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

FORM 40-F

(Check One) ☐ Registration statement pursua	ant to Section 12 of the Securities	Exchange Act of 1934
	or	
☑ Annual report pursuant to Sec	ction 13(a) or 15(d) of the Securitie	s Exchange Act of 1934
F	For the fiscal year ended November 30, 20	21
	Commission file number: 001-35203	
	RATECHNOLOGIE xact name of registrant as specified in its cha	
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)
(Address and T	2015 Peel Street, 11 th Floor Montreal, Québec, Canada H3A 1T8 (514) 336-7800 Telephone Number of Registrant's Principal E	xecutive Offices)
	CT Corporation System 28 Liberty Street, New York, New York 100 (212) 894-8940 nd Telephone Number (Including Area Code)	
	Copies to:	
	Jocelyn Lafond Theratechnologies Inc. 2015 Peel Street, 11 th Floor Montreal, Québec, H3A 1T8 CANADA (438) 315-6607	
Securities regis	stered 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 register	ed or to be registered pursuant to Section 12	(g) of the Act: None
	ere is a reporting obligation pursuant to Section rts, indicate by check mark the information file	
☑ Annual Information Form	☑ Audited Annual	Financial Statements
Indicate the number of outstanding shares of ϵ by the annual report: 95,121,639	each of the issuer's classes of capital or com	mon stock as of the close of the period covered
Indicate by check mark whether the registrar	nt: (1) has filed all reports required to be file	ed by Section 13 or 15(d) of the Exchange Act

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12

Yes ☑No □

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.

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 grow	th 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.		
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.		
Auditor Name: KPMG LLP Auditor Location: N	Montreal, Canada Auditor Firm ID: 85	
† 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.		

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 tesamorelin;
- our success in obtaining commercially attractive pricing and 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 the intravenous push, or IV Push, mode of administration of Trogarzo® by the FDA;
- 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 finance or finding a partner to conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population:
- our capacity to pursue the conduct of our Phase 1 clinical trial using our TH1902 PDC in various types of cancers;
- our capacity to pursue the development of our other PDCs 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, including our commercial regular practice associated with the sale of our products;
- 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 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 SV® and Trogarzo® will not change their respective current safety profile;
- no recall or market withdrawal of 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 SV® and Trogarzo® will be available;
- our relations with third-party suppliers of EGRIFTA SV[®] and Trogarzo[®] will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply 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 integration of U.S. employees into our U.S. subsidiary will not be disruptive to our business and will strengthen our commercial capabilities in the United States;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- we will succeed in developing the Pen or any other device for use with the F8 Formulation and the FDA will approve the use of such device for the F8 Formulation;
- we will have the financial means or will find a partner to conduct a Phase 3 clinical trial 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;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate strong efficacy results;
- 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, 2021, 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, 2021 and 2020, 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, 2021 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, 2021, 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 un 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, 2021, 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: Alain Trudeau, its Chair, Gary Littlejohn, Gérald A. Lacoste, and Frank Holler.

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, 2021 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 Alain Trudeau is the financial expert of the Audit Committee. The SEC has indicated that the designation or identification of Mr. Trudeau as an audit committee financial expert does not deem him an "expert" for any purpose, impose any duties, obligations or liability on Mr. Trudeau 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.

Alain Trudeau. Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal and is a fellow of the Quebec CPA order. 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.

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.

Frank Holler. Mr. Holler holds an MBA and BA (Economics) from the University of British Columbia. Prior to joining the Corporation, Mr. Holler was President and CEO of Xenon Pharmaceuticals Inc. from 1999 to 2003 after having been President and CEO of ID Biomedical Corporation from 1991 to 1998. In addition, he was a founding director of Angiotech Pharmaceuticals. Mr. Holler also acted as Vice-President of Investment Banking with Merrill Lynch Canada and Wood Gundy Inc. (now CIBC World Markets).

