481) | 21 |
| Total equity | | 3,224 | 24,834 |
| Commitments | 26 | | |
| Subsequent event | 29 | | |
| Total liabilities and equity | | \$ 100,142 | \$ 117,555 |

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, 2020 and 2019

| | Note | 2020 | 2019 |
|--|-------|--------------------|--------------------|
| Revenue | 3 | \$ 66,053 | \$ 63,216 |
| Operating expenses | | | |
| Cost of sales | | | |
| Cost of goods sold | | 20,970 | 21,125 |
| Other production-related costs | 9 | 1,051 | 67 |
| Amortization of other asset | 13 | 4,881 | 4,884 |
| Research and development expenses net of tax credits of \$296 (2019 – nil) | | 18,019 | 10,841 |
| Selling expenses | | 26,859 | 26,482 |
| General and administrative expenses | | 12,230 | 8,330 |
| Total operating expenses | | 84,010 | 71,729 |
| Loss from operating activities | | (17,957) | (8,513) |
| Finance income | 5 | 299 | 1,097 |
| Finance costs | 5 | (4,993) | (5,080) |
| | | (4,694) | (3,983) |
| Loss before income taxes | | (22,651) | (12,496) |
| Income taxes | | (16) | - |
| Net loss | | (22,667) | (12,496) |
| Other comprehensive income (loss), net of tax | | | |
| Items that may be reclassified to net profit (loss) in the future | | | |
| Net change in fair value of FVOCI financial assets, net of tax | | 14 | 83 |
| Exchange difference on translation of foreign operations | | (516) | 33 |
| | | (502) | 116 |
| Total comprehensive loss | | \$ (23,169) | \$ (12,380) |
| Loss per share | | | |
| Basic and diluted | 20(f) | \$ (0.29) | \$ (0.16) |

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, 2020 and 2019

| | Note | Share capital | | Equity component of convertible unsecured senior notes | Contributed surplus | Deficit | Accumulated other comprehensive income (loss) | Total |
|--|-------|------------------|------------|--|---------------------|--------------|---|-----------|
| | | Number of shares | Amount | | | | | |
| Balance as at November 30, 2018 | | 76,877,679 | 286,828 | 4,457 | 8,788 | (264,966) | (95) | 35,012 |
| Total comprehensive loss | | | | | | | | |
| Net loss | | - | - | - | - | (12,496) | - | (12,496) |
| Other comprehensive income | | | | | | | | |
| Net change in fair value of FVOCI financial assets, net of tax | | - | - | - | - | - | 83 | 83 |
| Exchange differences on translation of foreign operations | | - | - | - | - | - | 33 | 33 |
| Total comprehensive loss | | - | - | - | - | (12,496) | 116 | (12,380) |
| Transactions with owners, recorded directly in equity | | | | | | | | |
| Issuance of common shares of Katana | | 900 | 5 | - | - | - | - | 5 |
| Share-based contingent consideration | | - | - | - | 1,028 | - | - | 1,028 |
| Share-based compensation plan | | | | | | | | |
| Share-based compensation for stock option plan | | - | - | - | 1,059 | - | - | 1,059 |
| Exercise of stock options | | | | | | | | |
| Monetary consideration | | 74,832 | 110 | - | - | - | - | 110 |
| Attributed value | | - | 92 | - | (92) | - | - | - |
| Total contributions by owners | | 75,732 | 207 | - | 1,995 | - | - | 2,202 |
| Balance as at November 30, 2019 | | 76,953,411 | \$ 287,035 | \$ 4,457 | \$ 10,783 | \$ (277,462) | \$ 21 | \$ 24,834 |
| Total comprehensive loss | | | | | | | | |
| Net loss | | - | - | - | - | (22,667) | - | (22,667) |
| Other comprehensive income | | | | | | | | |
| Net change in fair value of FVOCI financial assets, net of tax | | - | - | - | - | - | 14 | 14 |
| Exchange differences on translation of foreign operations | | - | - | - | - | - | (516) | (516) |
| Total comprehensive loss | | - | - | - | - | (22,667) | (502) | (23,169) |
| Share-based compensation plan | | | | | | | | |
| Share-based compensation for stock option plan | | - | - | - | 1,414 | - | - | 1,414 |
| Exercise of stock options | | | | | | | | |
| Monetary consideration | 20(e) | 60,000 | 145 | - | - | - | - | 145 |
| Attributed value | | - | 132 | - | (132) | - | - | - |
| Total contributions by owners | | 60,000 | 277 | - | 1,282 | - | - | 1,559 |
| Balance as at November 30, 2020 | | 77,013,411 | \$ 287,312 | \$ 4,457 | \$ 12,065 | \$ (300,129) | \$ (481) | \$ 3,224 |

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, 2020 and 2019

| | Note | 2020 | 2019 |
|--|--------|-------------|-------------|
| Cash flows from (used in) | | | |
| Operating | | | |
| Net loss | | \$ (22,667) | \$ (12,496) |
| Adjustments for | | | |
| Depreciation of property and equipment | 10 | 247 | 199 |
| Amortization of intangible assets and other asset | 12, 13 | 7,832 | 7,296 |
| Amortization of right-of-use assets | 11 | 441 | - |
| Share-based compensation for stock option plan and stock appreciation rights | | 1,427 | 1,087 |
| Write-down of inventories | 9 | 917 | 16 |
| Change in fair value of derivative financial assets | 20(b) | 166 | 647 |
| Change in fair value of liability related to deferred stock unit plan | 20(b) | (157) | (641) |
| Interest on convertible unsecured senior notes | 5 | 3,306 | 3,317 |
| Interest income | 5 | (299) | (1,097) |
| Accretion expense | 5 | 2,056 | 1,673 |
| Foreign exchange | | (549) | 32 |
| Lease inducements and amortization | | - | 238 |
| | | (7,280) | 271 |
| Change in operating assets and liabilities | | | |
| Trade and other receivables | | (2,253) | 831 |
| Tax credits and grants receivable | | (749) | - |
| Inventories | | (4,872) | (9,861) |
| Prepaid expenses and deposits | | (1,297) | (2,282) |
| Accounts payable and accrued liabilities | | 3,438 | 6,137 |
| Provisions | | (537) | 1,470 |
| Income taxes payable | | 16 | - |
| Deferred revenue | | (20) | 43 |
| | | (6,274) | (3,662) |
| Total cash from used in operating activities | | (13,554) | (3,391) |
| Financing | | | |
| Interest paid on convertible unsecured senior notes | | (3,306) | (3,417) |
| Repayment of long-term obligations | | (3,500) | (3,500) |
| Proceeds from exercise of stock options | | 145 | 110 |
| Payment of lease liability | | (568) | - |
| Total cash used in financing activities | | (7,229) | (6,807) |
| Investing | | | |
| Acquisition of intangible assets | | - | (2,407) |
| Acquisition of property and equipment | 10 | (32) | (1,215) |
| Proceeds from sale of bonds and money market funds | | 4,506 | 2,482 |
| Acquisition of bonds and money market funds | | (59) | (192) |
| Interest received | | 401 | 1,199 |
| Acquisition of derivative financial assets | | (40) | (21) |
| Proceeds from sale of derivative financial assets | | - | 24 |
| Total cash from (used in) in investing activities | | 4,776 | (130) |
| Net change in cash | | (16,007) | (10,328) |
| Cash, beginning of year | | 28,661 | 38,997 |
| Effect of foreign exchange on cash | | 83 | (8) |
| Cash, end of year | | \$ 12,737 | \$ 28,661 |

See Note 22 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, 2020 and 2019

Theratechnologies Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs.

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, Suite 1100, 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, 2021.

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.

Effective December 1, 2019, lease liabilities are measured at present value of lease payments not paid at commencement date. See Note 1(a) below.

Equity-classified share-based payment arrangements are measured at fair value at the grant date pursuant to IFRS 2, *Share-based Payment*.

The methods used to measure fair value are discussed further in Note 25.

Functional and presentation currency

The Company’s functional currency is the United States dollar (“US\$”).

All financial information presented in US\$ 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, 2020 and 2019

1. Basis of preparation (continued)

Initial application of new or amended accounting standards

(a) Leases

In January 2016, the IASB issued IFRS 16, Leases, which replaced IAS 17, Leases. IFRS 16 sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract, the customer (lessee) and the supplier (lessor). IFRS 16 eliminates the classification of leases as either operating leases or finance leases, 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.

The Company has adopted IFRS 16 using the modified retrospective transition approach, with the effect of initially applying this standard recognized at the date of initial application, i.e. December 1, 2019. Under this method, the Company elected to measure right-of-use of asset as equal to lease liability, adjusted for amounts previously recorded for deferred lease inducements or prepaid rent as at the date of adoption. Accordingly, the cumulative effect of initially applying IFRS 16 is nil on the opening balance of deficit as at December 1, 2019. The comparative information has not been restated, i.e. it is presented, as previously reported, under IAS 17 and related interpretations.

Transition options and practical expedients

The Company has elected to apply the following transition options and practical expedients available under IFRS 16:

- Lease definition: to grandfather the assessment of which transactions are leases on the date of initial application. Accordingly, the Company applied IFRS 16 only to contracts that were previously identified as leases under IAS 17 and IFRIC 4, Determining whether an Arrangement *Contains* a Lease, and applied the definition of leases under IFRS 16 only to contracts entered on or after the date of initial application; and
- Short-term leases and leases of low-value items recognition exemptions: related lease payments are recognized as an expense on a straight-line basis or another basis if that basis is more representative.

Impact of adopting IFRS 16

The most significant impact as a result of adopting IFRS 16 related to the accounting for the Company's operating leases, since the nature of expenses related to most of the Company's leases changed as IFRS 16 replaced the straight-line operating lease expense with a amortization charge for right-of-use assets and interest expense on lease liabilities.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

1. Basis of preparation (continued)

(a) Leases (continued)

Under IAS 17, the Company classified each of its leases at the inception date as either a finance lease or an operating lease, based on the extent to which risks and rewards of ownership were transferred to the Company. The Company's leases were classified as operating leases as they did not transfer substantially all the risks and rewards of ownership to the Company. Lease payments related to the Company's operating leases were recognized as rent expense in general and administrative expenses, selling expenses and research and development expenses in the consolidated statements of net loss and comprehensive loss on a straight-line basis over the lease term and presented as part of cash flows from operating activities in the consolidated statements of cash flows. Deferred lease inducements were recognized under other liabilities, in the consolidated statement of financial position as at November 30, 2019.

Upon adoption of IFRS 16, the Company recognized right-of-use assets for leases previously classified as operating leases. Right-of-use assets were measured for an amount equal to the lease liability adjusted for deferred lease inducements. Lease liabilities were measured at the present value of the remaining lease payments on a discounted basis, using the incremental borrowing rate at the date of initial application.

The following table summarizes the impacts of adopting IFRS 16 on the Company's consolidated statement of financial position as at December 1, 2019:

| Impact of adopting IFRS 16 as at December 1, 2019 | Increase (decrease) |
|---|------------------------|
| Assets | |
| Non-current assets: | |
| Right-of-use of assets | \$ 2,954 |
| Total assets | \$ 2,954 |
| Liabilities | |
| Non-current liabilities: | |
| Lease liabilities | \$ 3,192 |
| Other liabilities | (238) |
| Total liabilities | \$ 2,954 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

1. Basis of preparation (continued)

(a) Leases (continued)

- (i) Lease liabilities of \$3,192 and related right-of-use assets of \$2,954 were recognized and presented separately on the consolidated statement of financial position. There was no adjustment from the adoption of IFRS 16 on the opening deficit as at December 1, 2019 due to the Company's choice of transition method.
- (ii) Deferred lease inducements related to previous operating leases were derecognized.

Reconciliation of operating lease commitments to lease liabilities recognized

When measuring lease liabilities, the Company discounted lease payments using its incremental borrowing rate as at December 1, 2019. The weighted average incremental borrowing rate applied as at December 1, 2019 was 7.1%. The lease liabilities as at December 1, 2019 can be reconciled to the operating lease commitments as at November 30, 2019 as follows:

| Reconciliation of operating lease commitment to operating lease liabilities | |
|---|---------|
| Operating lease commitments as at November 30, 2019 | \$4,035 |
| Effect of discounting | (843) |
| Discounted lease liabilities as at December 1, 2019 | \$3,192 |

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

1. Basis of preparation (continued)

Use of estimates and judgments (continued)

Judgments in applying accounting policies (continued)

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

1. Basis of preparation (continued)

Use of estimates and judgments (continued)

Judgments in applying accounting policies (continued)

Sales allowances

Management uses judgment in estimating provisions for sale allowances such as cash discounts, returns, rebates and chargebacks. The product revenue we recognize quarter over quarter is net of these estimated allowances. Such estimates require the need to make estimates about matters that are inherently uncertain. The Company's estimates are based on our historical claims as supplemented by management's judgment (see Notes 2 (Revenue recognition) and 3 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.

COVID-19 pandemic

The COVID-19 pandemic continues to cause significant financial market and social dislocation. The situation is dynamic with various cities and countries around the world responding in different ways to address the outbreak. While the Company has experienced the impact of the outbreak of the Coronavirus (COVID-19) on its operations, it had continued to operate during the current pandemic. During the year ended November 30, 2020, the Company recognized payroll subsidiaries totaling \$453 principally under the Canadian Emergency Wage Subsidy program. These subsidies were recorded as a reduction in the associated personnel costs which the Company incurred, and were recognized in research and development, selling and general and administrative expenses. In the event of a prolonged continuation of the pandemic, it is not clear what the potential impact may be on the Company's business, financial position and financial performance.

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

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 (loss).

Foreign operations

The assets and liabilities of foreign operations whose functional currency is not the US\$ are translated into US\$ 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 (loss). 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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Revenue recognition (continued)

Revenue from contracts with customers – Net sales (continued)

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Property and equipment (continued)

Recognition and measurement (continued)

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.

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 | 20% |
| | and straight-line | 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Property and equipment (continued)

Depreciation (continued)

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, 2020 and 2019, no development expenditures were capitalized.

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*® are amortized at fixed rates based on their estimated useful life of 111 months on a straight-line basis. Commercialization rights – Trogarzo® 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® 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Financial instruments (continued)

(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.

(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 (loss). When an investment is derecognized, gains or losses accumulated in other comprehensive income (loss) 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 (loss). 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 (loss) and are never reclassified in profit or loss.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Financial instruments (continued)

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

The Company currently classifies its bonds as financial assets measured at FVOCI.

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

All financial assets not classified as measured at amortized cost or FVOCI as described above are measured at FVPL. 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 FVPL.

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.

(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 FVPL.

- Financial liabilities measured at amortized cost

This category includes all financial liabilities, other than those measured at FVPL. 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Financial instruments (continued)

(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 conversation 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 components in proportion to their initial carrying amounts.

(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 financial 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.

At each reporting date, the Company recognizes loss allowances for expect credit losses ("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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Financial instruments (continued)

(viii) Impairment of financial assets

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.

Leases

Policy applicable effective December 1, 2019

At inception, the Company assesses whether a contract is, or contains, a lease based on whether the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Company recognizes a right-of-use asset and a lease liability at the commencement date of the lease, i.e. the date the underlying asset, is available for use.

The details of the new significant accounting policies in relation to the Company's leases are set out below.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Leases (continued)

Right-of-use assets

Right-of-use assets are measured at cost, less any accumulated amortization and accumulated impairment losses, and adjusted for remeasurement of lease liabilities. Cost of right-of-use assets comprises:

- the initial measurement amount of the lease liabilities recognized;
- any lease payments made at or before the commencement date, less any lease incentives received;
- any initial direct costs incurred; and
- an estimate of costs to dismantle and remove the underlying asset, restore the site on which it is located or restore the underlying asset to the condition required by the terms and conditions of the lease contract.

Right-of-use assets are amortized on a straight-line basis over the lesser of i) the estimated useful life of the underlying assets; and ii) the lease term. Right-of-use assets are assessed for impairment whenever there is an indication that the right-of-use assets may be impaired.

Lease liabilities

Lease liabilities are initially measured at the present value of the lease payments that are not paid at the commencement date over the lease term. The present value of the lease payments is determined using the lessee's incremental borrowing rate at the commencement date if the interest rate implicit in the lease is not readily determinable. The incremental borrowing rate is a function of the lessee's incremental borrowing rate, the nature of the underlying asset, the location of the asset, the length of the lease and the currency of the lease contract. Generally, the Company uses the lessee's incremental borrowing rate for the present value. At the commencement date, lease payments generally include fixed payments, less any lease incentives receivable, variable lease payments that depend on an index (e.g. based on inflation index) or a specified rate, and payments of penalties for terminating the lease, if the lease term reflects the lessee exercising the option to terminate the lease. Lease payments also include amounts expected to be paid under residual value guarantees and the exercise price of a purchase option if the Company is reasonably certain to exercise that option.

Variable lease payments that do not depend on an index or a specified rate are not included in the measurement of lease liabilities but instead are recognized as expenses in the period in which the event or condition that triggers the payment occurs.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Leases (continued)

Lease liabilities (continued)

After the commencement date, the carrying amount of lease liabilities is increased to reflect the accretion of interest and reduced to reflect lease payments made. In addition, the carrying amount of lease liabilities is remeasured when there is a change in future lease payments arising from a change in an index or specified rate, if there is a modification to the lease terms and conditions, a change in the estimate of the amount expected to be payable under residual value guarantee, or if the Company changes its assessment of whether it will exercise a termination, extension or purchase option. The remeasurement amount of the lease liabilities is recognized as an adjustment to the right-of-use asset, or in the consolidated statement of comprehensive loss when the carrying amount of the right-of-use asset is reduced to zero.

Classification and presentation of lease-related expenses

Amortization charge for right-of-use assets, expenses related to variable lease payments not included in the measurement of lease liabilities and loss (gain) related to lease modifications are allocated in the Company's consolidated statement of comprehensive loss based on their function within the Company, while interest expense on lease liabilities is presented within finance costs.

Policy applicable before December 1, 2019

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Provisions (continued)

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 (loss) or in equity.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

Income taxes (continued)

Deferred tax (continued)

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

2. Significant accounting policies (continued)

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.

Government assistance

Government grants are recognized only when the Company has reasonable assurance that it meets the conditions and will receive the grants. Government grants related to assets are recognized in the consolidated statement of financial position as a deduction from the carrying amount of the related asset. They are then recognized in profit or loss over the estimated useful life of the amortization asset that the grants were used to acquire, as a deduction from the amortization expense.

Other government grants are recognized in profit or loss as a deduction from the related expenses, such as salaries for the Canadian Emergency Wage Subsidy program.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

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.

Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after December 1, 2020 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these consolidated financial statements.

The following amended standards and interpretations are not expected to have a significant impact on the Company's consolidated financial statements:

- Amendments to References to Conceptual Framework in IFRS and;
- Definition of Material (Amendments to IAS 1, *Presentation of Financial Statements*, and IAS 8, *Accounting Policies, Changes in Accounting Estimates and Errors*).

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

3. Revenue

United States

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 SV*® in the United States. In such a role, RxCrossroads purchases *EGRIFTA SV*® from the Company and takes title thereto when the goods arrive in their warehouse. RxCrossroads’ purchases of *EGRIFTA SV*® are triggered by its expectations of market demand over a certain period of time. With respect to *EGRIFTA SV*®, RxCrossroads fulfills orders received from authorized wholesalers and delivers *EGRIFTA SV*® directly to that authorized wholesaler’s client, namely, a specialty pharmacy forming part of the Company’s network of specialty pharmacies. See Note 27.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

3. Revenue (continued)

Canada

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

Europe

On July 9, 2020, the Company entered into pre-wholesaling services agreement with Loxxess Pharma GmbH, or Loxxess, pursuant to which Loxxess agreed to act as our third-party service logistics provider, or Loxxess Agreement, in certain key European countries, including Germany, France, Italy, Austria, The Netherlands, Portugal, Switzerland, United Kingdom, Norway, Sweden, Finland and Denmark. Loxxess is also capable of serving other European countries, including Israel and Turkey. Pursuant to the Loxxess Agreement, Loxxess receives customers' orders, stores, packages and ships Trogarzo® to European hospitals and pharmacies. Loxxess is also responsible, on our behalf, to collect payments of the goods sold to those hospitals and pharmacies. The hospitals and pharmacies dispense Trogarzo® to patients.