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, 2021 and 2020:

AUDITORS FEES

Fees	Fiscal Year Ended November 30, 2021 (CAD)	Fiscal Year Ended November 30, 2020 (CAD)
Audit Fees ⁽¹⁾	\$639,382	\$497,667
Audit-Related Fees ⁽²⁾	\$48,943	\$89,175
Tax Fees ⁽³⁾	\$170,027	\$54,563
Total:	\$858,352	\$641,405

- (1) Refers to the aggregate fees billed by our external auditors for audit services, including interim reviews and work performed in connection with securities fillings.
- (2) Refers to the aggregate fees billed for professional services rendered by our external auditors for translation and accounting consultations.
 (3) Refers to the aggregate fees billed for professional services rendered by our external auditors for tax compliance, transfer pricing, tax
- (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, 2021, 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, 2021 information with respect to the Corporation's known contractual obligations (stated in U.S. dollars).

		Less than 1			More than
Contractual Obligations	Total	Year	1 to 3 Years	3 to 5 Years	5 years
Convertible unsecured senior notes, including interest	64,113,000	3,306,000	60,807,000		
Lease Liabilities	2,973,000	624,000	1,275,000	1,074,000	_
Purchase Obligations (1)	8,575,000	8,575,000			
Total	\$ 75,661,000	\$ 12,505,000	\$ 62,082,000	\$ 1,074,000	\$

(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, 2021, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to \$6,598,000 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 \$1,253,000 in connection with its oncology platform and \$724,000 in connection with the F8 Formulation and the Pen developed for the F8 Formulation.

Long-term obligations are contingent upon occurrence of certain stated event under commercialization rights and license agreements.

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, 2021 and 2020, 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 pediatric 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 13 (Intangible Assets) to the audited consolidated financial statements of the Registrant for the year ended November 30, 2021 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, 2021, 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: Isl Paul Lévesque

Name: Paul Lévesque Title: President and

Chief Executive Officer

Date: February 24, 2022

EXHIBIT INDEX

Exhibit	
99.1	Annual Information Form dated February 23, 2022 for the financial year ended November 30, 2021
99.2	Management's Discussion and Analysis for the year ended November 30, 2021
99.3	Audited Consolidated Annual Financial Statements for the years ended November 30, 2021 and 2020
99.4	Certificate of CEO dated February 24, 2022 pursuant to Rule 13a-14(a) of the Exchange Act
99.5	Certificate of CFO dated February 24, 2022 pursuant to Rule 13a-14(a) of the Exchange Act
99.6	Certificate of CEO dated February 24, 2022 pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.7	Certificate of CFO dated February 24, 2022 pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.8	Consent of KPMG LLP
101	Interactive Data File (formatted as Inline XBRL)
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

ANNUAL INFORMATION FORM Financial Year Ended November 30, 2021



February 23, 2022

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 SV*® (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. *EGRIFTA SV* is our registered trademark in the United States and this mark is used in the United States 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 the potential treatment of 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 in European countries.
- *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.
- *SORT1* + *Technology* is our trademark and refers to our licensed platform to develop peptide-drug conjugates, or PDC.
- 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 23, 2022, 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 pricing and reimbursement conditions of other competing drugs or therapies that are or may become available;
- our ability to protect and maintain our intellectual property rights in tesamorelin;
- our success in obtaining commercially attractive pricing and 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 the intravenous push, or IV Push, mode of administration of Trogarzo® by the United States Food and Drug Administration, or FDA;
- the approval of a new formulation of tesamorelin, or F8 Formulation, by the FDA;
- the approval of our amended protocol by the FDA regarding our planned Phase 3 trial in NASH using tesamorelin;
- our capacity to develop a multi-dose pen injector, or Pen, for use with the F8 Formulation;
- our capacity to finance or finding a partner to conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- our capacity to pursue the conduct of our Phase 1 clinical trial using our TH1902 PDC in various types of cancers;
- our capacity to pursue the development of our other PDCs in the field of oncology;
- our capacity to enter into a partnership agreement with a third party regarding our TH1902 PDC for Greater China;
- 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, including our commercial practice associated with the sale of our products;
- 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 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 SV®* and Trogarzo® will not change their respective current safety profile;
- no recall or market withdrawal of 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 SV*® and Trogarzo® will be available;
- our relations with third-party suppliers of *EGRIFTA SV*® and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *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 integration of U.S. employees into our U.S. subsidiary will not be disruptive to our business and will strengthen our commercial and medical affairs capabilities in the United States;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- we will succeed in developing the Pen or any other device for use with the F8 Formulation and the FDA will approve the use of such device for the F8 Formulation;
- we will have the financial means or will find a partner to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our current Phase 3 trial protocol evaluating the use of tesamorelin for the potential 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;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate strong efficacy results;
- we will succeed in entering into a partnership agreement with a third party for TH1902 in Greater China;
- 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 subsequent to 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.