Net sales by product were as follows:

| | 2020 | 2019 |
|----------------------------|-----------|-----------|
| <i>EGRIFTA</i> ® net sales | \$ 35,399 | \$ 35,520 |
| Trogarzo® net sales | 30,654 | 27,696 |
| | \$ 66,053 | \$ 63,216 |

Net sales by geography were as follows:

| | 2020 | 2019 |
|---------------|-----------|-----------|
| Canada | \$ 354 | \$ 295 |
| United States | 65,455 | 62,921 |
| Europe | 244 | - |
| | \$ 66,053 | \$ 63,216 |

4. Personnel expenses

| | Note | 2020 | 2019 |
|---|-----------|-----------|----------|
| Salaries and short-term employee benefits | | \$ 7,564 | \$ 5,402 |
| Post-employment benefits | | 458 | 295 |
| Share-based compensation | 20(b),(e) | 1,297 | 1,059 |
| Termination benefits | | 876 | 87 |
| | | \$ 10,195 | \$ 6,843 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

5. Finance income and finance costs

| | Note | 2020 | 2019 |
|---|------------|------------|------------|
| Interest income | | \$ 299 | \$ 1,097 |
| Finance income | | 299 | 1,097 |
| Accretion expense | 16, 17, 18 | (2,056) | (1,673) |
| Interest on convertible unsecured senior notes | | (3,306) | (3,317) |
| Bank charges | | (40) | (39) |
| Net foreign currency gain (loss) | | 418 | (45) |
| Loss on financial instruments carried at fair value | | (9) | (6) |
| Finance costs | | (4,993) | (5,080) |
| Net finance cost recognized in net profit or loss | | \$ (4,694) | \$ (3,983) |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

6. Bonds and money market funds

| | 2020 | 2019 |
|---------------------|---------|----------|
| Bonds | \$ 634 | \$ 5,246 |
| Money market funds | 7,397 | 7,337 |
| | 8,031 | 12,583 |
| Current portion | (8,031) | (11,964) |
| Non-current portion | \$ - | \$ 619 |

As at November 30, 2020, bonds were interest-bearing financial assets with stated interest rates ranging from 2.2% to 4.1% (2019 – 1.7% to 4.8%) and had an average maturity of 0.06 years (2019 – 0.5 years).

7. Trade and other receivables

| | 2020 | 2019 |
|----------------------|-----------|-----------|
| Trade receivables | \$ 10,947 | \$ 9,538 |
| Sales tax receivable | 407 | 253 |
| Other receivables | 1,076 | 325 |
| | \$ 12,430 | \$ 10,116 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

8. Tax credits and grants receivable

| | 2020 |
|---|--------|
| Balance as at November 30, 2019 | \$ - |
| Tax credits and grants recognized in net loss | 749 |
| Effect of change in exchange rates | 6 |
| Balance as at November 30, 2020 | \$ 755 |

Tax credits receivable comprise grants receivable, and research and development investment tax credits receivable 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.

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

| | |
|------|-----------|
| 2024 | \$ 458 |
| 2025 | 1,365 |
| 2026 | 1,676 |
| 2027 | 2,309 |
| 2028 | 2,561 |
| 2029 | 1,726 |
| 2030 | 855 |
| 2031 | 598 |
| 2032 | 313 |
| 2033 | 207 |
| 2039 | 193 |
| 2040 | 454 |
| | \$ 12,715 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

9. Inventories

| | 2020 | 2019 |
|------------------|-----------|-----------|
| Raw materials | \$ 2,290 | \$ 3,011 |
| Work in progress | 488 | 2,467 |
| Finished goods | 22,367 | 15,451 |
| | \$ 25,145 | \$ 20,929 |

Inventories were written down to net realizable value by an amount of \$917 in 2020 (2019 – \$16), of which \$910 (2019 – nil) was recorded in cost of sales as other production-related costs and \$7 (2019 – \$16) was recorded in cost of goods sold.

Included in the 2020 write-down is a provision of \$660 on excess stock of *EGRIFTA*® as a result of the Company's decision to switch patients to and only actively commercialize the new *EGRIFTA SV*® formulation in the United States.

The write-downs in 2019 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, 2020 and 2019

10. Property and equipment

| | Computer equipment | Laboratory equipment | Office furniture and equipment | Leasehold improvements | Total |
|---------------------------------|-----------------------|-------------------------|--------------------------------------|---------------------------|----------|
| Cost | | | | | |
| 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 |
| Additions | 41 | - | - | - | 41 |
| Balance as at November 30, 2020 | \$ 272 | \$ 107 | \$ 334 | \$ 642 | \$ 1,355 |
| Accumulated depreciation | | | | | |
| 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 |
| Depreciation | 75 | 18 | 56 | 98 | 247 |
| Balance as at November 30, 2020 | \$ 162 | \$ 50 | \$ 114 | \$ 164 | \$ 490 |
| Net carrying amounts | | | | | |
| November 30, 2020 | \$ 110 | \$ 57 | \$ 220 | \$ 478 | \$ 865 |
| November 30, 2019 | \$ 144 | \$ 75 | \$ 276 | \$ 576 | \$ 1,071 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

11. Right-of-use assets

| | 2020 |
|---|----------|
| Balance as at November 30, 2019 | \$ - |
| Impact of initial adoption of IFRS 16 (Note 1(a)) | 2,954 |
| Amortization | (441) |
| Effect of change in exchange rates | 105 |
| Balance as at November 30, 2020 | \$ 2,618 |

12. Intangible assets

| | Commercialization rights – Trogarzo® North American Territory | Commercialization rights – Trogarzo® European Territory | Commercialization rights – EGRIFTA SV® | Oncology platform | Total |
|--|--|---|--|----------------------|--------|
| Cost | | | | | |
| Balance as at 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 and 2020 | \$ 11,972 | \$ 7,612 | \$ 14,041 | \$ 3,449 | 37,074 |
| Accumulated amortization | | | | | |
| 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 |
| Amortization | 1,055 | 384 | 1,512 | - | 2,951 |
| Balance as at November 30, 2020 | \$ 2,213 | \$ 384 | \$ 9,948 | \$ - | 12,545 |
| Net carrying amounts | | | | | |
| November 30, 2020 | \$ 9,759 | \$ 7,228 | \$ 4,093 | \$ 3,449 | 24,529 |
| November 30, 2019 | \$ 10,814 | \$ 7,612 | \$ 5,605 | \$ 3,449 | 27,480 |

The amortization expense of \$2,951 (2019 – \$2,412) 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, 2020 and 2019

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”) granting the Company the exclusive right to market Trogarzo® in Canada and in the United States. 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 was responsible for seeking its approval from the US Food and Drug Administration (“FDA”), whereas the Company is responsible, but has no obligation, to seek 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; and
- (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, 2020 and 2019

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 | Note | Commercial milestone payment |
|--|------|---------------------------------|
| (i) Achieving aggregate net sales of \$20,000 over four consecutive quarters of the Company's financial year | 16 | \$7,000 (paid in 2019 and 2020) |
| (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 |

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”).

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

12. Intangible assets (continued)

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, 2020 and 2019

12. Intangible assets (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 licence 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 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, CA\$2 million will be paid through the issuance of common shares of the Company.

The second milestone payment of CA\$2.3 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

12. Intangible assets (continued)

Oncology platform (continued)

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.

In August 2019, the acquisition agreement was amended to provide for an adjustment to the purchase price of CA\$1.08 million in the event the Company could indirectly benefit from a CA\$1.2 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 CA\$500 thousand was paid in cash in October 2019, whereas the second installment of CA\$580 thousand will be paid at the same time as the CA\$2.3 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 (CA\$500 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 CA\$25 thousand for the first five years and CA\$100 thousand thereafter, until royalties become payable beginning with the first commercial sale of a product developed using the licensed technology.

The royalties payable under the Licence Agreement vary between 1% and 2.5% on net sales of a product based on the licensed 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

12. Intangible assets (continued)

Oncology platform (continued)

The Company must 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: CA\$50 thousand upon the successful enrolment of the first patient in the first Phase 1 human clinical trial;
- (ii) Second milestone payment: CA\$100 thousand upon the successful enrolment of the first patient in the first Phase 2 human clinical trial; and
- (iii) Third milestone payment: CA\$200 thousand upon the successful enrolment of the first patient in the first Phase 3 human clinical trial.

Also, the Company must pay CA\$200 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

13. Other asset

| Cost | | |
|--|----|--------|
| Balance as at November 30, 2018, 2019 and 2020 | \$ | 19,530 |
| Accumulated amortization | | |
| Balance as at November 30, 2018 | \$ | 2,442 |
| Amortization | | 4,884 |
| Balance as at November 30, 2019 | \$ | 7,326 |
| Amortization | | 4,881 |
| Balance as at November 30, 2020 | \$ | 12,207 |
| Net carrying amounts | | |
| November 30, 2020 | \$ | 7,323 |
| November 30, 2019 | \$ | 12,204 |

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 subsequent 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, 2020 and 2019

14. Accounts payable and accrued liabilities

| | Note | 2020 | 2019 |
|--|-------|-----------|-----------|
| Trade payables | | \$ 17,510 | \$ 13,106 |
| Accrued liabilities and other payables | | 13,911 | 15,028 |
| Salaries and benefits due to key management personnel | 28 | 776 | 555 |
| Employee salaries and benefits payable | | 724 | 473 |
| Liability related to deferred stock unit plan | 20(b) | 508 | 625 |
| Accrued interest payable on convertible unsecured senior notes | 17 | 1,386 | 1,386 |
| | | \$ 34,815 | \$ 31,173 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

15. Provisions

| | Chargebacks and rebates | Returns | Other | Total |
|---------------------------------|----------------------------|---------|---------|----------|
| Balance as at December 1, 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 |
| Provisions made | 10,314 | 948 | 2,973 | 14,235 |
| Provisions used | (10,818) | (935) | (3,019) | (14,772) |
| Balance as at November 30, 2020 | \$ 1,678 | \$ 260 | \$ 9 | \$ 1,947 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

16. Long-term obligations

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

| | Commercialization rights – Trogarzo® North American Territory | Commercialization rights – Trogarzo® European Territory | Total |
|---|--|---|----------|
| Balance as at November 30, 2018 | \$ - | \$ - | \$ - |
| Additions | 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 |
| Accretion expense | 83 | 96 | 179 |
| Payment | (3,500) | - | (3,500) |
| Current portion as at November 30, 2020 | \$ - | \$ 4,666 | \$ 4,666 |

Commercialization rights – Trogarzo® North American Territory

Under the terms of the TaiMed Agreement, a commercial milestone of \$7,000 was 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 was made in June 2020.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

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, 2019 | | 50,741 |
| Accretion expense | | 1,662 |
| Convertible unsecured senior notes as at November 30, 2020 | \$ | 52,403 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

18. Leases liabilities

| | Carrying value |
|------------------------------------|---------------------------|
| Balance as at December 1, 2019 | \$ 3,192 |
| Accretion expense | 215 |
| Lease payments | (568) |
| Effect of change in exchange rates | 141 |
| Balance as at November 30, 2020 | 2,980 |
| Current portion | (425) |
| Non-current portion | \$ 2,555 |

19. Other liabilities

| | Note | 2020 | 2019 |
|----------------------------|-------------|-------------|-------------|
| Deferred lease inducements | | \$ - | \$238 |
| Stock appreciation rights | 20(c) | 41 | 28 |
| | | \$ 41 | \$266 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. 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, 2020 and 2019.

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

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, 2020 and 2019

20. 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”). 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, 2020, \$33 (2019 – \$23) 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, 2020, a gain of \$157 (2019 – charge of \$641) was recognized within finance costs (Note 5). As at November 30, 2020, the Company had a total 220,171 DSUs outstanding (2019 – 204,357 DSUs) and a liability related to the DSUs of \$508 (2019 – liability of \$625).

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, 2020, the cash-settled forward stock contracts outstanding correspond to a total of 220,171 common shares (2019 – 204,357 common shares) at a price of \$5.75 per share (2019 – \$5.86 per share) expiring on December 21, 2021 (2019 – December 21, 2020). As at November 30, 2020, the fair value of cash-settled forward stock contracts was \$520 (2019 – \$637) and is recorded in derivative financial assets. During the year ended November 30, 2020, a loss of \$166 (2019 – \$647) related to the change in fair value of derivative financial assets was recognized within finance costs (Note 5).

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. Share capital (continued)

(c) Share Appreciation Rights (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 of three years.

For the year ended November 30, 2020, \$13 (2019 – \$28) was recorded as share-based compensation expense for the SARs plan. Since these awards will be cash-settled, the fair value of SARs granted is estimated at each reporting period using the Black-Scholes model and the following weighted average assumptions.

| | Measurement date as at November 30, 2020 |
|------------------------------|---|
| Risk-free interest rate | 0.67% |
| Expected volatility | 64.6% |
| Average option life in years | 6.25 years |
| Grant-date share price | \$2.31 (CA\$3.00) |
| Option exercise price | \$2.31 (CA\$3.00) |

THERATECHNOLOGIES INC.

Notes to Consolidated Financial Statements (continued)
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Years ended November 30, 2020 and 2019

20. Share capital (continued)

(c) Share Appreciation Rights SARs (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 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. No SARs were granted in 2020.

| | Number of SARs | Weighted average grant date fair value |
|------|-------------------|--|
| 2019 | 40,000 | \$ 1.31 (CA\$1.70) |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. 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 7,700,000 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, 2020, 2,379,863 options could still be granted by the Company under the plan (2019 – 1,632,851).

The Company issued 487,421 options to Paul Lévesque, the President and Chief Executive Officer of the Company, on April 15, 2020 as inducement to enter into his employment agreement with the Company. These 487,421 options vest equally over a three-year period, have an exercise price of CA\$2.87 and have a 10-year term.

The Company has also issued an additional 590,300 options to its senior management, employees and directors since the beginning of its last fiscal year.

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. 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 | |
|--|----------------------|--|---------|
| | | CA\$ | US\$ |
| Options as at December 1, 2018 | 2,172,705 | 3.15 | 2.37 |
| Granted | 406,400 | 8.19 | 6.20 |
| Expired | (88,489) | 6.07 | 4.56 |
| Exercised (share price: CA\$7.78 (US\$5.82)) | (74,832) | 1.96 | 1.46 |
| Options outstanding as at November 30, 2019 | 2,415,784 | \$ 3.94 | \$ 2.96 |
| Granted – CA\$ | 1,077,721 | 3.06 | 2.25 |
| Forfeited and expired – CA\$ | (229,812) | 4.72 | 3.47 |
| Exercised (share price: CA\$8.65 (US\$6.57)) | (60,000) | 3.38 | 2.40 |
| Options outstanding as at November 30, 2020 – CA\$ | 3,203,693 | 3.59 | 2.76 |
| Options granted and outstanding as at November 30, 2020 – US\$ | 12,500 | - | 2.35 |
| Options exercisable as at November 30, 2020 – CA\$ | 2,063,672 | 3.43 | 2.64 |
| Options exercisable as at November 30, 2019 – CA\$ | 1,864,727 | \$ 2.69 | \$ 2.02 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. Share capital (continued)

(e) Stock option plan (continued)

The following table provides stock option information as at November 30, 2020 (options exercisable in CA\$).

| Price range | | Number of options outstanding | Weighted average remaining life (years) | Weighted average exercise price | |
|--------------|-------------|-------------------------------|---|---------------------------------|------|
| CA\$ | US\$ | | | CA\$ | US\$ |
| 0.25 – 1.19 | 0.19 – 0.92 | 814,660 | 2.95 | 0.64 | 0.49 |
| 2.01 – 3.75 | 1.55 – 2.89 | 1,521,721 | 8.03 | 2.72 | 2.10 |
| 3.76 – 6.00 | 2.89 – 4.62 | 230,000 | 6.35 | 5.96 | 4.59 |
| 6.01 – 9.00 | 4.62 – 6.93 | 424,000 | 8.03 | 8.06 | 6.20 |
| 9.01 – 10.00 | 6.93 – 1.70 | 213,312 | 7.35 | 9.56 | 7.36 |
| | | 3,203,693 | 6.57 | 3.59 | 2.76 |

The following table provides stock option information as at November 30, 2020 (options exercisable in US\$).

| Price range | | Number of options outstanding | Weighted average remaining life (years) | Weighted average exercise price | |
|-------------|--|-------------------------------|---|---------------------------------|--|
| US\$ | | | | US\$ | |
| 1.55 – 2.89 | | 12,500 | 10.0 | 2.35 | |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. Share capital (continued)

(e) Stock option plan (continued)

For the year ended November 30, 2020, \$1,414 (2019 – \$1,059) was recorded as share-based compensation expense for the stock option plan. The fair value of options granted in 2020 and 2019 was estimated at the grant date using the Black-Scholes model and the following weighted average assumptions.

| Options exercisable in CA\$ | 2020 | 2019 |
|------------------------------|--------------------|--------------------|
| Risk-free interest rate | 0.95% | 2.15% |
| Expected volatility | 74% | 57% |
| Average option life in years | 8.5 years | 8 years |
| Grant-date share price | \$ 2.35 (CA\$3.05) | \$ 6.15 (CA\$8.19) |
| Option exercise price | \$ 2.35 (CA\$3.05) | \$ 6.15 (CA\$8.19) |

| Options exercisable in US\$ | 2020 |
|------------------------------|-----------|
| Risk-free interest rate | 0.74% |
| Expected volatility | 78% |
| Average option life in years | 8.5 years |
| Grant-date share price | \$ 2.35 |
| Option exercise price | \$ 2.35 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. Share capital (continued)

(e) Stock option plan (continued)

The risk-free interest rate is based on the implied yield on a Canadian or U.S. 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, 2020 and 2019.

| Options exercisable in CA\$ | Number of stock options granted | | Weighted average grant date fair value |
|-----------------------------|---------------------------------|----|--|
| 2020 | 1,077,721 | \$ | 1.71 (CA\$2.22) |
| 2019 | 406,400 | \$ | 3.69 (CA\$4.92) |

| Options exercisable in US\$ | Number of stock options granted | | Weighted average grant date fair value |
|-----------------------------|---------------------------------|----|--|
| 2020 | 12,500 | \$ | 2.35 |

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, 2020 and 2019

20. Share capital (continued)

(f) Loss per share

The calculation of basic loss per share was based on the net loss attributable to common shareholders of the Company of \$22,667 (2019 – \$12,496) and a weighted average number of common shares outstanding of 76,991,635 (2019 – 76,928,287), calculated as follows.

| | 2020 | 2019 |
|---|------------|------------|
| Issued common shares as at December 1 | 76,953,411 | 76,877,679 |
| Effect of share options exercised | 38,224 | 49,920 |
| Effect of public issue common shares | - | 688 |
| Weighted average number of common shares, basic and diluted | 76,991,635 | 76,928,287 |

For the year ended November 30, 2020, 3,216,193 (2019 – 2,415,784) 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

20. Share capital (continued)

(g) Accumulated other comprehensive income (loss)

| | 2020 | 2019 |
|---|----------|---------|
| Unrealized losses on FVOCI financial assets, net of tax | \$ 2 | \$ (12) |
| Cumulative exchange difference on translation of foreign operations | (483) | 33 |
| | \$ (481) | \$ 21 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

21. Income taxes

The following table presents the components of the current and deferred tax expenses (recovery).

| | 2020 | 2019 |
|---|------------|------------|
| Current tax expense | \$ 16 | \$ - |
| Deferred tax expense (recovery) | | |
| Origination and reversal of temporary differences | \$ (4,890) | \$ (2,484) |
| Change in unrecognized deductible temporary differences | 4,890 | 2,484 |
| Total deferred tax expense (recovery) | \$ - | \$ - |
| Total current and deferred tax expense | \$ 16 | \$ - |

Reconciliation between effective and applicable tax amounts

| | 2020 | 2019 |
|---|------------|------------|
| Income taxes at domestic tax statutory rate | \$ (6,004) | \$ (3,325) |
| Change in unrecognized deductible temporary differences | 4,890 | 2,484 |
| Impact of differences in statutory tax rates | 742 | 518 |
| Non-deductible expenses and other | 388 | 323 |
| Total income tax expense | \$ 16 | \$ - |

The applicable statutory tax rates were 26.5% in 2020 and 26.6% in 2019. 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, 2020 and 2019

21. Income taxes (continued)

Unrecognized deferred tax assets

As at November 30, unrecognized deferred tax assets were as follows.

| | 2020 | 2019 |
|---------------------------------------|-----------|-----------|
| Research and development expenses | \$ 24,924 | \$ 23,262 |
| Non-capital losses | 31,725 | 30,470 |
| Property and equipment | 242 | 282 |
| Intellectual property and patent fees | 2,952 | 2,900 |
| Available deductions and other | 5,045 | 3,335 |
| | \$ 64,888 | \$ 60,249 |

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, 2020 and 2019

21. Income taxes (continued)

Unrecognized deferred tax assets (continued)

As at November 30, 2020 and 2019, the amounts and expiry dates of Canadian tax attributes for which no deferred tax asset was recognized were as follows:

| | 2020 | | 2019 | |
|--|-----------|------------|-----------|------------|
| | Federal | Provincial | Federal | Provincial |
| Research and development expenses, without time limitation | \$ 85,792 | \$ 104,822 | \$ 79,698 | \$ 98,321 |
| Losses carried forward | | | | |
| 2027 | 5,760 | 5,753 | 414 | 407 |
| 2028 | 35,640 | 17,347 | 34,876 | 16,975 |
| 2029 | 14,993 | 12,672 | 14,671 | 12,400 |
| 2030 | 8,803 | 8,800 | 8,614 | 8,611 |
| 2031 | 18,129 | 16,092 | 17,740 | 15,748 |
| 2032 | 12,282 | 11,278 | 12,019 | 11,036 |
| 2033 | 8,826 | 8,742 | 8,636 | 8,555 |
| 2034 | 8,082 | 8,011 | 7,909 | 7,839 |
| 2037 | 7,212 | 7,126 | 7,057 | 6,973 |
| 2038 | 2,104 | 2,025 | 1,964 | 1,886 |
| 2039 | 1,386 | 1,347 | 6,024 | 5,952 |
| 2040 | 6,928 | 6,921 | - | - |
| Other temporary differences, without time limitation | | | | |
| Excess of tax value of property and equipment over carrying value | 959 | 870 | 1,128 | 998 |
| Excess of tax value of intellectual property and patent fees over carrying value | 11,136 | 11,131 | 10,897 | 10,892 |
| Available deductions and other | 50,470 | 7,619 | 43,291 | 1,430 |

As at November 30, 2020 and 2019, no deferred tax liability was recognized for temporary differences arising from investments in subsidiaries because the Company controls the decisions affecting the realization of such liabilities and it is probable that the temporary differences will not reverse in the foreseeable future.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

22. Supplemental cash flow disclosures

The Company entered into the following transactions, which had no impact on its cash flows.

| | 2020 | 2019 |
|--|-------|-------|
| Additions to property and equipment included in accounts payable and accrued liabilities | \$ 12 | \$ 3 |
| Additions to intangible assets included in accounts payable and accrued liabilities | - | 9 |
| 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 |
| Initial recognition of right-of-use assets and lease liabilities | 3,192 | - |
| Reclassification of other liabilities to right-of-use-assets | 238 | - |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

23. 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.

The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 27), other receivable 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 \$10,947 (2019 – \$9,538), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the years ended November 30, 2020 and 2019. 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 (2020 – \$8,031; 2019 – \$12,583). As at November 30, 2020, 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 24, 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, 2020 and 2019

23. Financial instruments (continued)**Liquidity risk (continued)**

The following are amounts due on the contractual maturities of financial liabilities as at November 30, 2020 and 2019.

| | | | 2020 | | |
|--|------------------------|---------------------------------|-------------------------|--------------------------|--------------------------|
| | Carrying amount | Total contractual amount | Less than 1 year | From 1 to 2 years | More than 3 years |
| Accounts payable and accrued liabilities | \$ 34,815 | 34,815 | \$ 34,815 | \$ - | \$ - |
| Convertible unsecured senior notes, including interest | 52,403 | 67,419 | 3,306 | 64,113 | - |
| Long-term obligations | 4,666 | 5,000 | 5,000 | - | - |
| Lease liabilities | 2,980 | 3,640 | 621 | 1,267 | 1,752 |
| | \$ 94,864 | \$ 110,874 | \$ 43,742 | \$ 65,380 | \$ 1,752 |

| | | | 2019 | | |
|--|------------------------|---------------------------------|-------------------------|--------------------------|--------------------------|
| | Carrying amount | Total contractual amount | Less than 1 year | From 1 to 2 years | More than 3 years |
| 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 | - |
| | \$ 89,901 | \$ 110,398 | \$ 37,979 | \$ 11,613 | \$ 60,806 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

23. Financial instruments (continued)

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 US\$, primarily cash, sale of goods and expenses incurred in CA\$ and Euro.

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 US\$ 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 CA\$ or Euro denominated obligations.

The following table presents the significant items in the original currencies exposed to currency risk as at November 30, 2020 and 2019.

| | 2020 | | 2019 | |
|---|----------------|----------------|--------------|------------|
| | CA\$ | EURO | CA\$ | EURO |
| Cash | 871 | 36 | 740 | 533 |
| Bonds and money market funds | 821 | - | 6,982 | - |
| Trade and other receivables | 522 | 1,052 | 328 | 447 |
| Tax credits and grants receivable | 942 | 25 | - | - |
| Accounts payables and accrued liabilities | (4,937) | (4,496) | (5,101) | (793) |
| Lease liabilities | (2,109) | (1,138) | - | - |
| Total exposure | (3,890) | (4,521) | 2,949 | 187 |

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

23. Financial instruments (continued)**Currency risk (continued)**

The following exchange rates are those applicable as at November 30, 2020 and 2019.

| | Average rate | 2020 Reporting date rate | Average rate | 2019 Reporting date rate |
|-------------|--------------|-----------------------------|--------------|-----------------------------|
| CA\$ – US\$ | 0.7445 | 0.7695 | 0.7524 | 0.7530 |
| Euro – US\$ | 1.1325 | 1.1928 | 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 CA\$ or the Euro would have a positive impact on net earnings as follows, assuming that all other variables remained constant.

| | 2020 | | 2019 | |
|-----------------|-------|-------|------|------|
| | CA\$ | EURO | CA\$ | EURO |
| Positive impact | (195) | (226) | 147 | 9 |

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

Interestrisk

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 (loss).

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

23. Financial instruments (continued)

Interest rate risk (continued)

Based on the value of the Company's short- and long-term bonds as at November 30, 2020, an assumed 0.5% decrease in market interest rates would have increased the fair value of these bonds and the accumulated other comprehensive income (loss) by approximately nil (2019 – \$14); 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, 2020 of \$28,124 (2019 – \$39,032), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately \$141 (2019 – \$195); 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

24. 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, 2020, cash, bonds and money market funds amounted to \$20,768 (2019 – \$41,244). Subsequent to year-end, the Company raised aggregate proceeds of \$42,668 from the public offering of units (see Note 29). 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 from the consolidated statement of financial position date.

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 equity and convertible unsecured senior notes.

The Company is not subject to any externally imposed capital requirements.

25. 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 financial 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

25. Determination of fair values (continued)

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 their relatively short period to maturity.

Bonds and money market funds and derivative financial assets and financial 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, 2020 was approximately \$43,125 (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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

26. Commitments

(a) 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*[®] and Trogarzo[®]. As at November 30, 2020, the Company had outstanding purchase orders and minimum payments required under these agreements amounting to \$14,042 (2019 – \$20,311) for the manufacture of Trogarzo[®], *EGRIFTA SV*[®] and for various services.

The Company also has research commitments and outstanding clinical material purchase orders amounting to \$586 in connection with the oncology platform and \$1,217 in connection with a new formulation of tesamorelin and of a multi-dose pen injector developed for this new formulation.

(b) Credit facilities

The Company has a CA\$1,500 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, 2020 and 2019, the Company did not have any borrowings outstanding under these facilities.

(c) Licence agreement

On February 4, 2020, the Company entered into an amended and restated licence agreement with the Massachusetts General Hospital ("MGH"), as amended on April 15, 2020, 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 general 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 to pay a low single-digit royalty on all sales of *EGRIFTA*[®] and *EGRIFTA SV*[®] 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 any fatty liver disease, including Non-Alcoholic Fatty Liver Disease or NASH in the general population.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

26. Commitments (continued)

(d) Post-approval commitments

In connection with the approval of Trogarzo® in Europe, we are required to conduct a pediatric investigation plan, or PIP, and a post-authorization efficacy study, or Registry. The PIP comprises two studies: the first one consists in evaluating the pharmacokinetics, pharmacodynamics, safety and tolerability of Trogarzo® in children from 6 to less than 18 years of age with HIV-1 infection in order to provide pharmacokinetics and pharmacodynamics data to support the extrapolation of efficacy from adults; and the second study is a modelling and simulation study to evaluate the use of Trogarzo® in the treatment of HIV-1 infection resistant to at least one agent in three different classes in children from 6 to less than 18 years of age. The Registry consists primarily in evaluating the long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals by comparing the virologic, immunologic and clinical outcomes of patients receiving Trogarzo® treatment versus matched patients not receiving Trogarzo®. The study comprising the Registry should be conducted over a five-year period. The cost of the Registry, estimated to be approximately 4,000 Euros, will be borne as to 52% by TaiMed and as to 48% by the Company.

27. Operating segments

The Company has a single operating segment. As described in Note 3, almost all of the Company's revenues are generated from one customer, RxCrossroads, which is domiciled in the United States.

| | 2020 | 2019 |
|--------------|-----------|-----------|
| RxCrossroads | \$ 63,909 | \$ 60,853 |
| Others | 2,144 | 2,363 |
| | \$ 66,053 | \$ 63,216 |

All of the Company's non-current assets are located in Canada and Ireland, as is the Company's head office. Of the Company's non-current assets of \$35,335, \$34,006 are located in Canada and \$1,329 are located in Ireland.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2020 and 2019

28. 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:

| | 2020 | 2019 |
|------------------------------|----------|----------|
| Short-term employee benefits | \$ 2,384 | \$ 2,016 |
| Post-employment benefits | 97 | 67 |
| Share-based compensation | 925 | 847 |
| Termination benefits | 864 | - |
| | \$ 4,270 | \$ 2,930 |

As at November 30, 2020, the key management personnel controlled 1.4% (2019 – 1.4%) of the voting shares of the Company and held 0.0% (2019 – 0.3%) of the convertible unsecured senior notes.

29. Subsequent event

On January 19, 2021, the Company completed a public offering for the sale and issuance of 16,727,900 units of the Company for a gross cash consideration of \$46,002, including the full exercise of the over allotment option. Share issue costs are estimated at \$3,334 resulting in net proceeds of \$42,668.

Each unit is comprised of one common share of the Company and one-half of one common share purchase warrant of the Company (each whole warrant, a "Warrant"). Each Warrant entitles the holder to purchase one common share of the Company at an exercise price of \$3.18 until January 19, 2024.



Agreement

Pre-wholesaling Services

between

Theratechnologies Europe Limited

4th Floor | 2 Hume Street | Dublin 2 | D02 DV24
Ireland

and

Loxess Pharma GmbH

Amberger Str. 1 - 3
82538 Geretsried-Gelting
Germany

On 23rd of June, 2020

This agreement (the “Agreement”) is made BY and BETWEEN

Theratechnologies Europe Limited whose registered office is located at 4th Floor, 2 Hume Street, Dublin 2, D02 DV24, Ireland with VAT registered under number IE3588622WH, represented by **[REDACTED: Name and Title]**.

Herein after named **THA** or **Client**.

AND

Loxxess Pharma GmbH whose registered office is located in Oberheisinger Str. 11, 93073 Neutraubling, Germany , represented by **[REDACTED: Name and Title]**.

Herein after named **LOX** or **Supplier**.

RECITALS

WHEREAS, THA is a pharmaceutical company duly authorized by the Irish Health Authorities (hereinafter HPRA, formally named The Health Products Regulatory Authority) as certified in III EXHIBIT – TERRITORY and is or will be Marketing Authorization Holder and/or Local Representative for the Products listed in IV EXHIBIT – PRODUCT LIST / SHIPMENT MODE & SERVICE, and according to the current pharmaceutical regulations, wishes to contract out the provision of the warehousing, picking, shipping, and sales administration services from LOX.

WHEREAS, LOX is a specialist in logistic services provider in the area of warehousing and transport management of all types of pharmaceutical products and has the required capabilities and adequate facilities to undertake the warehousing, picking, transport organization as well as order entry and accounts receivables accounting (invoicing and cash collecting) of such products. LOX is duly authorized by the local pharmaceutical authorities, as it is certified in II EXHIBIT — LOXXESS AUTHORIZATION.

WHEREAS, this Agreement between THA and LOX sets forth the terms and conditions governing LOX' provisioning, and delivery of Services by LOX to THA and THA's use of the Services.

WHEREAS all activities of LOX and THA shall be performed independently of each other as independent contractual parties. Nothing in the content of this Agreement or otherwise shall be construed, for any purpose whatsoever, as establishing a position in respect of the one party as a representative, joint venture partner or employee of the other party or as authorizing either of the parties to make any agreements which shall be contractually binding on the other.

NOW THEREFORE IT IS AGREED, as follows:

1. SCOPE OF AGREEMENT

From the Effective Date (as defined below in clause 1.10) LOX shall provide THA with the services described in this Agreement and further described in the attached V EXHIBIT — SERVICES. LOX shall provide the Services in respect of the products listed in the attached IV EXHIBIT – PRODUCT LIST / SHIPMENT MODE & SERVICE. Exhibit IV may be amended by THA from time to time, by submitting a letter to LOX signed off by the THA Person (or designate) and to be confirmed by LOX. LOX shall render the following Services to THA exclusively in countries listed in III EXHIBIT — TERRITORY for the duration of this Agreement. Exhibit IV may be amended by the Parties from time to time, by submitting a letter to the other Party signed off by one Parties Quality Director/RP, the adapted version of the exhibit will only be valid after it has been countersigned by the other Party.

1.1. Warehouse Service

- a. The Warehouse Service shall include receiving, storage, picking and despatch of Products as specified in this Section.
- b. THA will forecast and determine inventory levels of the Product(s) required for distribution to customers in the Territory and will deliver those quantities of the Products to the Facility.
- c. It is THA sole responsibility to maintain sufficient stock levels to fulfil customer demand for each Product in the Territory.
- d. THA will liaise with its suppliers to ensure that they adhere to shipment and delivery Specifications for packaging and shipping the Products to LOX.
- e. THA will provide Product quantity data for Products to be received from its suppliers.
- f. LOX shall receive Products from THA suppliers at the Facility after having been informed
 - I. unload supplier vehicles and visually check the Products for damage.
 - II. check the Products against the shipment paperwork (delivery note/pack list) to confirm the Products and quantities received against the Products and quantities expected and documented.
 - III. provide a signature, qualified as necessary, for goods received at the Facility from THA's suppliers.
 - IV. raise and communicate to THA immediately following receipt "Materialzugangsschein" (MZS, Goods-In Reports) for any Products that are:
 - damaged (including photograph of damage if requested); or

- not in accordance with the delivery note.
- g. LOX will enter all received Products into LOX's warehouse management system within **[REDACTED: Time Period]** of receipt.
- h. THA will receive and act upon "Goods-In Exception Reports" by informing LOX within **[REDACTED: Time Period]** of the appropriate action to take.

1.2. Storage and Inventory Management

- a. LOX shall store and handle the Products in accordance with the Specifications established in writing by THA and in accordance with Good Distribution Practice.
- b. LOX shall provide all Products storage mediums, mechanical handling equipment and personnel as required to undertake the Services within this Agreement.
- c. LOX shall perform inventory count of the Products stocked via cycle count and one annual physical inventory counts of the stock without prejudice to THA's right to make further audits and inventories of the Products in stock at any moment. LOX will in this case provide personnel for the inventory counts on THA cost (see Fees – Special Activities).
- d. LOX shall keep inventory records for **[REDACTED: Time Period]**.
- e. LOX shall provide a warehouse management system for accurately managing at item level the total inventory on an ongoing basis including, Product name, Product code number, lot number, expiration date, receipt date at LOX, Product quantity, location, status and accurately recording the volumes of Product Lost, Product Damaged and the volume of Products despatched by LOX.

1.3. Picking and packing the products in response to orders

- a. LOX shall receive orders directly from customers in writing (e.g., via fax, email).
- b. Customer orders will be picked, packed and shipped within the time standards established in the Standards of Service (see V EXHIBIT—SERVICES, Clause **Erreur ! Source du renvoi introuvable. Erreur ! Source du renvoi introuvable.**).
- c. LOX shall pick customer orders from stock using FEFO (first expired first out) method and will confirm all picks in the LOX warehouse management system.
- d. LOX shall provide all consumable materials as required for warehousing and distribution operations (stretch wrap, labels, shipping cases, etc).
- e. LOX shall print all documents related to the Services.
- f. LOX shall assemble orders into despatch configurations of pallet(s) or shipping cases dependent upon order size or customer specification.
- g. LOX shall assign the transport carrier for each shipment according to 1.7.

1.4. Returns

- a. LOX shall manage Products returns within the Facility and undertake a visual check to identify Products, expiry date and obvious damage.

- b. Any specific/exceptional situation will be evaluated by both parties.

1.5. Products Recall Information service

- a. LOX will record batches shipped against customer orders where applicable and interrogate and report when requested.

1.6. Customer Service

The Customer Service shall include receiving orders directly from THA's customers and replying to customer queries as specified this Clause.

LOX shall maintain the customer data in LOX's system in accordance with information received from THA.

1.6.1. Receipt of orders from THA's customers

- a. Loxxess shall receive written orders from THA's customers either automatically (i.e. via EDIFACT) or manually (i.e. via fax or email).
- b. For **[REDACTED: Territory]**, LOX shall ensure the customer has the legal and regulatory right to buy the Products. For all other countries it is THA's responsibility to ensure the authorised customers has the legal and regulatory right to buy the Products. New customers have to be first approved by THA.
- c. LOX shall maintain the price data in the LOX's system in accordance with information received from THA.

1.6.2. Management of queries from customers

- a. Queries from customers during normal working hours on a Business Day to be acknowledged within **[REDACTED: Time Period]** and resolved in a timely manner.
- b. LOX shall respond to proof of delivery queries from THA's customers.

1.7. Transport service

- a. LOX will sub-contract transport services for shipments from LOX to THA's customers to independent, Third Party transport carriers.
- b. The Transport Service shall include the outbound transport service, which means delivery of Products from the Facility to customers; as well as the collection of returns from customers and delivery of returns to the Facility, when required.
- c. LOX shall take reasonable care to ensure that Products are safely and securely loaded onto the vehicles for transport so as to avoid injury to people and damage to the Products.
- d. LOX shall accurately record any delivery problems or incidents.
- e. It is agreed that it will be LOX's responsibility to organize outbound transportation according to the Quality Agreement and any applicable law and regulation based on the selection of THA. The process will be as follow :
 - THA will be responsible for the selection of service for the goods (temperature controlled).

-based on that selection LOX will make if available a recommendation of transport service providers that LOX has qualified and audited (controlled).

-THA will have to select the transport service provider, preferable one proposed by LOX.

1.8. Finance Service

- a. The Finance Service shall include invoicing, cash collection, reminders and financial reporting.
- b. THA will set the price of the Products and will provide LOX with new and revised/updated price information.
- c. THA will set the invoice payment terms (normally **[REDACTED: Time Period]**) and will provide LOX with new and revised/updated payment terms.
- d. THA shall retain full legal and beneficial ownership of all the Products until they have been delivered to the customer and title to them has been transferred to the customer within the applicable terms of business and applicable laws. LOX shall not acquire any right, title or interest in any Product as a result of the Agreement.
- e. On THA's behalf, LOX shall issue invoices in LOX's name, including VAT if applicable in respect of all Products supplied, each such invoice to be issued on the day of despatch of the Products to the customer in accordance with the payment terms provided by THA.
- f. LOX bears sole responsibility for collecting all debts from customers, however, LOX does not accept responsibility for bad debts and will subsequently recharge THA with respect to any debts which are, in spite of LOX's reasonable endeavours to collect them, outstanding after **[REDACTED: Time Period]**.
- g. LOX shall store each original invoice.
- h. Monitor payments into bank statement against invoices raised.
- i. Make all reasonable efforts by sending up to three reminders (every **[REDACTED: Time Period]**) to collect outstanding balances of the payment being due. After this time, any obligations of LOX relating to debt collection will expire and outstanding will be invoiced to THA (Exhibit X).
- j. At the end of each month LOX will issue an invoice to THA for the amount of fee (**[REDACTED: Time Period]** term of payment after date of invoice).
- k. At the end of each month THA will issue an invoice to LOX for the sum of all invoices arose from LOX to the customers (term of payment: at the end of each month all amounts collected in the month with a payment period of **[REDACTED: Time Period]** or respectively longer, if THA is offering longer payment periods to its customers).