TABLE OF CONTENTS

	ED EVENTS IN FISCAL YEAR 2021 AND OUTLOOK	1 3
ITEM 1	CORPORATE STRUCTURE	3
1.1 1.2	NAME, ADDRESS AND INCORPORATION SUBSIDIARIES	3
ITEM 2	OUR BUSINESS	4
2.1	OVERVIEW	4
2.1	THREE-YEAR HISTORY	5
2.2	OUR 2022 BUSINESS STRATEGY AND OBJECTIVES	9
2.3	PRODUCTS	10
2.5	COMMERCIALIZATION ACTIVITIES	13
2.6	RESEARCH AND DEVELOPMENT ACTIVITIES	19
2.7	COMPETITION	25
2.8	GOVERNMENT REGULATION	26
2.9	PHARMACEUTICAL PRICING AND REIMBURSEMENT	28
2.10	INTELLECTUAL PROPERTY	31
2.11	EMPLOYEES	35
2.12	FACILITIES	35
2.13	ENVIRONMENT	35
ITEM 3	RISK FACTORS	36
3.1	RISKS RELATED TO THE COVID-19 PANDEMIC	36
3.2	RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS	37
3.3	RISKS RELATED TO RESEARCH AND DEVELOPMENT ACTIVITIES	43
3.4	RISKS RELATED TO OUR INTELLECTUAL PROPERTY	48
3.5	REGULATORY RISKS	50
3.6	LITIGATION RISKS	52
3.7	GEO-POLITICAL RISKS	53
3.8	OTHER RISKS RELATED TO OUR BUSINESS	54
3.9	RISKS RELATED TO OUR COMMON SHARES	57
ITEM 4	DIRECTORS AND EXECUTIVE OFFICERS	60
4.1	DIRECTORS	60
4.2	AUDIT COMMITTEE	69
4.3	EXECUTIVE OFFICERS	70
4.4	CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS	73
4.5	SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS	74
ITEM 5	INTERESTS OF EXPERTS	75
ITEM 6	SECURITIES OF THE COMPANY	76
6.1	AUTHORIZED SHARE CAPITAL	76
6.2	DIVIDEND POLICY	76
6.3	TRANSFER AGENT AND REGISTRAR	76
ITEM 7	MARKET FOR SECURITIES	77
7.1	PRICE RANGE AND TRADING VOLUME	77
7.2	PRIOR SALES	78
ITEM 8	LEGAL PROCEEDINGS	80
ITEM 9	MATERIAL CONTRACTS	81
_	ADDITIONAL INFORMATION	87
APPEND	IX A – AUDIT COMMITTEE CHARTER	88

SELECTED EVENTS IN FISCAL YEAR 2021 AND OUTLOOK

The following summary highlights selected events that occurred in the fiscal year 2021 up to the date of this AIF as well as our business objectives described elsewhere in this AIF for the fiscal year 2022. 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

- Launch of Trogarzo® in Italy;
- US \$50,000,000 at-the-market facility in place; and
- Internalization of commercial and medical teams effective March 14, 2022.