1.9. Value Added Services (optional)

- a. Relabelling and repackaging for local market shall include those secondary packaging operations that are routine in the Territory.

- b. Repackaging shall include those secondary or tertiary packaging operations which are carried out on a regular basis according to procedures agreed from time to time between LOX and THA.
- c. Destruction of expired, obsolete or damaged Products shall include physical destruction of the Products by incineration, provision of a certificate of destruction and maintenance of a Product audit trail related to the certificate of destruction.
- d. Samples and promotional materials: if LOX will be entitled to manage samples and promotional materials for THA for the Territory, the services scope will be the same as for sale product.
- e. Recall Service shall include the following activities: LOX, if so instructed by THA shall co-operate in the event of Product recall and to accept the Products returned by customers upon recall or withdrawal by THA. Unless THA instructs otherwise, LOX shall store the Products returned according to the terms and conditions of this Agreement, ensuring that the recalled Products returned are stored separately from other products stored at the Facility. In any case recall service will be done in compliance with any applicable **[REDACTED: Territory]** regulation.
- f. Evaluation of returns for booking back to stock: LOX will do an extended check of returned goods, based on a specific checklist. The outcome of the check will be submitted to THA, who has to state its approval before boxes can be booked back to stock.
- g. For value added services THA will pay a separate fee based on cost per activity as stated in Exhibit VIII.

1.10. This Agreement shall commence on 1st of July, 2020 ("Effective Date").

1.11. LOX shall refrain from directly shipping and distributing Products out of the Territory.

1.12. In case of conflict of information between this Agreement and the QTA regarding the description in this clause 1, the QTA will be referenced.

2. REGULATORY REQUIREMENTS

2.1. LOX will receive from THA the Pharmaceutical and / or health Products agreed at any time. LOX will store them in the warehouse area defined in V EXHIBIT - SERVICES (such area being designed for such purpose) and it will use the necessary operational resources in order to render the Services, according to each Marketing Authorizations approved conditions. LOX shall not change the Warehouse area without prior approval of THA.

2.2. In providing the Services LOX shall comply with the Good Distribution Practices and all other applicable rules and regulations governing the warehousing, storage, picking and shipment of pharmaceutical products.

2.3. LOX shall obtain and maintain all regulatory permits and licenses necessary to render the Services in the Territory.

2.4. LOX shall provide the Services according to the Quality Agreement agreed or to be agreed between the Parties and attached to this Agreement in VIII EXHIBIT – QUALITY AGREEMENT.

2.5. Furthermore, LOX agrees that it shall not engage in any conduct on THA's behalf which is in violation of, or potentially in violation of, any applicable Laws in the Territory.

2.6. The premises used by LOX for the Services shall at any time meet the applicable national and **[REDACTED: Territory]** rules of the pharmaceutical and/or health laws in force and the remarks received during the inspections developed by the Health Authorities.

2.7. LOX shall ensure that the storage of the Products of THA is done within the correct range of temperature and other conditions specified by THA for each Product in the Quality Agreement.

3. DELIVERY, LIABILITY AND OWNERSHIP OF THE PRODUCTS

3.1. Delivery of the Products from the supplier will be arranged by THA itself, and the risk of loss or damage of the Products will remain in THA until delivered at the LOX warehouse as stated in Exhibit IV.

LOX shall be liable against the Replacement Cost (where replacement cost means **[REDACTED: Definition of Replacement Cost]**) of any Products that have been lost or damaged through the negligence or default of LOX. LOX shall only be liable for Products during the period from **[REDACTED: Period of Time]**.

Loss Allowance for lost or damaged products or Losses means **[REDACTED: Percentage]** of the total value at Replacement Cost of all the Client's Products received by the Supplier during a calendar year with a minimum of **[REDACTED: Amount]**. Losses means costs, claims, demands, liabilities, expenses, damages or losses.

3.2. THA declares that it is the rightful owner of the Products. THA declares and warranties that the Products do not infringe any third party intellectual properties rights.

3.3. THA declares and warranties that the Products are manufactured in accordance to the applicable **[REDACTED: Territory]** GMP and to any applicable law and regulation. THA shall

indemnify and hold LOX harmless from any damages claims, demands, liabilities, suits or expenses of any kind arising from any personal injury or death arising out defects in the Products.

3.4. THA confirms that the Products have the appropriate marketing authorizations issued by the MoH or any other competent organization at any time.

3.5. Non-compliance of any statement contained in the above Clauses 3.2 and 3.3 is and will be of the exclusive responsibility of THA. THA will assume any consequence, exempting LOX from any responsibility in this regard.

3.6. Title to all Products handled by LOX pursuant to this Agreement shall remain at all times with THA and shall not pass to LOX under any circumstances. All goods shall at all times be considered as property owned by THA while such goods are located in any LOX warehouse or otherwise stored under this Agreement.

4. LIABILITY AND INSURANCE

General Principles

4.1. Except as provided in this Agreement, and taking into account the Loss Allowance, LOX shall be liable to THA for the loss, damage or destruction of any Products as a result of defective performance of the Services, provided that such loss, damage or destruction are a consequence of intention or gross negligence of LOX. LOX's liability in accordance to this article 4.1 shall be at Replacement Cost (as defined in clause 4.2) of such Products (excluding VAT) in the applicable Territory.

For the liability for Products during the internal handling caused by Supplier German Law 467 ff HGB ('Handelsgesetzbuch') will be applied. In all cases calculation base are Replacement Cost. Supplier's maximum liability of risk of loss or damage to the Products during handling is [REDACTED: Amount] per occurrence as long as the below mentioned maximum is not reached. For inventory discrepancies the maximum liability of the Supplier is [REDACTED: Amount] per occurrence and [REDACTED: Amount] taking into account the Loss Allowance as long as the below mentioned maximum is not reached.

The maximum aggregate liability of either Party arising out of this Agreement, whether in tort or for breach of contract or otherwise (excepting as a consequence of wilful misconduct or gross negligence of the Client or of the Supplier as provided for above; in case of gross negligence only the above mentioned maximum apply for the Supplier) shall be limited to the Fees (excluding transport fees) due and payable by the Client to the Supplier in the first [REDACTED: Time Period] following the Effective Date or any subsequent [REDACTED: Time Period] period.

Neither party shall be liable to the other for any loss of profits, loss of goodwill or reputation or other remote, consequential or pure economic loss.

4.2. LOX shall prepare and THA shall review the aggregation of the volume of Product Write-Off in respect of each Year at the end of that Year. Where the aggregate Product Write-Off, after taking in account positive stock deviations, of that Year is negative, LOX shall pay to the Client an amount equal to the Replacement Cost, but only to the extent that the value in that Year at Replacement Costs of such negative Product Write-Off is greater than the Loss Allowance. Replacement Cost is the actual cost to THA of manufacturing or purchasing a replacement for the Product and transportation to the relevant Distribution Centre. Where THA itself does not manufacture the Products but purchases it from an Affiliate, the Product Cost means the transfer price excluding any mark-up of the Products from that Affiliate to THA and where it purchases the Products from a third party, then the Product Cost means the purchase price paid by THA, THA having used all reasonable endeavours to mitigate its loss and to obtain the best price commercially available to it. Exceptions are cases in which due to reasons which are not in caused by the Supplier and which influence the marketability (i.e. due to expiry dates or official measures) lower costs have to be assumed.

4.3. LOX shall be responsible for physical protection of Products against tampering and more generally from any access by non-authorized personnel or third parties during the products stay in LOX warehouse and from logistic platform to the final customer including all intermediate.

4.4. LOX shall not be liable for damages caused by terrorist actions, these being defined as the use of violence or threats by an individual or an organisation against the Government or the general public.

4.5. LOX will not be liable for damages, claims or losses caused by THA's negligence.

4.6. In case Suppliers engages 3rd party providers to fulfil further tasks based on request of THA (i.e. IT providers), Supplier's liability is clearly and entirely limited to the liability of the 3rd party provider to Supplier. Supplier has to share information about liability with Client.

4.7. Subject to the other provisions in this Agreement, and in particular, but not limited to clauses 4.1 above during the Term the Supplier will at its own cost procure and maintain:

- (a) Public Liability Insurance with limits of not less than **[REDACTED: Amount]** per occurrence
- (b) Employer's Liability Insurance with a limit of not less than **[REDACTED: Amount]** or the relevant statutory limit (whichever is the higher) per occurrence;

- (c) Liability Insurance for risk of loss or damage to the Products during handling with limits of not less than **[REDACTED: Amount]** per occurrence.
- (d) Liability Insurance for inventory discrepancies with limits of not less than **[REDACTED: Amount]** per occurrence and **[REDACTED: Amount]** per anno.

Products in Transport

4.8. In case Supplier selects a 3rd party transport provider, the Supplier's liability is clearly and entirely limited to the selection of a freight forwarder that is suitable for the collection and forwarding of shipments of Client's Products from the Supplier's Warehouse to the recipients as required for this contract. The evidences have to be produced by Client. In case 3rd party transport provider is defined by Client, Supplier's liability is clearly and entirely excluded.

Due to the above-mentioned exclusion of liability, Supplier will transfer its titles to insurance benefits to the Client or its insurance, provided that damage has been caused at the Clients freight and that the freight forwarded allows a transfer of title. For each claim there will be a handling charge for Loxxess.

Alternatively, in cases where the freight forwarder does not allow a transfer of title, Supplier will administrate the regress. In this case Clients agrees, to accept the result of the regress (charged according to time spend based on the fees for special services).

4.9. The Client acknowledges that it is responsible for insuring the Products at its own expense during transit. It is client's choice to have Products in inbound and outbound insured above and beyond the insurance coverage provided by law at Client cost. Inbound and outbound deliveries will be insured by Client itself if deemed necessary and are not part of the insurance coverage by Supplier.

Products in LOX's Warehouse

4.10. LOX is responsible for the correct storage of the Products belonging to THA, for the state of conservation of such Products and for strict compliance with current legislation concerning storage of pharmaceuticals and health products. Notwithstanding the foregoing, THA shall maintain insurance throughout the Term of the Agreement with a reputable insurer of reputable financial standing covering:

- a) The Client acknowledges that it is responsible for insuring the Products at its own expense. The Client asked the Supplier to have the Stock insurance of the Products covered via the Suppliers insurance. Therefore the Supplier shall take out a property insurance for clients products during the storage at Suppliers facility for fire, aircraft crash, explosion, lightning (FLEXA), earthquake, hail, storm, flood, burst pipes (incl. Sprinkler leakage), burglary, consequential accidental environment damages and give LOX a waiver of subrogation. This insurance should also cover related additional costs of cleanup, demolition works, disposal costs of the stored products, extinguishing

devices and environment. The Client is asked to inform the Supplier until the **[REDACTED: Time Period]** regarding the stock value (incl. changes) (value basis product costs) declaration basis month end of the foregone month. The details of the coverage and limits can be provided to Client upon request.

- b) Product and general liability insurance to cover any loss, cost, expense, liability, action, demand, claim or proceeding in respect of bodily injury to or illness or death to a third party and or damage to third party property in the minimum sum each and every loss for occurrences during the Term which may lead to a claim.

4.11. THA shall produce to LOX, on request, copies of all insurance policies referred to in clause 4.7 and 4.8 or other evidence confirming the existence and extent of the cover given by such policies together with receipts or other evidence of payment of the latest premiums due under those policies

4.12. LOX and THA shall not take or fail to take any reasonable action, or permit anything to occur in relation to it, which would entitle an insurer to refuse to pay any claim under the policies required by this clause or cause of the above mentioned insurance policies to be invalidated or avoided.

4.13. For each claim there will be a handling charge for Loxxess.

Claims procedure

4.14. In case THA becomes aware of damaged or lost Products, the following procedure shall apply: THA will submit to LOX's Customer Service Department a claim letter which must include the details regarding the damaged / lost Products, as well as the sale invoice that evidences the claimed amount. THA shall send the claim letter within **[REDACTED: Time Period]** after THA became aware of the accident, and it may be done by means of an e-mail containing scanned documents.

THA acknowledges that it is responsible for insuring the Products at its own expense where LOX is not liable for their loss or damage under clause 4.8 and 4.10.

4.15. LOX or it's landlord shall during this Agreement keep the warehouse building properly and sufficiently insured against fire, storm, water and earthquake.

5. SERVICE FEE

5.1. In return of the Services being provided by LOX under this Agreement, THA shall pay a service fee (the "Service Fee") as detailed in VI EXHIBIT – SERVICE FEE to this Agreement.

5.2. The above mentioned Service fee as well as separate fees for other services will be subject to automatic annual adjustments, based on the percentage change in the Producer Price Index for 'Storage' for the Storage and 'Warehousing' for all other services by reference to the Retail Price Index published by the German Federal Statistical Office, such increases or decreases not to take place more than once a year and the first such increase or decrease not to take place earlier than the first anniversary of this Agreement. In the case of 3rd party transport providers, increases will be passed on at cost in full at time of increase.

5.3. All Fees shall be exclusive of any value added tax when applicable.

5.4. Any uncontested amounts payable under this Agreement shall be due and payable within **[REDACTED: Time Period]** after issue of **[REDACTED: Time Period]** invoice to which the amount relates.

5.5. Neither Party shall have the right to set off any amounts due from it under this Agreement against any amounts due to it whether under this Agreement or otherwise.

5.6. In the event of any delay in payment, LOX shall have the right to specify an annual interest on arrears, which shall be due and payable monthly, in an amount of **[REDACTED: Percentage]** percentage points above the basic interest rate.

5.7. The prices stated in VI EXHIBIT – SERVICE FEE are exclusive of V.A.T or any taxes that become effective during this Agreement.

5.8. In good faith, both parties agree to hold an assessment period of **[REDACTED: Time Period]** from the Effective Date. THA agrees to pay the Fees for the Services (including the agreed upon minimum charges) in accordance with the provisions of VI EXHIBIT – SERVICE FEE. The quantities of Products to be managed by LOX as part of the Services represent the best forecast that THA could reasonably make according to the market conditions at the time this Agreement was executed and such figures are provided to LOX in good faith. In the event that the quantities vary from the forecast by more than **[REDACTED: Percentage]**, the Fees may be reviewed by both parties in good faith and by written amendment to this agreement.

5.9. If the Client fails to pay any uncontested amount payable by it under this Agreement and Client has been repeatedly informed about the situation by Supplier by sending three reminders, Supplier shall be entitled to stop providing its services until Client has paid overdue items. The validity of this agreement will not be affected by this measurement Client obligation to pay will persist. Moreover Supplier can request upfront payment for its services in case of no payment.

6. TERM.

6.1 The term of this Agreement shall commence on the "Effective Date" stated on Article 1.10 of this Agreement and shall continue in full force and effect for an initial term of one year (the "Initial Term"). After the Initial Term the Agreement will automatically be renewed for additional one-year terms, unless either party, at least **[REDACTED: Time Period]** prior to the expiration of the Initial Term or any renewal term, gives written notice of termination.

6.2 During the Term the Client agrees that it shall not obtain services analogous to the Services in relation to the Products in the Territory from any other supplier.

7 RECORDS AND REGISTERS

7.1 LOX will keep **[REDACTED: Time Period]** record storage on the IT system after the expiry date of the batch, for a minimum of **[REDACTED: Time Period]**. The information stored will be related to the destination of the shipments, dates and respective batch numbers.

7.2 Registers of batch distribution, which should be validated, will contain the information stated by the pharmaceutical regulations in force whenever applicable according to law. This information will be at THA's disposal on request, the same working day requested, and within a term up to **[REDACTED: Time Period]**.

7.3 LOX and THA commit to run electronic communication by means of data file transmission in order to exchange information related to the object of the present Agreement.

7.4 Both parties will subscribe to the corresponding Information Transfer Agreement included in Exhibit **Erreur ! Source du renvoi introuvable.**

8 AUDITS AND INVENTORIES

8.1 During the term of this Agreement, THA shall have the right to perform (i) quality audit per year (ii) once per year inventory of its stored goods.

8.2 LOX shall maintain complete and accurate records as evidence to support LOX's charges hereunder.

8.3 The dates for these audits should have been previously agreed by both parties. Each party shall bear its own costs in connection with such audits.

8.4 In addition to the mentioned audits, THA will be able to carry out any control, count or quality audit at any time. The expenses of these audits will be charged using the agreed tariffs at the moment of execution.

8.5 These actions should be communicated to LOX with at least **[REDACTED: Time Period]** prior notice, and they will be done at LOX warehouse within working hours and days.

9 INFORMATION EXCHANGE AND CONFIDENTIALITY, AND IT SUPPORT CONTROL

See VII EXHIBIT - INFORMATION TRANSFER AND CONFIDENTIALITY AGREEMENT.

10 OTHER SERVICES

10.1 THA could entrust LOX special services not included in present agreement, such as special storage, destruction, handling, packaging or additional administrative tasks.

10.2 A written request will be addressed to LOX detailing the additional service required. LOX will answer the request with the procedure to apply and quotation if required.

10.3 THA and LOX will previously agree on the operational procedure to apply.

11 TRANSPORT AGREEMENT

11.1 It is THA's responsibility to select the optimal transport solution for its products to comply with GDP regulations and all relevant regulations of pharmaceutical products deliveries. LOX will manage and monitor the transportation solution selected by THA.

11.2 General Conditions of Transport Services

11.2.1 The present conditions are applicable to the contracted services unless a specific agreement has been reached for a particular product or service.

11.2.2 Service will be provided in labour working days from Monday to Friday, except complementary services contracted for delivery and/or pick up on Saturdays.

11.2.3 LOX will endeavour to have the products delivered by the transport company in a timely manner (normal next day regular service Monday to Friday ca. **[REDACTED: Percentage]** delivered next day or Monday). It will not be considered as a non-fulfilment of the delivery term if the delivery has not been possible due to receiver's absence, change of address, unpaid amounts, closure

due to vacations, second delivery attempt, force majeure, acts of Nature or other circumstances not attributable to LOX.

11.2.4 Managing of claims will be done via written communication from THA, within the next **[REDACTED: Time Period]** from the claim received and containing facts sufficient to identify the shipment(s) of property involved including transport documents and delivery receipts.

12 PAYMENT CONDITIONS

12.1 LOX shall issue its invoices for the Services on a monthly basis.

12.2 THA shall pay all correctly issued invoices within **[REDACTED: Time Period]** from the date of invoice.

13 TERMINATION

13.1 Either Party shall be entitled to terminate this Agreement with immediate effect by written notice to the other if:

(a) the other Party commits any continuing or material breach of any of the provisions of this Agreement and, in the case of such a breach which is capable of remedy, fails to remedy the breach within thirty **[REDACTED: Time Period]** of being notified of such breach;

(b) the other enters liquidation either compulsory or voluntary (save for the purpose of reconstruction or amalgamation without insolvency) or if a receiver or an administrator is appointed in respect of the whole or any part of its assets (or if any petition for the appointment of such receiver or administrator is presented to any court) or if it makes an assignment for the benefit of, or composition with, its creditors generally or threatens to do any of these things or if it undergoes any analogous occurrence under foreign law;

13.2 For the purposes of clause 13.1 (a) a breach shall be considered capable of remedy if the breaching Party can comply with the provision in question in all respects other than as to the time of performance.

13.3 Any failure to pay any uncontested amount within **[REDACTED: Time Period]** of its due date shall be considered a material breach of this Agreement.

13.4 This Agreement may be terminated at any time with the written agreement of the Parties.

13.5 Upon the termination or expiration of this Agreement LOX shall, at the request of THA with reasonable notice deliver to THA:

(a) a status report on the Services at the date of termination or expiry;

(b) all THAs Products;

(c) all THAs information, including without limitation customers' information and sales data, independently of its form (including, but not limited to, any reproduction, notes and summaries, print-outs or copies of information stored in electronic or computerized systems), save that LOX may alternatively delete or destroy any of THA's information in electronic form or embodied in any document or material created by LOX or its Affiliates, after confirmation that THA has received such, and shall certify such deletion or destruction. Any such destruction will adhere to any country regulation pertaining to its storage tenure and destruction. Notwithstanding the foregoing, LOX may retain one copy of THA's information in the files of legal counsel solely for archival purposes.

13.6 In the event that notice is given to terminate so that the current Term is not fulfilled, then the full fees until end of the Term (or minimum charges whichever is the higher) as set out in VI EXHIBIT – SERVICE FEE will be invoiced by LOX to THA. However, this does not apply if THA terminates the Agreement according to this section 13.1 a) or b), section 17, or if a THA's affiliate succeed to this agreement or sign a new agreement with LOX for similar services on conditions to be defined.

13.7 LOX is not obliged to forward orders which LOXs receives after termination to the THA. Within **[REDACTED: Time Period]** after termination LOX shall promptly inform respective customers if LOX still receives orders (the Fees for Special Services apply as listed in VI EXHIBIT – SERVICE FEE, specifying to such customers an appropriate contact person at THA or THA's designee.

In case LOX receives returns concerning THA's products after termination, LOX shall document their receiving and forward them to THA (the Fees for returns and transport apply as listed in VI EXHIBIT – SERVICE FEE).

Invoice copies and books to be retained by legal terms will be stored at LOXs warehouse at THA's cost during the Term. In case of termination, LOX might have to store such records for any legally required period, with storage costs for the remaining years invoiced to THA for the remaining years at once in full upfront and as per the costs set down in VI EXHIBIT – SERVICE FEE.

13.8 Upon the termination or expiration of this Agreement THA shall at the request of the LOX return to LOX with reasonable notice all LOX information, independently of its form (including, but not limited to, any reproduction, notes and summaries, print-outs or copies of Information stored in electronic or computerized systems), save that THA may alternatively delete or destroy any LOX information in electronic form or embodied in any document or material created by LOX or its Affiliates, and shall certify such deletion or destruction; any such destruction will adhere to and take into account any country regulation pertaining to its storage tenure and destruction. Customer information and Sales data of THA's products will not have to be returned to LOX or

deleted. Notwithstanding the foregoing, THA may retain one copy of LOX information in the files of legal counsel solely for archival purposes.

13.9 Any waiver by either Party of a breach of any provision of this Agreement shall not be considered as a waiver of any subsequent breach of the same or any other provision.

13.10 The rights to terminate this Agreement given by this clause shall not prejudice any other right or remedy of either Party in respect of the breach concerned (if any) or any other breach.

13.11 Upon the termination of this Agreement for any reason, subject as otherwise provided in this Agreement and to any rights or obligations which have accrued prior to termination, neither Party shall have any further obligations to the other under this Agreement.

14. TRADEMARKS

14.1 LOX shall not have itself registered as the owner of THA's trademarks or names, nor shall it apply for any registration which might conflict with THA's trademarks and names; furthermore, LOX shall not interfere in any other way whatsoever with such trademarks and names; except in each case with the consent of THA.

14.2 LOX undertakes to use neither the name nor the trademarks of THA in its advertising unless required to do so by law.

14.3 THA warrants that the goods are marketable in the European Union and that they hold appropriate product licences for all goods.

15 SEVERABILITY

In the event any court or agency of competent jurisdiction determines that any portion of this Agreement is void or unenforceable, the remainder of this Agreement shall continue unaffected.

16 ASSIGNMENT

This Agreement may not be transferred or assigned, either totally or in part, by either of the parties hereto, to any third party, without the prior written consent of the other party, except that Principal may sub-contract any obligations it has upon approval of Distributor as long as it continues to be responsible for the performance of these obligations.

17 FORCE MAJEURE EVENT

17.1 In this Agreement, “force majeure” shall mean any cause preventing either Party from performing any or all of its obligations which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the Party so prevented.

17.2 If either Party is prevented or delayed in the performance of any of its obligations under this Agreement by force majeure, that Party shall forthwith serve notice in writing on the other Party specifying the nature and extent of the circumstances giving rise to force majeure, and shall, subject to service of such notice, have no liability in respect of the performance of such of its obligations as are prevented by the force majeure events during the continuation of such events, and for such time after they cease as is necessary for that Party, using its best efforts, to recommence its affected operations in order for it to perform its obligations.

17.3 If either Party is prevented from performance of its obligations for a continuous period in excess of **[REDACTED: Time Period]**, either Party may terminate this Agreement forthwith on service of written notice upon the Party so prevented, in which case neither Party shall have any liability to the other except that rights and liabilities which accrued prior to such termination shall continue to subsist.

17.4 The Party claiming to be prevented or delayed in the performance of any of its obligations under this Agreement by reason of force majeure shall use its best efforts to bring the force majeure event to a close or to find a solution by which the agreement may be performed despite the continuance of the force majeure event.

17.5 Force majeure may not excuse any failure to pay any amount when due under this Agreement.

18 REGULATORY AUTHORITIES

18.1. This Agreement shall be governed by the laws of Germany.

18.2. All disputes or claims of any sort arising from or relating to this Agreement, or the validity or breach thereof, shall first be discussed by the Parties hereto, who shall try to settle the dispute among themselves. Should they fail to agree, both parties agree to submit themselves to the jurisdiction of the Courts of Munich/Germany, renouncing expressly to any other jurisdiction that could concern them.

19 STATEMENT OF EXHIBITS

- I EXHIBIT – CLIENTS AUTHORIZATION
- II EXHIBIT – LOXXESS AUTHORIZATION
- III EXHIBIT – TERRITORY
- IV EXHIBIT – PRODUCT LIST / SHIPMENT MODE & SERVICE
- V EXHIBIT – SERVICES
- VI EXHIBIT – SERVICE FEE
- VII EXHIBIT – INFORMATION TRANSFER AND CONFIDENTIALITY AGREEMENT
- VIII EXHIBIT – QUALITY AGREEMENT
- IX EXHIBIT – CONTACT LISTS

All modification or supplement to the contract or its exhibits will be valid only in written and duly signed in all its pages by both parties.

Executed in two original counterparts,

Date: July 9, 2020

Date: July 20, 2020

Signed: /s/ Conor Walshe

Signed: /s/ Helmut Müller-Neumayr

General Manager

Managing Director

Theratechnologies Europe Limited

Loxxess Pharma GmbH

EXHIBITS

I. EXHIBIT – CLIENTS AUTHORIZATION

[REDACTED: Clients Authorization]

II. EXHIBIT - LOXXESS AUTHORIZATION

[REDACTED: Loxxess Authorization]

III. EXHIBIT - TERRITORY

[REDACTED: Territory]

IV. EXHIBIT – PRODUCT LIST / SHIPMENT MODE & SERVICE

[REDACTED: Product List / Shipment Mode & Service]

V. EXHIBIT - SERVICES

[REDACTED: Services]

VI. EXHIBIT – SERVICE FEE

[REDACTED: Service Fee]

VII. EXHIBIT - INFORMATION TRANSFER AND CONFIDENTIALITY AGREEMENT

[REDACTED: Information Transfer and Confidentiality Agreement]

VIII. EXHIBIT – QUALITY AGREEMENT

[REDACTED: Quality Agreement]

IX. EXHIBIT - CONTACT LISTS

[REDACTED: Contact Lists]

MASTER SERVICES AGREEMENT

This MASTER SERVICES AGREEMENT (hereinafter the “**Agreement**”) is entered into on December 18, 2020 (the “**Effective Date**”) between the following Parties:

BETWEEN: **THERATECHNOLOGIES INC.**, a corporation governed by the laws of Quebec, having a place of business at 1100-2015 Peel Street, Montreal, Quebec H3A 1T8
(hereinafter the “**Client**”)

AND: **WORLDWIDE CLINICAL TRIALS, INC.**, having a place of business at 600 Park Offices Drive, Suite 200, Research Triangle Park, Durham, NC 27709600 Park Offices Drive, Suite 200, Research Triangle Park, Durham, NC 27709, USA
(hereinafter together with its Affiliates, the “**Supplier**”)
(hereinafter, collectively, the “**Parties**”)

WHEREAS Client is 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;

WHEREAS Supplier is engaged in providing services to pharmaceutical companies in support of their clinical research and product development activities;

WHEREAS Client wishes to retain the services of Supplier on a non-exclusive basis for the purposes set forth herein, and Supplier agrees to provide such services, the whole in accordance with the terms and conditions of this Agreement;

WHEREAS, Client agrees to compensate Supplier for its services.

NOW, THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

1. SERVICES

- 1.1 Supplier, itself or through one of its Affiliates (if applicable), hereby agrees to perform the services (the “**Services**”) in accordance with the terms of this Agreement and any associated Statement(s) of Work (as hereinafter defined). In the event that Client requires the performance of Services, it shall enter into a Statement of Work, defined as a separate written agreement between Client and Supplier, specifying the basic parameters of a project, including, without limitation, the assumptions, the costs, payment schedule, and the time period for completing a project, or, as applicable, other Services to be performed by Supplier for Client (the “**Statement of Work**”). The Statement of Work shall be substantially in the form as that attached hereto as Schedule A. To the extent any term or provision of a Statement of Work conflict with the terms and provisions of this Agreement, the terms and provisions of this Agreement shall prevail, except to the extent the Parties

agree, or the applicable Statement of Work expressly and specifically states an intent to supersede this Agreement on a specific matter. Once executed by the Parties, the Statement of Work is deemed part of this Agreement and is included herein by reference and the Parties are bound by its terms and conditions.

1.2 Each Statement of Work shall include the following:

- 1.2.1 a reference to this Agreement and include a detailed description of the Services to be provided by Supplier to Client and items to be delivered by Supplier to Client (the “**Deliverables**”);
- 1.2.2 the fees and/or expenses payable by Client to Supplier (collectively, the “**Fees**”) for the Services and Deliverables (each, a “**Fee Schedule**”);
- 1.2.3 the date of the commencement of the Services and/or date of delivery of the Services and Deliverables; and
- 1.2.4 a signature block for each Party.

Supplier shall perform the Services within the estimated time frame set forth in the applicable Statement of Work. Such time estimate assumes, however, the full cooperation of Client, Regulatory Authorities, Ethics Committees and investigators and other third Parties not under Supplier’s control, and shall be subject to adjustment (including costs) if the work for the Services is delayed due to circumstances not attributable to Supplier.

1.3 **Changes.** At any time during the Term, Client may provide a written notice to Supplier requesting an amendment to the Services set forth in a Statement of Work or, if Supplier believes a change in the scope or scale of Services is necessary or advisable, Supplier shall so advise Client. Either Party shall respond to any such request within **[REDACTED: Time Period]** of receiving it. If any such variation causes an increase or decrease in the cost of the Services, the Parties shall negotiate in good faith any proposed revision including an equitable adjustment to the Fees and execute a Change Order (“**Change Order**”) to the applicable Statement of Work within a reasonable amount of time. Each change will be discussed, agreed and recorded in an out of scope log (“**Out of Scope Log**”) prior to being formalised in a Change Order on the achievement of an agreed threshold. In the event Supplier provides additional services or expends resources at Client’s written request and in strict accordance with Client’s requirements, in the absence of a Change Order or Out of Scope Log, Client will compensate and/or reimburse Supplier for all reasonable fees and reasonable costs incurred. In the event Client fails to adhere to the terms of this provision and to compensate and/or reimburse Supplier for out of scope Services within a reasonable amount of time, Supplier reserves the right to suspend Services until such payment obligations have been met. If the Parties are unable to agree on a proposed amendment to the Services set forth in a Statement of Work, the original Statement of Work shall govern, unless either Party terminates such Statement of Work pursuant to Article 4.

1.4 Supplier shall use its skill and ability in performing the Services. Supplier shall conduct all work and provide all Deliverables in accordance with accepted standards of the pharmaceutical industry. Supplier warrants that it has adequate facilities and sufficient

competent staff allowing for the performance of the Services in accordance with this Agreement.

- 1.5 **Compliance with Laws/Agreements.** The Parties shall perform their obligations under this Agreement and each Statement of Work in accordance with the terms of this Agreement, the applicable Statement of Work, applicable provisions of the Study protocol, agreed upon standard operating procedures, the current Guidelines for Good Clinical Practice and the Declaration of Helsinki (as applicable to Services and in accordance with the specific standards and versions identified in the applicable Study protocol), all applicable laws and regulations, and applicable data privacy regulations, including (as applicable to Services) the European Union’s General Data Protection Regulation (“**GDPR**”) and the California Consumer Privacy Act (“**CCPA**”). Notwithstanding the foregoing, the Parties acknowledge that CCPA exempts “information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, pursuant to good clinical practice guidelines issued by the International Council for Harmonisation or pursuant to human subject protection requirements of the U.S. Food and Drug Administration.” Cal. Civ. Code § 1798.145(c). Each Party shall ensure that all consents and authorizations required by applicable law are obtained, such that the other Party and each of the other Party’s permitted employees, agents, contractors, and representatives are permitted to access and/or process Personal Data of the other Party’s employees, agents, contractors, and representatives, for the purpose of fulfilling any obligation under this Agreement or for the purpose of complying with any requirement under applicable law or any other legal or regulatory requirement to which the Parties are subject. In addition, where GDPR is in scope, the terms of the Data Processing Agreement attached to this Agreement as Schedule B incorporated herein by reference shall apply with respect to the applicable processing activity.

The Parties and their respective owners, officers, directors, employees or agents have not and shall not pay, give, offer or promise to pay or give, or authorize the payment, directly or indirectly, of any money or anything of value to any foreign government official or employee (including employees of state-owned institutions), for the purpose of (i) influencing any act or decision of such official or of such government, (ii) inducing that person to do or omit doing any act in violation of his or her lawful duty, (iii) securing an improper advantage, or (iv) influencing such official to use his influence with the government to effect or influence the decision of such government, in order to assist Client or Supplier in obtaining or retaining business for or with or directing business to any person.

Each Party agrees to comply with all applicable anticorruption laws, rules and regulations. The Parties agree to reasonably cooperate with each other’s diligence efforts in order to satisfy each Party’s obligations under the United States Foreign Corrupt Practices Act, as amended (“**FCPA**”), the UK Bribery Act and any implementing legislation under the OECD Convention Against Bribery of Foreign Government Officials in International Business Transactions. Each Party represents, warrants and covenants that it maintains adequate internal controls and accurate books and records to the extent required in order to comply with applicable anti-corruption laws (collectively the “**Applicable Laws**”).

- 1.6 *[Voluntarily Deleted]*

- 1.7 Without limiting either Party's other contractual and legal rights it may have, any anticipated delay in the completion of the Services or delivery of the Deliverables shall be communicated in writing by Supplier to Client as soon as possible.
- 1.8 **Transfer of Obligations.** Each Statement of Work shall constitute a unique agreement and shall stand alone with respect to any other Statement of Work entered into under this Agreement. As required under Title 21 CFR Part 312.52 or such other substantially equivalent regulation as may be required by the applicable jurisdiction where the Study is conducted, including but not limited to Directive 2001/20/EC and Directive 2005/28/EC, the Parties shall document in writing the transfer by Client to Supplier of any of Client's responsibilities under Title 21 CFR Part 312, Subpart D or such other substantially equivalent regulation as may be required by the applicable jurisdiction where the Study is conducted. Notwithstanding the foregoing, Client will retain the ultimate authority and oversight over and responsibility for each Study.
- 1.9 **Work Product.** During the Term of each Statement of Work, Supplier shall maintain all materials and all other data or documents included in the Trial Master File obtained or generated by Supplier in the course of providing the relevant Services in accordance with Supplier's standard operating procedures, including all computerized records and files ("**Work Product**"), in a secure area reasonably protected from fire, theft and destruction. At the expiration or termination of a Statement of Work and subject to satisfaction of the Parties' obligations thereunder, Supplier shall, at Client's expense, provide for the disposition of the Work Product as agreed in the applicable Statement of Work. The Statement of Work shall provide that Supplier (a) deliver the Work Product, in the form in which Supplier currently holds them, to a designated Client location or to such other entity or at such other address as Client may specify, (b) retain the materials for the period of time specified in the Statement of Work, or (c) destroy all such materials except for those which Supplier is required by law or regulation to store or maintain. Upon expiration or termination of a Statement of Work, any storage, destruction or shipping costs or services relating to such disposition of the Work Product will be billed by Supplier to Client as Pass-through Expenses (as defined below) and all regulatory responsibilities with respect to the maintenance of such Work Product shall be conferred to Client, as evidenced by Client's written acknowledgement of acceptance. Notwithstanding the foregoing, Supplier may retain copies of any portion of the Work Product as may be reasonably necessary for regulatory or insurance purposes and one electronic, archival backup copy in accordance with Supplier's data retention standard operating procedures, subject to its ongoing obligation to maintain the confidentiality of such materials. For the avoidance of doubt study records, documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced, ("**Records**") are not required by regulatory bodies to be retained beyond the contractual agreement with the Client. By default, all Records will be returned to Client at Client's expense if not specified otherwise in a Statement of Work.

2. FEES

- 2.1 The Parties agree that the fees and other reimbursements that Supplier will receive for performing the Services hereunder will be outlined in each Statement of Work and are subject to the following terms and conditions.

- 2.2 **Compensation for Services.** As compensation for providing the Services, Client shall pay Supplier in accordance with the terms in this Agreement and each applicable Statement of Work. Each Statement of Work will include as attachments a Study budget containing Supplier's estimated service fees and Pass-through Expenses (the "**Fee Schedule**"), a payment schedule (the "**Payment Schedule**") and a timeline showing performance milestones (the "**Timeline**").
- 2.3 **Pass-through Expenses.** Client will reimburse Supplier for travel and other reasonable out-of-pocket expenses, exclusive of grant payments (described below), incurred by Supplier as identified in the Budget or otherwise approved by the Client which Supplier will invoice to the Client without mark-up ("**Pass-through Expenses**"). Pass-through Expenses shall include, but shall not be limited to lodging, travel, third party vendor costs, and other reasonable costs.
- 2.4 **Invoices.** Supplier shall be required to provide Client with a **[REDACTED: Time Period]** reasonably detailed invoice by email to Client (insert Client's email address) on a **[REDACTED: Time Period]** basis with appropriate supporting summary documentation, detailed back-up of Pass-through Expenses, including actual expense reports and/or expense receipts will not be provided to Client. Supplier shall retain receipts for review by Client upon Client's written request.
- 2.5 **Payment Schedule.** Client agrees to pay for Services and Pass-through Expenses in accordance with the Payment Schedule outlined in each Statement of Work or associated Change Order.
- 2.6 **Payment Terms.** Client shall pay for all Services, Pass-through Expenses and other items invoiced in accordance with the terms of this Agreement within **[REDACTED: Time Period]** following the receipt of an invoice by Client from Supplier. Supplier reserves the right to suspend Services in the event undisputed invoices are not paid in accordance with the payment terms contained herein. All payments will be made in the currency noted in the Statement of Work. All fees for Services and Pass-through Expenses under this Agreement are stated exclusive of any local, state, federal or foreign sales and use taxes, VAT, if any, as any such taxes shall be paid by Client. If such taxes are applicable under local regulations, Supplier will add these taxes to the invoices at the relevant rate. Supplier reserves the right to apply inflation to fees for new and ongoing services that extend beyond the Term agreed in the applicable Statement of Work. Payments shall be made by Client via wire transfer of immediately available funds to Supplier's account set forth in the applicable Statement of Work.
- 2.7 **Project Delays.** In the event Client delays, suspends or places a hold on the Study for any reason, Client shall promptly provide Supplier with written notice of such delay, hold or suspension, and Client and Supplier will, within **[REDACTED: Time Period]** of such notice, agree on appropriate revisions to the applicable Statement of Work and each Party will complete its respective duties and obligations as described in any resulting Change Order. During the period following Supplier's receipt of Client's notice of delay, hold or suspension, Client will compensate Supplier for additional service fees and Pass-through Expenses incurred by Supplier as a result of such delay or suspension, as agreed to and as set forth in any such resulting Change Order.

2.8 In the event that a Study is delayed or placed on-hold for more than **[REDACTED: Time Period]**, Client shall have the right to retain, at its expense, all core team members of Supplier allocated to the performance of the Services at their contracted rate for the duration of the delay or on-hold period. Such contracted rate shall be detailed in each Statement of Work. If Client does not wish to retain any core team members for the duration of the delay or on-hold period, Supplier shall have the right to reallocate any and all such staff after such **[REDACTED: Time Period]**. If the delay or on-hold period continues for **[REDACTED: Time Period]**, either Party may, by provision of written notice, immediately terminate the applicable Statement of Work.

2.9 **Disputed Invoices.** In the event Client disputes one or more items in an invoice, Client will notify Supplier in writing within **[REDACTED: Time Period]** of receipt of the invoice and such notice shall contain a reasonably detailed description of the item(s) being disputed and the basis therefor. Supplier will respond to Client within **[REDACTED: Time Period]** of receipt of the notification. This written communication pattern will continue until Supplier has provided Client with sufficient justification for the disputed item(s) or until the Parties agree to a resolution of the disputed amount. Client shall pay the undisputed portion of the invoice in accordance with the payment terms and shall use its best efforts to pay the disputed amount within **[REDACTED: Time Period]** of resolution of the dispute. In the event the Parties are unable to reach a satisfactory resolution within **[REDACTED: Time Period]** of the original invoice, either Party may pursue alternative remedies in accordance with this Agreement.

3. **THIRD PARTY AGREEMENT.**

3.1 **Third Party Providers.** Supplier may retain one (1) or more third-party providers to perform, in whole or part, Services required under any Statement of Work governed by this Agreement. Supplier shall ensure each third-party provider is bound by terms and conditions at least as restrictive as the obligations outlined in this Agreement regarding intellectual property and confidential information in connection with the performance of Services under any Statement of Work.

In the event Supplier contracts with third party providers of its choosing, Supplier hereby agrees to manage and assume responsibility for such third party provider's performance and shall be liable for the acts or omissions of such third party provider as if they were acts or omissions of Supplier.

In the event Client requests Supplier to use a particular third party provider, and Supplier, at its reasonable discretion, does not wish to contract with such third party provider, then Client shall contract directly with such third party provider (a "**Client Designated Provider**"). In no case will Supplier be liable to Client for Client Designated Provider's performance or non-conformance with any obligations under this Agreement or the instruction or supervision of such Client Designated Provider.

3.2 **Institutions/Investigators.** Supplier's Services under a Statement of Work may include identifying potential medical institutions ("**Institutions**") or clinical investigators ("**Investigators**") (Institutions and Investigators together, the "**Sites**") and/or negotiating, executing and/or administering contracts with such Parties which will govern their participation in the Study ("**Clinical Trial Agreements**"). If, pursuant to a Statement of

Work, Client delegates to Supplier the responsibility for negotiating and/or executing Clinical Trial Agreements, the following provisions will apply:

- (a) Client may provide Supplier with a list of suggested Sites to be recruited by Supplier for a Study. Supplier shall notify Client in writing as to any listed Site with which Supplier does not wish to contract.
- (b) Selection of all Sites will be subject to approval by Client prior to initiation of any Study-related activities involving that Site or the start of any negotiations with such Site.
- (c) Where Supplier is negotiating Clinical Trial Agreements on behalf of Client, Supplier templates and fallback parameters shall be used. Templates, parameters and negotiation process will be subject to approval by Client prior to the start of negotiation with the Sites and shall be incorporated into a Contract and Budget Plan executed by the Parties.
- (d) In **[REDACTED: Territory]** regions, local laws, practices and logistical considerations may make it necessary or preferable for Supplier to act as a contracting party to the Clinical Trial Agreements. For such regions, Supplier may enter into Clinical Trial Agreements directly as an agent on behalf of Client. Unless otherwise required by applicable law, each template shall clearly identify the agency relationship between Client and Supplier and all Client rights and obligations under the Clinical Trial Agreement shall remain with Client as principal.
- (e) If a Site requests indemnification from Client, standard indemnification language, generated by the Client, will be provided to the Site. If the Site requests changes to the standard language, Supplier will negotiate with the Site on Client's behalf after receipt of Client's instructions and, if agreed, Client will issue a letter of indemnification directly to the Site. Client acknowledges that Supplier shall have no indemnification obligation to any Site relative to the Study drug or the applicable Study protocol. In addition, Supplier shall not be deemed to have failed to perform under this Agreement in the event a Site declines participation in a Study as a result of Client's refusal to indemnify such Site.
- (f) Client may elect that grant payments to Sites be administered on its behalf by Supplier, acting solely as payment agent unless otherwise agreed to by Supplier in writing. Supplier shall distribute all payments to Sites according to the provisions of the applicable Clinical Trial Agreement and Statement of Work. Client acknowledges and agrees that Client will manage all administration of payments or other obligations to Sites for Services rendered in connection with relevant Studies solely out of funds provided to Supplier from Client for this specific purpose. Furthermore, Client acknowledges and agrees that Supplier intends to maintain a cash neutral policy with regard to Site payments. In the event Supplier or the Sites incur bank fees with respect to the remittance of these grant payments, such fees will be borne by Client. All payments to Sites and any associated bank fees will be made by Supplier solely from the funds that have been specifically provided by Client to Supplier for this purpose and not from Supplier funds. Supplier will not be liable for payments not made on a timely basis to any Site as a result of Client's failure to provide, in advance, sufficient funds for such payments.

The Parties acknowledge and agree that, for the purposes of this Agreement or any Statement of Work, Sites shall not be considered as employees, agents or subcontractors of Supplier and that Sites will be required to exercise their own independent medical judgement. Supplier's responsibilities with respect to Sites shall be limited to those specifically set forth in the applicable Statement of Work.

4. TERM OF AGREEMENT

4.1 This Agreement shall become effective as of the Effective Date and, unless otherwise terminated, shall continue in full force and effect for a period of three (3) years (the "**Initial Term**"). Thereafter, this Agreement shall automatically renew for periods of one (1) year (each a "**Renewal Term**") (the Initial Term and any Renewal Term collectively referred to as the "**Term**") unless either Party provides notice of intent not to renew the Agreement within **[REDACTED: Time Period]** of the expiration date of the applicable Term or Renewal Term. Termination of this Agreement shall not affect any Statement of Work and each Statement of Work shall continue in full force and effect until its expiration date or final payment is received, unless specifically earlier terminated in accordance with the terms of this Agreement or the terms of that Statement of Work.

4.2 TERMINATION

Client or Supplier may terminate this Agreement or any applicable Statement of Work immediately upon written notice from a Party to the other, if:

4.2.1 patient safety concerns;

4.2.2 the other Party becomes insolvent, makes an assignment of its property for the benefit of its creditors, is wound up or declared bankrupt, is subject to a petition in bankruptcy or liquidation or avails itself of any bankruptcy or insolvency legislation, or shall petition for or consent to any relief under any insolvency, re-organization, receivership, liquidation, compromise, or any moratorium statute, whether now or hereafter in effect, or shall make an assignment for the benefit of its creditors, or shall petition for the appointment of a receiver, liquidator, trustee, or custodian for all or a substantial part of its assets, or if a receiver, liquidator, trustee or custodian is appointed for all or a substantial part of its assets and is not discharged within **[REDACTED: Time Period]** after the date of such appointment; or

4.2.3 the other Party breaches any of the terms of Article 8 or Article 9.

4.3 Client or Supplier may terminate this Agreement upon notice in writing from a Party to the other if the other Party is in material breach of any of its obligations hereunder and does not remedy such breach within a period of **[REDACTED: Time Period]** following receipt of a written notice of the default or breach from the other Party, the Party giving notice may, at its option, immediately terminate this Agreement, or the Statement of Work, as applicable, at the end of the **[REDACTED: Time Period]**. For the avoidance of doubt, non-payment hereunder shall automatically be deemed a material breach.

4.4 This Agreement may be terminated by Client at any time during the Term, in whole or in part, including with respect to any Statement of Work (without terminating the rest of the Agreement) (other than for breach by Supplier), on **[REDACTED: Time Period]** prior

written notice to Supplier. In the event of termination in accordance with this Article 4.4, the Parties shall without delay:

4.4.1 reasonably cooperate with each other to provide for an orderly cessation of Supplier's Services;

4.4.2 discontinue performance of the Services;

4.4.3 preserve Services in progress and complete Deliverables resulting from such Services;

4.4.4 take commercially reasonable efforts to mitigate any additional expense or cost; and

4.4.5 deliver to Client all Deliverables, documents and materials containing Confidential Information (as defined in Section 9 of this Agreement) in accordance with Section 9.5 and all work product, including all copies or excerpts thereof;

4.4.6 Client's obligation with respect to termination shall be to pay to Supplier any Fees for all Services actually performed (based on units completed) and expenses incurred or irrevocably committed to third Parties up to the effective date of termination in accordance with the contracted payment terms. In addition, Client shall pay all reasonable fees and expenses incurred by Supplier that are necessary or reasonably required in connection with the orderly cessation of the Services. Upon satisfaction of the Parties' obligations under this Section 4.4.6, Supplier shall deliver all final Deliverables to Client and the Parties shall execute a final reconciliation and release agreement pertaining to the applicable Statement of Work. If a Study, Statement of Work, or the Agreement is cancelled or terminated before the Services have been performed completely, Supplier shall refund to Client any funds advanced to Supplier for fees and costs not yet incurred or due to the extent that the payments for the liabilities associated with such fees or costs can reasonably be avoided in whole or in part.

4.4.7 Supplier shall have the right to terminate this Agreement or any Statement of Work hereunder (other than for breach by Client) at any time by giving appropriate written notice at least **[REDACTED: Time Period]** prior to the desired termination date; provided, however, if Supplier terminates this Agreement while any Statement of Work remains in effect, the terms of this Agreement will continue in force until Supplier has completed the Services under the applicable Statement of Work and has received full payment therefor.

4.5 The obligations set forth in Articles 2, 8, 9, 10, 12 and 16 and in Sections 4.4, 13.1 and 20.6 shall remain in full force and effect for the period set forth in such Articles and Sections, or if none, the applicable statute of limitations period applicable to a claim for breach of such provision.

5. INDEPENDENT CONTRACTOR STATUS

The Parties' relationship, as established by this Agreement, is solely that of independent contractors; this Agreement shall therefore not be construed as creating, without limitation, an employer-employee relationship, a joint venture, a partnership or an employment-employer

relation between Client and Supplier. Subject to Section 3.2(d) and/or as may be expressly agreed otherwise in a Statement of Work in the case of legal representation in the **[REDACTED: Territory]**, neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

The employees of Supplier providing the Services and delivering the Deliverables are exclusively Supplier's employees. As such, Supplier shall be solely responsible for recruiting, selecting, assigning, supervising, evaluating, disciplining and controlling all aspects of the work performed by any of its employees and for ensuring that such employees comply with all ethical and quality standards in performing the Services contemplated hereunder. .

6. INSURANCE

6.1 For each applicable Statement of Work, Client hereby represents and warrants that it shall maintain adequate clinical trial and product liability insurance coverage, with insurance companies having an A. M. Best Rating of "A-, VII" or better, consistent with industry standards to cover all personal injury, death or loss suffered as a result of the Study drug, participation in the trial or the trial screening process. Other than as set forth in Section 11.1, to the extent that Supplier provides depot services to Client, Supplier does not take any responsibility for loss or damage to the Study drug while stored at Supplier's premises or in transit. Client hereby acknowledges that Supplier does not carry separate property insurance to cover the value of the Study drug(s). Client shall provide Supplier with a copy of Client's effective Certificate of Insurance, Insurance Policy, and any additional policy documents or such other documented evidence reasonably requested by Supplier to confirm that it has such coverage. Furthermore, for each Study, Client shall execute a Clinical Trial Insurance Declaration in a form substantially similar to Schedule C attached hereto. Client shall maintain such insurance for the entire duration of the Study and shall notify Supplier of any changes in coverage which impact the coverage requirements set forth above. Supplier agrees that during the Term it shall carry and maintain in full force and effect at its own expense the following insurance policies with insurers currently rated A-, VII or better by A.M. Best:

6.1.2 Workers Compensation and Occupational Disease insurance with statutory coverage and limits pursuant to the laws, rules and regulations of the jurisdictions in which any employee or agent of Supplier performs work under this Agreement;

6.1.3 Employers Liability insurance with minimum limits of **[REDACTED: Amount]** per accident or disease;

6.1.4 Commercial General Liability insurance including coverage for premises and operations, products and completed operations, contractual liability, bodily injury, property damage, and personal injury and advertising injury with a minimum policy limit of **[REDACTED: Amount]** per occurrence and **[REDACTED: Amount]** in the annual aggregate;

6.1.5 Products Liability insurance including bodily injury and property damage for all products and work supplied under this Agreement with a minimum policy limit of **[REDACTED: Amount]** per occurrence and **[REDACTED: Amount]** in the annual aggregate. This coverage can be satisfied through a General Liability policy including coverage for products and completed operations;

6.1.6 Commercial Umbrella Liability insurance which will provide excess, follow-form coverage above all liability limits required herein except for Products liability with per occurrence and annual aggregate limits of at least **[REDACTED: Amount]**;

6.1.7 Professional Errors and Omissions liability insurance with coverage for the performance or failure to perform any professional services provided by Supplier under this Agreement with limits of **[REDACTED: Amount]** per claim and **[REDACTED: Amount]** in the annual aggregate; Throughout the Term of this Agreement, the Errors & Omissions Liability insurance's retroactive date will be no later than the Effective Date of this Agreement

6.1.8 Information Security and Privacy Liability insurance including but not limited to coverage for privacy and network security liability: 1st and 3rd party liability, wrongful disclosure of data, disclosure of HIPAA protected health information; breach of security, downtime, Identification theft, web hosting (if applicable), credit monitoring service and with a minimum policy limit of **[REDACTED: Amount]** each occurrence or claim and **[REDACTED: Amount]** in the annual aggregate; and, such other insurance as Supplier may reasonably deem necessary to ensure the performance of its obligations under this Agreement;

6.1.9 Crime insurance (including Employee Dishonesty), with coverage for loss arising out of or in connection with any fraudulent or dishonest acts committed by the employees of Supplier, acting alone or in collusion with others, in an amount of at least **[REDACTED: Amount]**; and, such other insurance as Supplier may reasonably deem necessary to ensure the performance of its obligations under this Agreement. Supplier does not have Crime insurance (including Employee Dishonesty coverage) but is in the process of obtaining a Crime policy which covers Employee Dishonesty and Supplier will make best efforts to acquire policy in Q1 of 2021;

6.1.10 Network Security and Privacy Liability insurance (if applicable) including but not limited to coverage for privacy and network security liability: 1st and 3rd party liability, wrongful disclosure of data, disclosure of protected health information; breach of security, downtime, identification theft, web hosting (if applicable), credit monitoring service and with a minimum policy limit of **[REDACTED: Amount]** each occurrence or claim and **[REDACTED: Amount]** in the annual aggregate; and

6.1.11 Cyber Liability Coverage ((including HIPAA, GDPR breach, regulatory investigation defense and computer fraud , with coverage for loss arising out of or in connection with any fraudulent or dishonest acts committed by an employee of Supplier, acting alone, with a minimum policy limit of **[REDACTED: Amount]** each occurrence or claim and **[REDACTED: Amount]** in the annual aggregate.

6.2 **Certificates of Insurance and Additional Insureds.** Each Party agrees to provide the other Party with certificates of insurance for all required policies of insurance. Supplier shall cause insurer(s) to endorse all insurance policies to name Client as additional named insureds.

6.3 **Supplier's Policy is Primary Cover.** All insurance policies afforded by Supplier and Supplier's subcontractors shall be primary to and not contributing to any other insurance, self-insurance or captive insurance maintained by Client or its Affiliates.

6.4 **Satisfaction of Limits.** The limits required under this Agreement can be satisfied through any combination of primary and umbrella/excess insurance.

6.5 **No Relief from Obligations.** Approval or acceptance of any either Party's insurance policies by either Party shall not relieve either Party of any obligations contained herein, including either Party's obligations as part of this Agreement, whether claims are within, outside or in excess of either Party's policy limits, and regardless of solvency or insolvency of the insurer(s) that issues such coverage. Such insurance shall not preclude either Party from taking any actions that are available to it under any provision of this Agreement or otherwise under Applicable Law.

7. REPRESENTATIONS AND WARRANTIES

7.1 Each Party represents and warrants that:

7.1.1 it has been duly incorporated and validly exists under all Applicable Laws governing its existence;

7.1.2 it has the requisite capacity and powers to enter into this Agreement and to perform its obligations hereunder;

7.1.3 the execution of this Agreement by each Party and the performance of its obligations hereunder will not constitute a violation or breach of any obligation of any agreement between each Party and any third party;

7.1.4 it has all required permits, approvals, consents, waivers, licences, registrations or similar authorizations which are necessary to perform under this Agreement (collectively, the "**Authorizations**") and that such Authorizations are and will remain valid, in force and in good standing throughout the Term;

7.1.5 the performance under this Agreement will not infringe, misappropriate or violate the Intellectual Property of any third party.

7.2 **Disclaimer.** Client acknowledges that the results of the Studies for which the Services are to be provided hereunder are inherently uncertain and that, accordingly, there can be no assurance, representation or warranty by Supplier that the product covered by this Agreement can, either during the Term of this Agreement or thereafter, be successfully developed or receive the required approval by the regulatory authorities. Client further acknowledges that the development of the protocol concept and scientific rationale shall be the sole responsibility of Client regardless of Supplier's involvement in Study design or protocol-writing (or lack thereof).

8. EMPLOYEES; NON-SOLICITATION.

Supplier's staff is not, nor shall they be deemed to be at any time during the Term of this Agreement, the employees of Client. In consideration of the fees and benefits provided in this Agreement, Client agrees that, without Supplier's prior written consent, during the Term of this Agreement and for a period of **[REDACTED: Time Period]** following its expiration or other termination, neither Client nor any of its Affiliates shall directly solicit for employment or contract, attempt to employ or contract with, or assist any other entity in employing, contracting with or soliciting for employment or contract any employee who is at that time employed/contracted by Supplier and who had been employed/contracted by Supplier in connection with one or more Statement(s) of Work issued hereunder; provided, however, that Client and its Affiliates shall be

entitled to recruit and employ Supplier's employee(s) if such employee(s) have responded to an advertising of a general nature posted by Client or a third party acting as agent to Client seeking to fill out one or more positions with Client. In the event of a breach of this Section 8, Supplier shall be entitled to liquidated damages from Client in an amount equal **[REDACTED: Amount of damages]**. The Parties expressly agree that this amount is not a penalty but is a reasonable estimate of the damages that would result from any breach. In the event that legal action becomes necessary for the enforcement of all or any part of this provision or to collect the liquidated damages provided for herein, the prevailing party shall receive in addition to any other damages or relief awarded, its reasonable attorneys' fees, together with appropriate costs and interest. Client acknowledges that in the event of a breach of this Section 8, Supplier shall be entitled to recover injunctive relief as well as liquidated damages, and that the liquidated damages provision included herein does not provide Supplier with an adequate remedy at law for any such breach.

9. CONFIDENTIALITY

9.1 The Parties acknowledge and agree that in the course of performing Services hereunder, either Party may be exposed to or be given confidential or proprietary information of the other Party ("**Confidential Information**"). The Parties agree to hold all Confidential Information in secrecy during the term of this Agreement and for a period of **[REDACTED: Time Period]** after its termination or expiry and they shall disclose Confidential Information to third Parties only on a need-to-know basis. Without limiting the generality of the foregoing, Confidential Information shall include, without limitation:

9.1.1 scientific information, clinical data, efficacy and safety data, formulas, methods and processes, testing techniques, analytical test method, test samples and prototypes, information gathered or viewed during a site visit, audit or inspection of a Party, analyses, source codes specifications, pricing strategies, customer lists, proposals, contracts, technical and/or financial information, protocols, brochures, employee information, research and development programs, databases, software, and , technological or other know-how;

9.1.2 Intellectual Property belonging to or used by either Party or one of its Affiliates, as well as any information that is or may be subject to an Intellectual Property right of the latter;

9.1.3 any summary, Client or Supplier list, report, analysis, compilation, memorandum, note, excerpt, study or other written information, including the Deliverables and any document developed or prepared by either Party or its employees in connection with providing the Services and delivering the Deliverables;

9.1.4 any information provided by either Party that is identified as "confidential"; the provisions of this Agreement.

9.2 Confidential Information shall be deemed to be all such information given by the disclosing Party to the receiving Party except for information (i) that is currently known or becomes generally known to the public other than through disclosure by the receiving Party in breach of this Agreement, (ii) in respect of which there is written proof that the receiving Party had or obtained access thereto on a non-confidential basis and that came from a source that was not bound by a confidentiality agreement with disclosing Party or its Affiliates or by a contractual, legal or

fiduciary obligation otherwise prohibiting the transmission of the Confidential Information, (iii) as evidenced by written records, is independently developed by receiving Party without the use of the Confidential Information, or (iv) already in possession of the receiving Party as indicated in its written records; or (v) required by any law, rule, regulation, order, decision, decree, or subpoena or other judicial, administrative, or legal process to be disclosed.

9.3 Receiving Party understands and agrees that disclosing Party is entitled to protect its Confidential Information and that the unauthorized use or disclosure thereof may cause serious harm to the disclosing Party. Throughout the Term of the Agreement and after the termination or expiry thereof, receiving Party shall protect the confidentiality of the disclosing Party's Confidential Information and shall not use, disclose or publish such information (for its benefit or the benefit of another Party) nor disclose it to another Person (including any employee of the disclosing Party), unless required for the purposes of providing the Services or delivering the Deliverables. Receiving Party shall also take reasonable measures to prevent any inadvertent disclosure of any Confidential Information. Receiving Party shall ensure that the disclosure of Confidential Information to its directors, officers, employees, consultants, students or other persons involved in the provision of the Services is made on a "need to know" basis, and that each of them is bound in writing to observe the confidentiality obligations of this Agreement or similarly stringent provisions.

9.4 Notwithstanding Section 9.3, receiving Party may disclose any Confidential Information if required by law or if the receiving Party is compelled to disclose the Confidential Information by order of a court or any other competent authority, on condition that the receiving Party (i) notifies the disclosing Party of its obligation to disclose such Confidential Information within a reasonable period of time to allow the disclosing Party to take any necessary measures to prevent such disclosure, (ii) make the confidential nature of the Confidential Information known to such authority or court. The receiving Party shall also collaborate with the disclosing Party in order to allow the disclosing Party to obtain any measure to prevent the disclosure of the Confidential Information. Where measures to prevent the disclosure of the Confidential Information are not obtained, the receiving Party may only disclose the portion of the Confidential Information it is compelled to disclose.

9.5 Unless otherwise agreed in writing, within **[REDACTED: Time Period]** after the termination or expiry of the Agreement or upon the written request by the disclosing Party, the receiving Party shall return to the disclosing Party (or destroy if so instructed) all Confidential Information in documentary or permanent form including any and all copies thereof, except for one archival copy that the receiving Party can keep for its records (which may be electronic). The disclosing Party may require the receiving Party to confirm, that the Confidential Information and material pertaining to disclosing Party's IP were either returned or destroyed.

9.6 Both Parties shall ensure that all of its officers, employees, consultants, agents, subcontractors, third party vendors, investigators or contractors who receive such Confidential Information understand and shall be bound by confidentiality provisions at least as stringent as the confidentiality obligations in this Agreement.

9.7 The Parties agree that each Party is and shall remain the exclusive owner of its Confidential Information and all patent, copyright, trade secret and other intellectual property rights therein unless and until a further agreement is executed.

9.8 The Parties acknowledge that any violation of the terms of this Section 9 may result in irreparable injury and damage to disclosing Party that is not adequately compensable in money damages, and for which disclosing Party may have no adequate remedy at law. Accordingly, the receiving Party agrees that the disclosing Party shall be entitled to seek (without waiving any additional rights or remedies, including monetary damages, otherwise available to the disclosing Party at law, in equity, or by statute) preliminary and permanent injunctive relief in the event of a breach or intended or threatened breach by the receiving Party.

10. INTELLECTUAL PROPERTY RIGHTS

10.1 “**Background IP**” means the Intellectual Property that Supplier owns or otherwise controls (i) as of the Effective Date, or (ii) that it develops or otherwise acquires after the Effective Date and that (A) does not rely on any of the Confidential Information disclosed by Client. Client acknowledges that all computer programs, applications, algorithms, databases, methods, techniques, processes and other materials and ideas used by Supplier in performance of the work under this Agreement, and not supplied to Supplier by Client, are the exclusive property of Supplier or its licensors. Client agrees that any improvements, alterations or enhancements to this Background IP during the Term of this Agreement or the Study shall be the sole property of Supplier. Subject to Section 10 hereof, in no event shall Supplier be precluded from use of its general knowledge, skills and experience, and any of its ideas, concepts, know-how and techniques used or developed by it in the course of providing Services under this Agreement.

10.2 “**Intellectual Property**” means any intellectual property rights, whether registered or not, including those rights arising out of or related to: (i) proprietary and non-public business information, including any inventions (whether patentable or not), improvements, technologies, trade secrets, discoveries, formulae, recipes, confidential information, methods, algorithms, processes, designs, technology, technical data, schematics, formulae, customer lists, databases, computer programs (including source code), know-how, and documentation relating to any of the foregoing; (ii) registered industrial designs or applications for industrial designs, designs, design registrations, design registration applications and integrated circuit topographies, (iii) copyrightable works, copyright, registered copyright and applications for copyright registration; (iv) issued patents, patent applications and reissues, divisions, continuations, renewals, extensions and continuations in part of issued patents or patent applications; (v) registered trademarks, trademark applications, unregistered trademarks, logos, slogans, domain names, social media identifiers, brand names, and the good-will associated therewith; and (vi) any other rights, either past, present or future in intellectual property.

10.3 Except for Background IP, all discoveries, improvements, data, material or other developments solely or jointly obtained, conceived, developed, or reduced to practice, or caused to be obtained, conceived or developed, or reduced to practice by Supplier in the course of Supplier’s performance of the Services (“**Client IP**”) shall be disclosed in writing promptly by Supplier to Client, and shall be the sole and exclusive property of Client, to the extent applicable as a “work for hire”.

10.4 To the extent that the Intellectual Property in the Client IP is not already owned by Client pursuant to any Applicable Laws, Supplier agrees to assign and transfer, and hereby assigns and transfers, to Client Intellectual Property in the Client IP to the full extent permitted by Applicable Laws. This transfer of the Intellectual Property shall include any future extension of the term of

the protection or of the rights granted pursuant to any laws, regulations, decrees or international conventions. Supplier irrevocably waives and represents that all authors of the Client IP have irrevocably waived their moral rights therein to the full extent permitted by Applicable Laws.

10.5 At Client's request, Supplier shall promptly provide a copy of any source material and documentation in its possession that is required to exploit the Client IP, including for the purposes of improving same. Except for Background IP, Supplier acknowledges that unless agreed otherwise, any samples, prototypes, or other similar material produced in connection with the performance of the Services shall become the property Client.

10.6 During the Term of the Agreement and after its termination or expiry, Supplier, at no cost to Client: (i) undertakes to cooperate with Client, its lawyers or patent agents in order to prepare any patent application, application to register copyright or other application to secure intellectual property protection covering or relating to the Client IP; (ii) agrees, when requested by Client and for no additional consideration, to promptly sign, any instrument and agreement (and obtain the signature of any inventors, authors and any other contributors to the Client IP) and to take any necessary action to ensure the assignment of all of the Client IP to Client; (iii) agrees to communicate to Client, as soon as possible, all information and facts relating to the Client IP. The decision to file an application for a patent, industrial design, copyright or any other intellectual property protection or to maintain the Client IP as a trade secret is at the sole discretion of Client and Supplier is bound by such decision.

10.7 Supplier irrevocably appoints and mandates Client as mandatary, agent and proxy in order to sign and file any document on behalf of Supplier and to take any actions permitted by law in order to fulfill the obligations of Supplier under Section 10.6 herein if Supplier is unable to fulfill its obligations as provided under Section 10.6 herein, or is unwilling to do so, or is prevented from doing so.

10.8 Supplier agrees and undertakes to never knowingly incorporate any Intellectual Property or confidential information of any third party in the Deliverables without the prior written consent of Client.

10.9 Nothing under this Section or any other Section of this Agreement shall be construed as (i) granting to any Party any rights under any patent, copyright or other intellectual property right of the other Party (ii) granting to any Party any rights in or to the Confidential Information of the other Party other than the limited right to use such Confidential Information solely for the purposes expressly permitted by Section 9 of this Agreement.

11. PERSONAL INFORMATION

In order to carry out the Services, the Parties recognize that Supplier may have access to information about identifiable individuals or that allow identification of individuals ("**Personal Information**"). For the purposes of applicable privacy laws, Supplier (and not Client) shall have control over all Personal Information and Supplier shall not transfer copies of material related to the Services bearing any Personal Information to Client, except where required under Applicable Laws. Supplier shall be solely responsible for complying with applicable privacy laws, including in connection with the collection, use and disclosure of Personal Information. Client agree not to request any access to Personal Information collected by Supplier in connection with the Services rendered or Deliverables delivered under this Agreement.

12. PUBLICATION

12.1 Supplier shall not disclose, publish or present the results of any analysis or research conducted as part of the Services rendered or Deliverables delivered pursuant to this Agreement, or relating to the Confidential Information or the Client IP, or part thereof without the prior written consent of Client. For greater certainty, this prohibition includes the presentation of results made via the publication of sections, abstracts, posters or monographs, the giving of oral presentations or seminars, as well as the submission of those results to any editor or reviewer for the purpose of making a scientific publications.

12.2 Supplier shall, as required by Client, delete any Confidential Information or material pertaining to the Client IP in its possession or control prior to any Client authorized publication or presentation authorized by Client and Supplier shall address any reasonable comments made by Client regarding such publication or presentation with a view to preserve the Intellectual Property and the Client IP.

12.3 Either Party will not issue any press release or make any other public announcement relating to this Agreement or any activities covered by this Agreement without the prior written consent of the other Party, except, if required, under applicable securities laws.

12.4 Unless otherwise provided in this Agreement, neither Party shall use the name or logo of the other Party in any advertising, promotional or sales literature or in any publicity without the prior written consent of the other Party. Notwithstanding the foregoing, Client may disclose the name of Supplier in compliance with any requirements for the registration or recognition of Intellectual Property in the Deliverables and the assignment thereof to Client under the Applicable Laws.

13. RECORD KEEPING AND AUDIT RIGHTS

13.1 **Financial Record Audits.** Supplier shall keep full and accurate records and accounts of all its activities in connection with this Agreement, including reasonable substantiation of all Services and Deliverables provided and expenses incurred. Supplier shall retain all records and accounts and shall not destroy any records or accounts in connection with this Agreement without the written approval of Client for a period of **[REDACTED: Time Period]** or such later period as required by law.

13.2 Quality GxP Audits by Sponsor

a) Supplier agrees that Client may conduct audits of Supplier's premises to verify compliance with this Agreement. Any audits conducted by Client will be undertaken at a reasonable time during normal business hours with reasonable prior notice to Supplier (i.e. no less than **[REDACTED: Time Period]** prior to commencing the audit, and subject to availability of relevant Supplier staff and any prior Supplier inspection or audit commitments) These Client audits are conducted at the Client's sole cost and expense and may include review of: (i) the facilities where the Services are being, will be or have been conducted; (ii) related Study documentation; and (iii) any other relevant information necessary for Client to confirm that the Services are being or will be or have been conducted in conformance with applicable standard operating procedures, the specific Statements of Work, this Agreement, and in compliance with applicable laws and regulations. Supplier will provide copies of any materials reasonably requested by Client

during such Client audit. The Client representative conducting the audit of Supplier under this section shall not be a Competitor of Supplier. For purposes of this Section a “Competitor” of Supplier means a service provider that performs services substantially similar to the Services Supplier performs for its customers.

(b) Client QA or its representative may conduct audits of a Site to enable Client to assess whether the Services are being provided in accordance with this Agreement and shall work directly with such Sites and Supplier’s project team in connection with such audit. Supplier will in good faith and as requested by Client in writing, assist Client in obtaining the information requested, or required in the conduct of the audit. Client shall not disclose to any third party any Confidential Information of Supplier disclosed to Client in the course of an audit except in accordance with the confidentiality obligations under this Agreement and in no event shall Client disclose Supplier Confidential Information to a Competitor of Supplier. If requested to Client in writing, Client shall reimburse Supplier for out of pocket costs for the provision of Supplier personnel to assist with translation during the conduct of an audit.

(c) If Corrective and Preventive Actions (“CAPAs”) are necessary at the Site or in connection with the investigation or as a result of an audit, Client and Supplier shall agree in writing as to any Services to be provided by Supplier in connection with the CAPA and Client shall compensate Supplier for all related fees expenses to be incurred, provided that Client shall not be liable for any Service fees or expenses directly arising out of a CAPA to the extent any audit findings are the result of Supplier’s material breach of this Agreement or Statement of Work.

(d) For purposes of this Section, if any audit by Client is conducted by a party other than a Client employee (“**Third Party Auditor**”), the Third Party Auditor will be (i) duly qualified by Client to conduct an audit of the Services; and (ii) will, prior to any access to a Supplier facility or disclosure of any Confidential Information or materials by Supplier, have agreed to and execute a confidentiality and nondisclosure agreement with Supplier as to Supplier e Confidential Information that is consistent with and not less stringent than the confidentiality obligations in this Agreement.

14. INSPECTION BY REGULATORY AUTHORITIES. During the term of each Statement of Work, each Party will permit regulatory authorities to examine: (i) the facilities where the Services are being conducted; (ii) Study documentation; and (iii) any other relevant information, including information that may be designated by one or both of the Parties as confidential, reasonably necessary for regulatory authorities to confirm that the Services are being conducted in compliance with applicable laws and regulations. Each Party will notify the other as soon as possible, but no later than **[REDACTED: Time Period]** if any regulatory authority schedules, or without scheduling, begins an inspection that relates to the Services or the Parties’ respective obligations hereunder.

Each Party shall notify the other Party within **[REDACTED: Time Period]** of receipt of a non-routine inquiry, correspondence, inspection or other contact by a regulatory authority in connection with a Study, or this Agreement (each a “**Non-Routine Regulatory Contact**”) including, but not limited to, inspections of any Sites. For the avoidance of doubt, “Non-Routine Regulatory Contact” means any contact by a regulatory authority that is other than a contact that reasonable could be expected in the normal course of business.

Each Party shall immediately forward to the other Party copies of any correspondence or other documentation from or to any regulatory authority relating solely to a Study or this Agreement.

As to a regulatory finding, observation or other contact to which Supplier is required or is reasonably expected to submit a written response in relation to a Study or this Agreement, Supplier will use reasonable efforts to provide Client with a reasonable opportunity to review and comment on any response (“**Response**”) required from Supplier to a regulatory authority. Supplier shall in good faith consider the inclusion of any comments from Client in its Response but shall not be obligated to incorporate any such comments in a Response. In the event that Supplier does not incorporate Client comments in the Response, Supplier shall use reasonable efforts to notify Client prior to the submission of such Response in order to mutually resolve any issues. In any event Supplier shall promptly provide to Client a copy of the Response submitted by Supplier to any regulatory authority that (i) solely relates to a Study or this Agreement; or (ii) that would have a material negative impact on the ability of Supplier to provide the Services provided that Supplier shall not disclose any information relating to a third party or matter that does not have a material negative impact on the ability of Supplier to provide the Services.

Each Party acknowledges that it may not direct or manage the manner in which the other Party fulfils its obligation to permit/conduct inspections by a regulatory authority.

15. “Serious Breach” may include (a) the conditions and principles of GCP in connection with the trial or (b) the protocol relating to the trial, which is likely to effect to a significant degree: (i) the safety or physical or mental integrity of the subjects of the trial; or (ii) the scientific value of the trial.

15.1 Each Party will notify in writing the other of any Serious Breaches within **[REDACTED: Time Period]**.

15.2 Upon notification of a Serious Breach, the Parties will collaborate on the intended course of action; and inform together the relevant IRB or regulatory authority (for example, MHRA, FDA), if appropriate. Client shall be responsible for any reporting to the regulatory authority and ethics committee unless otherwise agreed in writing.

15.3 Either Party may inform relevant regulatory authorities of any such Serious Breach if, in its opinion, such reporting is required by regulation.

16. INDEMNIFICATION

16.1 Supplier agrees to indemnify, defend and hold Client, its Affiliates and their respective directors, officers, employees and other representatives harmless from and against any damage, loss, cost, claim or expense suffered or incurred by Client (including reasonable legal fees and costs) from any third party claim, demand, assessment, action, suit or proceeding (a “**Claim**”) as a result of:

16.1.1 any intentional misconduct by Supplier;

16.1.2 any negligence on the part of Supplier;

16.1.3 any material breach of this Agreement by Supplier.

16.2 Client shall indemnify Supplier and its Affiliates and their respective officers, directors, employees and agents (the “**Supplier Group**”) arising out of any Claim related to (i) Supplier’s performance of the Services, the applicable Statement of Work, or any protocol related thereto the Study drug’s harmful or otherwise adverse effect, including, without limitation, a Claim based upon the consumption, sale, distribution or marketing of any substance, including the Study drug, (ii) the breach of this Agreement or the applicable Statement of Work, or the negligence or intentional misconduct of Client, except to the extent such Claim is caused by Supplier’s material breach of this Agreement, gross negligence or wilful misconduct.

16.3 In the event Supplier incurs costs or expenses as a result of its becoming involved in, or being required to appear or otherwise participate in, a matter (i) relating to a Study that is the subject of a Claim or any proceeding, litigation, arbitration or some other dispute resolution mechanism, and (ii) where Supplier’s performance of the Services in a manner other than in compliance with this Agreement is not directly and in good faith at issue in such Claim, then Client shall reimburse Supplier for all such costs or expenses. The Parties agree to cooperate with each other and to use commercially reasonable best efforts in good faith to minimize Supplier’s participation in and the costs or expenses relating to such disputes.

16.4 Except for the indemnification obligations of either Party under Sections 16.1 and 16.2, under no circumstances shall either Party be liable under this Agreement for any indirect, incidental, special or consequential damages of the other Party resulting from such Party’s performance or failure to perform under this Agreement. In addition, and except for the indemnification obligations of Supplier under Section 16.1, in no event shall the collective, aggregate liability of the Supplier Group to Client exceed the amount of fees actually received by Supplier from Client pursuant to the Statement of Work from which such liability arose. The foregoing limitation of liability shall not be applicable in the event of a breach of Section 9 by either Party.

17. NON-DEBARMENT

17.1 Supplier certifies that it has not been debarred under Section 306 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §335a(a) or (b) or any equivalent local law or regulation. In the event that Supplier becomes debarred, Supplier agrees to notify Client immediately.

17.2 SUPPLIER CERTIFIES THAT IT WILL NOT USE IN ANY CAPACITY, IN CONNECTION WITH ANY SERVICES TO BE PERFORMED UNDER THIS AGREEMENT, ANY PERSON WHO HAS BEEN DEBARRED, PURSUANT TO ANY APPLICABLE LAWS, INCLUDING SECTION 306 OF THE UNITED STATES FEDERAL FOOD, DRUG AND COSMETIC ACT, 21 U.S.C §335A.

17.3 IN THE EVENT THAT SUPPLIER BECOMES AWARE OR RECEIVES NOTICE OF THE DEBARMENT OF ANY INDIVIDUAL, CORPORATION, PARTNERSHIP, OR ASSOCIATION PROVIDING SERVICES TO SUPPLIER, WHICH RELATE TO THE SERVICES BEING PROVIDED UNDER THIS AGREEMENT, SUPPLIER AGREES TO NOTIFY CLIENT IMMEDIATELY.

18. PRIMARY CONTACT

18.1 Both Parties shall designate a primary contact to coordinate and manage all aspects of the Services and Deliverables to be performed by or on behalf of Supplier. The primary contact shall

use his or her best efforts to respond to any communication from either Party within [REDACTED: Time Period] of his or her receipt of such communication.

19. NOTICES

19.1 No notice under this Agreement shall be effective unless sent in writing, by certified mail, return receipt requested, national courier service at the address set forth below. Either Party may specify a different address to receive notices by providing a written notice in this respect given in accordance with this Article.

If to Client:

[REDACTED: Address]

Attention: [REDACTED: Name]

Email: [REDACTED: Email]

If to Supplier:

[REDACTED: Address]

Attention: [REDACTED: Name]

20. MISCELLANEOUS

20.1 **Assignment.** Neither Party shall have the right to assign this Agreement or any of the rights or obligations hereunder, except that (a) Supplier may subcontract with such individuals or entities it deems necessary and appropriate in order to perform the Services and (b) either Party may assign this Agreement to (i) an Affiliate or (ii) a purchaser of or successor to that area of its business to which this Agreement is related (or, the case of Client, the outstanding Statement of Work relate), upon written notice, where such Affiliate or successor has the financial and operational capacity and ability to perform the assigning Party's obligations hereunder..

20.2 **Entire Agreement.** This Agreement constitutes the entire agreement entered into between the Parties regarding the subject matter hereof and cancels and supersedes any prior agreement verbal or in writing between the Parties with respect thereto. Each Party acknowledges that each and every provision of this Agreement was negotiated in good faith, understood, and for good and valuable consideration, agreed to by such Party. In the event of a conflict between the terms and conditions set forth in this Agreement and the terms and conditions set forth in any Statement of Work or any other document or invoice issued in connection with this Agreement, the terms and conditions set forth in this Agreement shall take precedence.

20.3 **Modification.** No supplement, amendment or modification to this Agreement shall be valid or binding unless set forth in writing and duly executed by all Parties. No waiver of a breach of any provision of this Agreement shall be effective or binding unless set forth in writing and duly executed by the Party purporting to give such waiver and, unless otherwise provided, shall be limited to the specific breach waived.

20.4 The Parties hereto agree to do all acts and things and to sign all documents necessary to give full force and effect to all provisions of this Agreement.

20.5 **Waiver.** Failure of a Party to insist upon the strict performance of any term or condition of this Agreement or to exercise any right, remedy or recourse hereunder shall not be construed as a continuing waiver of any such term and condition of this Agreement.

20.6 **Governing Law and Arbitration.** This Agreement shall be subject to, construed and enforced in accordance with the laws of the [REDACTED: Territory]. In the event a dispute relating to this Agreement or any Statement of Work arises between the Parties, the Parties shall confer in good faith to resolve the dispute through negotiations between respective senior executives of the Parties. In the event that the Parties are unable to resolve the dispute, disputes shall be settled by arbitration administered by the American Arbitration Association under its Commercial Arbitration Rules in [REDACTED: Territory]. Judgment shall be rendered by a mutually agreed upon single arbitrator. The provisions of this Section may be enforced by any court of competent jurisdiction, and the Party seeking enforcement shall be entitled to an award of all costs, fees and expenses, including reasonable attorneys' fees, to be paid by the Party against whom enforcement is ordered.

20.7 **Force Majeure.** Neither Client nor Supplier shall be liable for delays in performing or any failure to perform any of the terms of this Agreement or a Statement of Work caused by the effects of natural disaster, strike, war (declared or undeclared), insurrection, acts of terror, government sanction, restriction or prohibition, or other causes reasonably beyond its control and without its fault, but the Party failing to perform shall use all commercially reasonable efforts to resume performance of this Agreement as soon as reasonably feasible. Any episode of force majeure which continues for [REDACTED: Time Period] from the date of notification of its existence shall give the non-affected Party the right to terminate this Agreement upon [REDACTED: Time Period] additional notice.

20.8 **Severability.** If any provision or condition of this Agreement is determined to be void, invalid, illegal or unenforceable in whole or in part, such determination shall not impair or limit the validity, legality or enforceability of the remaining provisions hereof, which shall remain valid, mandatory and enforceable in accordance herewith, except if the principal intent of this Agreement is frustrated by such reformation or deletion in which case this Agreement shall terminate.

20.9 **Counterparts.** This Agreement may be executed in any number of counterparts, including by electronic signature, all of which taken together shall constitute one and the same instrument. In the event that any signature is delivered by facsimile transmission, by e-mail delivery of a ".pdf" format data file or other electronic means, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof.

20.10 The Parties have expressly agreed that this Agreement and all notices and other communications related thereto, including the Statements of Work, be drafted in English. *Les Parties à la présente ont expressément convenu que la présente entente et tous les avis et autres communications y reliés, incluant les énoncés de travaux, soient rédigés en Anglais.*

IN WITNESS WHEREOF, the Parties have signed this Agreement as of the Effective Date.

THERATECHNOLOGIES INC.

WORLDWIDE CLINICAL TRIALS, INC.

Per: /s/ Paul Lévesque
Name: Paul Lévesque
Title: President and Chief Executive Officer

Per: /s/ Anthony Hinman
Name: Anthony Hinman
Title: Legal Counsel

SCHEDULE A

FORM OF STATEMENT OF WORK

STATEMENT OF WORK NO. <@>

Between

THERATECHNOLOGIES INC. AND WORLDWIDE CLINICAL TRIALS, INC.,

This Statement of Work is entered into in accordance with Section 1.1 of the Master Services Agreement (the “**Agreement**”), entered into between Theratechnologies Inc. (the “**Client**”) and Worldwide Clinical Trials, Inc.(the “**Supplier**”) effective as of <@> 2020.

1. Supplier agrees to provide the Services and deliver the Deliverables to Client including, but not limited to, the Services described in **Erreur ! Source du renvoi introuvable.** attached hereto in consideration for the Fees detailed in the Fee Schedule attached hereto as Exhibit B. Supplier shall provide the Services and deliver the Deliverables to Client in accordance with the terms of the Agreement and this Statement of Work No. <@>.
2. This Statement of Work shall continue in force from the Effective Date until completion of the Services and delivery of the Deliverables hereunder unless the Statement of Work is terminated before, in accordance with the Agreement.
3. All capitalized terms used but not defined herein shall have the meanings ascribed to those terms in the Agreement.
4. The Parties agree that this Statement of Work is governed by and subject to the terms and conditions of the Agreement entered into between the Parties which shall apply to this Statement of Work as if said terms and conditions were fully set forth herein. If there is a conflict between this Statement of Work and the Agreement, the terms and conditions of the Agreement shall have precedence.

THERATECHNOLOGIES INC.

WORLDWIDE CLINICAL TRIALS, INC.

Per: _____
Name: _____
Title: _____

Per: _____
Name: _____
Title: _____

SCHEDULE B
DATA PROCESSING AGREEMENT

1. Defined Terms. For purposes of this Data Processing Agreement, “**GDPR**” means the European Union General Data Protection Regulation (Regulation (EU) 2016/679 together with any additional implementing legislation, rules or regulations that are issued by applicable supervisory authorities (“Data Protection Laws”). Capitalized terms used but not defined in this Exhibit D shall have the meanings ascribed to them in the Agreement. Subject to the foregoing, words and phrases used in this Data Processing Agreement shall, to the greatest extent possible, have the meanings given to them in the GDPR, including but not limited to the defined terms set forth in Article 4 and Article 9.

Specifically, the following terms shall have the following definitions:

a. “**Controller**” means the natural or legal person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of Personal Data; where the purposes and means of processing are determined by EU or Member State laws, the controller (or the criteria for nominating the controller) may be designated by those laws. Subject to Section 6 below, for purposes of this Data Processing Agreement Sponsor shall be the Controller as defined under GDPR.

b. “**EEA**” means the European Economic Area.

c. “**EEA Member State**” means one of the member states of the EEA.

d. “**EU Equivalent Protection Area**” means the area that comprises: (i) countries within the European Union, Iceland, Liechtenstein and Norway; and (ii) countries, sectors in countries (such as the Privacy Shield in the USA) and international organisations that the European Commission may, from time to time, officially recognise as ensuring an adequate level of protection as provided for in Article 45 of the GDPR.

e. “**Personal Data**” means any information relating to an identified or identifiable natural person (a “Data Subject”). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. For purposes of this Data Processing Agreement, Personal Data may include information relating to clinical trial subjects (including key-coded patient data), physicians, clinicians, healthcare professionals, consultants or other persons participating in Sponsor-sponsored clinical trials and research activities, whether such information is captured in electronic or printed (i.e. hard copy) format.

f. “**Personal Data Breach**” means any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data transmitted, stored or otherwise processed.

g. **“Processing”** means any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction. For purposes of this Data Processing Agreement, the word “process” and its derivatives shall be construed accordingly.

h. **“Processor”** means a natural or legal person, public authority, agency or other body which processes Personal Data on behalf of the Controller. Subject to Section 6 below, for purposes of this Data Processing Agreement, Worldwide shall be the Processor as defined under GDPR.

i. **“Subprocessor”** means any natural or legal person, public authority, agency or other body which processes Personal Data on behalf of Processor or any Affiliate of Processor.

j. **“Special Categories of Personal Data”** are Personal Data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership; genetic data or biometric data uniquely identifying a natural person; data concerning health or sex life and sexual orientation.

k. **“Transfer”** means to disclose or otherwise make Personal Data available to a third party, either by physical movement of the Personal Data to such third party or by enabling access to the Personal Data by other means.

l. **“UK GDPR”** means, as effective and pending the UK withdrawal from the EU, the UK Parliament’s amended incorporation of GDPR into UK law, together with further amendments to the Data Protection Act of 2018. For purposes of this Data Processing Agreement, any references to Data Protection Laws (inclusive of GDPR), or the EU/EEA in this Data Processing Agreement shall be deemed to be references to the equivalent provision in UK GDPR and the UK respectively, and shall apply mutatis mutandis where UK GDPR is effective and in scope.

2. **EU GDPR Compliance.**

a. During the term of the Agreement, Processor will process Personal Data on behalf of the Controller where so contracted under the applicable Work Order.

b. The Personal Data to be processed by the Processor concerns (i) the categories of data; (ii) the categories of data subjects; and (iii) the nature and purposes of the processing as set out in detail in the applicable Work Order.

c. **Controller:** Controller shall be solely responsible for i) determining the means and purpose of processing, ii) assessing the lawfulness and admissibility of processing in accordance with the GDPR, including but not limited to Articles 5 to 11; iii) safeguarding the rights of the Data Subjects in accordance with Articles 12 to 22 GDPR; and (iv) all other obligations expressly set forth for Controller under GDPR.

d. As a rule, Controller issues all instructions with regard to the processing of Personal Data in writing or in a documented electronic format. Verbal instructions must be confirmed by Controller immediately in writing or in a documented electronic format.

e. Processor shall comply with all Data Protection Laws and regulations governing the processing of Personal Data. Processor will also require its personnel and any other Subprocessor involved in the performance of the Agreement to comply with Data Protection Laws.

f. In the event that this Data Processing Agreement or any practices which could be or are employed in exercising rights hereunder are inconsistent with or do not satisfy the requirements of Data Protection Laws relating to the protection of Personal Data, the Parties shall take any action necessary to bring performance under this Data Processing Agreement into compliance with such Data Protection Laws, including amending or modifying this Data Processing Agreement.

3. Technical and Organizational Measures. In accordance with GDPR Article 28(1), Processor represents and warrants that it has implemented appropriate technical and organizational measures in such a manner that its processing of Personal Data will meet the requirements of the GDPR and ensure the protection of the rights of the Data Subjects.

4. Engagement of Subprocessors. In accordance with GDPR Article 28(2), Processor shall not engage any Subprocessor without prior specific or general written authorization of Controller. In the case of a general written authorization, Processor shall inform the Controller of any intended changes concerning the addition or replacement of other Subprocessors and give Controller the opportunity to object to such changes. Processor shall also comply with the requirements for subprocessing as set forth in Article 28(4), namely that the data protection obligations set forth therein shall be imposed upon the Subprocessor, so that Processor's contract with the Subprocessor contains sufficient guarantees that the processing to be performed by such Subprocessor will meet the requirements of the GDPR.

5. Authorized Purposes; Confidentiality; Security Measures; Etc. In accordance with GDPR Article 28(3), Processor shall:

a. process the Personal Data, including any Special Categories of Personal Data, only (i) as needed to provide the Services, (ii) in accordance with the documented instructions that it has received from Controller, including with regard to any Transfers, and (iii) as needed to comply with Union or EEA Member State law to which Processor is subject (in which case, Processor shall provide notice to Controller of such legal requirement prior to engaging in processing, unless that law prohibits this disclosure on important grounds of public interest);

b. ensure that persons authorized to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;

c. take all security measures required by GDPR Article 32, namely:

i. taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood and severity for the rights

and freedoms of natural persons, Processor shall implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk, including inter alia as appropriate: (A) the pseudonymisation and encryption of Personal Data; (B) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services; (C) the ability to restore the availability and access to Personal Data in a timely manner in the event of a physical or technical incident; and (D) a process for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing;

ii. in assessing the appropriate level of security, account shall be taken in particular of the risks that are presented by processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to Personal Data transmitted, stored or otherwise processed; and

iii. take steps to ensure that any natural person acting under the authority of Processor who has access to Personal Data does not engage in the processing of such Personal Data except on instructions from Controller, unless he or she is required to do so by Union or EEA Member State law;

d. taking into account the nature of the processing, Processor shall, at Controller's cost and expense, assist Controller by appropriate technical and organizational measures, insofar as this is possible, for the fulfilment of Controller's obligation to respond to requests for exercising the Data Subjects' rights under GDPR Chapter III. For the avoidance of doubt, Processor shall not be responsible for Data Subject Access Requests ("DSAR") issued to Sites, Site Processors, or Site Subprocessors. Site obligations with respect to DSARs shall be subject to the terms and conditions of their respective Clinical Trial Agreements and independent controller obligations as applicable;

e. Taking into account the nature of processing and the information available to Processor, Processor shall comply with (and shall reasonably assist Controller to comply with, at Controller's cost and expense) the obligations regarding security of processing (as set forth in GDPR Article 32), Personal Data Breaches (as set forth in GDPR Articles 33 and 34), data protection impact assessments (as set forth in GDPR Article 35), and prior consultation (as set forth in GDPR Article 36);

f. At Controller's instruction, and at Controller's cost and expense, Processor shall delete or return all the Personal Data to Controller after the end of the provision of Services relating to processing in accordance with the terms of the Agreement and applicable Work Order(s), and delete existing copies unless applicable Union or EEA Member State law requires storage of the Personal Data;

g. Processor shall, at Controller's reasonable request, make available to Controller all information necessary to demonstrate compliance with the obligations laid down in GDPR Article 28, and allow for and contribute to audits, including inspections, conducted by Controller or another auditor mandated by Controller (that is not a competitor of Processor) in accordance with the audit and inspection provisions set forth in the Agreement; and

h. Processor shall immediately inform Controller if, in its opinion, an instruction given for the processing of Personal Data infringes on Data Protection Laws. Processor is not, however, obliged to actively review Controller's instructions for compliance with Data Protection Laws.

6. Transfer of Data Outside of the [REDACTED: Territory]

a. Processor will only export Personal Data originating from the [REDACTED: Territory] out of the [REDACTED: Territory] Equivalent Protection Area on the documented instructions of the Controller, which would be deemed to have been given if such Transfer is identified in the applicable Work Order or other written documentation entered into under the Agreement, including project plans or written documentation filed within the Trial Master File (TMF). If the Processor is located outside the [REDACTED: Territory] Equivalent Protection Area, the Processor shall only make onward Transfers of the [REDACTED: Territory] Personal Data on the documented instructions of the Controller which would be deemed to have been given if such Transfer is identified in the applicable Work Order or other written documentation entered into under the Agreement, including project plans or written documentation filed within the TMF.

b. In the event of a Transfer outside of the [REDACTED: Territory] Equivalent Protection Area contemplated by Section 6b, the Parties shall comply with the relevant provisions of GDPR Chapter 5, including, as applicable implementation of adequate safeguards for such Transfers.

7. **Personal Data Breaches.** Processor will promptly and thoroughly investigate potential Personal Data Breaches occurring within its sphere of responsibility as the Processor under this Data Processing Agreement. In the event of any Personal Data Breach, Processor will notify Controller without undue delay. At minimum, such notification from Processor to Controller shall include the information required by GDPR Article 33(3). For the avoidance of doubt, Processor shall not be responsible for Personal Data Breaches committed by Sites, Site Processors, or Site Subprocessors. Sites' obligations with respect to Personal Data Breaches shall be subject to the terms and conditions of their respective Clinical Trial Agreements.

8. **Maintenance of Records.** Processor shall maintain (in writing, including in electronic form) all records required by Article 30(2) of the GDPR, and, to the extent they are applicable to Processor's Services for Controller, Processor shall make them available to Controller upon request.

9. **Incorporation into Agreement:** The Parties agree that the terms and provisions of this Data Processing Agreement shall be incorporated into the Agreement by reference. To the extent the terms of this Data Processing Agreement conflict with any terms of the Agreement pertaining to the subject matter of this Data Processing Agreement, the terms of this Data Processing Agreement shall prevail. All other provisions in the Agreement shall remain in full force and effect in accordance with their terms.

10. **Term and Survival:** The term of this Data Processing Agreement shall run concurrent with the Term of the Agreement; provided, however, the terms of this Data Processing Agreement shall survive termination of the Agreement to the extent Processor continues processing Personal Data under an applicable Work Order in accordance with the terms of this Data Processing Agreement or otherwise required by its record retention obligations under the Agreement, Data Protection Laws or other applicable law.

SCHEDULE C
FORM OF CLINICAL TRIAL INSURANCE DECLARATION

Declaration of Exclusions Form

This Declaration of Exclusions Form shall be executed by Sponsor in order to comply with the following provisions of **[REDACTED: Territory] Statutory Instrument 2004/1031 (as amended), Schedule 1, Part 2, (14)** and **MHRA Good Clinical Practice Guideline (“Gray Guide”), Section 1.3.8:**

- *“Provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor which may arise in relation to the clinical trial.” **[REDACTED: Territory] Statutory Instrument 2004/1031 (as amended), Schedule 1, Part 2, (14)***
- *“During inspections, examples have been identified where the insurance cover has not been adequate as a result of the exclusions listed on the insurance policy. ... There should be a process in place for the sponsor to check the insurance for each individual trial, it is recommended that this check is documented and filed in the TMF.” MHRA Good Clinical Practice Guideline (“Gray Guide”), Section 1.3.8:*
- *“Vendors are expected to have a mechanism in place for ensuring that there are no exclusions within the sponsor policy that affect the cover for the trial. This may be documented in a number of ways; for example, a copy of the policy could be included with the certificate, the certificate could clearly list the exclusions or there could be some form of **formal sign-off to verify that someone from the sponsor or vendor has checked that the exclusions are acceptable.**” MHRA Good Clinical Practice Guideline (“Gray Guide”), Section 1.3.8*

[REDACTED: Name] (“Sponsor”) hereby certifies that it has reviewed its clinical trial insurance policy for the **[REDACTED: Territory]** (the “Policy”) for XXX (the “Study”) against Protocol Version XXX, dated XXX (the “Protocol”) and confirms that coverage is appropriate for the Study and that there are no exclusions within the policy that would limit coverage for Sponsor or investigator for claims brought by **[REDACTED: Territory]** study subjects participating in the Study. Sponsor shall notify Worldwide Clinical Trials Global Project Lead (“GPL”) and sign an updated Declaration of Exclusions form in the event any amendments to the Protocol or Policy modifies coverage for Sponsor or investigator for claims brought by **[REDACTED: Territory]** study subjects participating in the Study.

IN WITNESS WHEREOF, this Agreement has been executed by a duly authorized representative of the Sponsor as of the date written below.

[REDACTED: Name]

By: _____

Name: _____

Title: _____

Date: _____

CERTIFICATION

I, Paul Lévesque, 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) 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
 - (d) 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 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 involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: February 25, 2021

By: /s/ Paul Lévesque
Paul Lévesque
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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) 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
 - (d) 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 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 involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: February 25, 2021

By: /s/ Philippe Dubuc
Philippe Dubuc
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

C E R T I F I C A T I O N P U R S U A N T T O 1 8 U . S . C . S E C T I O N 1 3 5 0
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES–OXLEY ACT OF 2002

In connection with the Annual Report on Form 40-F of Theratechnologies Inc. (the “Company”) for the fiscal year ended November 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Paul Lévesque, President and Chief Executive Officer of the Company certify pursuant to 18 U.S.C. Section 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, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2021

/s/ Paul Lévesque

Name: Paul Lévesque

Title: President and Chief Executive Officer

C E R T I F I C A T I O N P U R S U A N T T O 1 8 U . S . C . S E C T I O N 1 3 5 0
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES–OXLEY ACT OF 2002

In connection with the Annual Report on Form 40-F of Theratechnologies Inc. (the “Company”) for the fiscal year ended November 30, 2020, 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. Section 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, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 25, 2021

/s/ Philippe Dubuc

Name: Philippe Dubuc

Title: Senior Vice President and Chief Financial Officer



KPMG LLP
Tour KPMG, Suite 1500
600 de Maisonneuve Blvd. West
Montréal (Québec) H3A 0A3
Tel. 514-840-2100
Fax 514-840-2187
www.kpmg.ca

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, 2021, on the consolidated financial statements which comprise the consolidated statements of financial position as of November 30, 2020 and 2019, the related consolidated statements of net loss and comprehensive loss, changes in equity and cash flows for the years ended November 30, 2020 and 2019, and the related notes; which report refers to a change in its method of accounting for leases due to the adoption IFRS 16, and which report appears in the annual report on Form 40-F of Theratechnologies Inc. for the fiscal year ended November 30, 2020, and further consent to the use of such report in such annual report on Form 40-F.

A handwritten signature in black ink that reads 'KPMG LLP' with a horizontal line underneath.

February 25, 2021
Montreal, Canada