Regulatory Events

- Filing of a supplemental biologics license application, or sBLA, with the FDA for the IV Push mode of administration of Trogarzo®;
- FDA's grant of "Fast Track" designation to TH1902;
- Initiation of Phase 1 clinical trial studying TH1902 in various types of cancers; and
- Postponement of Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population until additional financing or a partner is secured.

Research and Development Events

- Additional pre-clinical data using TH1902 in various types of cancer showed that TH1902 could potentially treat sortilin-expressed cancers; and
- Initiation of the development of additional PDC using new payloads, including SN38.

Governance and Talent Acquisition Events

- Election and appointment of three (3) new independent directors to our board of directors;
- Hiring of a Global Commercial Officer and a Vice President, HIV-US, Commercial Operations; and
- Hiring of a Vice President, Human Resources.

2022 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 commercially attractive pricing and reimbursement for Trogarzo® in key European countries and launch Trogarzo® in some of these countries;
- We intend to launch the IV Push mode of administration of Trogarzo®;
- We intend to pursue the development of an intra-muscular mode of administration of Trogarzo®;
- We intend to secure additional financing or find a partner to initiate a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- We intend to initiate Part B of our Phase 1 clinical trial studying TH1902 in various types of cancer;
- We intend to seek potential partners for our SORT1+ TechnologyTM platform in markets where we are not planning on developing and conducting clinical trials;

•	We intend on pursuing potential product acquisitions, in-licensing transactions or other opportunities complementary to our business;
•	We plan on retaining and attracting a pool of diverse talents at all levels to participate and contribute to the successful execution of our business strategy and objectives; and
•	We plan on managing our financial position to ensure we can successfully execute on our 2022 business strategy and objectives.
	- 2 -

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. The information contained on our website is not part of this AIF.

1.2 <u>SUBSIDIARIES</u>

As at February 23, 2022, 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 2022.

ITEM 2 OUR BUSINESS

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, the United Kingdom and Israel.

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 May1st, 2014.

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 Italy. It is also available in France and Spain through access programs. Trogarzo® was also approved in Israel in January 2022. 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 a long-acting antiretroviral, or 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 $EGRIFTASV^{\circledR}$, 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 PDC derived from our licensed platform SORT1+ TechnologyTM that attaches to docetaxel, is designed to specifically target Sortilin, or SORT1, receptors expressed in cancer cells of various types of cancer and is being studied in a Phase 1 clinical trial. We are also working on the development of other PDCs.

Our plan to initiate a Phase 3 clinical trial to study tesamorelin for the treatment of NASH in the general population has been postponed until we can secure additional financings or find a partner. We have initiated our Phase 1 clinical trial using TH1902 in various types of cancer and the ongoing Part A of such Phase 1 is aimed at finding the maximum tolerated dose of TH1902. We plan on initiating Part B of the Phase 1 clinical trial in the current fiscal year to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, triple-negative breast cancer and other cancer types.

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 intended to be used with the F8 Formulation. We plan on filing an sBLA seeking the approval of the F8 Formulation in the first half of the current fiscal year.

We have also filed an sBLA with the FDA for the IV Push mode of administration of Trogarzo® and have begun enrolling patients for the development of an intramuscular mode of administration of Trogarzo®.

2.2 THREE-YEAR HISTORY

2021

- *Submission of sBLA to the FDA for the IV Push mode of administration of Trogarzo*®. On December 6, 2021, we announced the submission of an sBLA to the FDA for the IV Push mode of administration of Trogarzo®.
- *Renewal of Shelf Prospectus and ATM Program.* On November 23, 2021, we announced the filing of a short form base shelf prospectus with the Securities and Exchange Commission, or SEC, and Canadian securities regulatory authorities with the intent on filing a prospectus supplement to renew our prospectus supplement of July 23, 2021 relating to our US\$50,000,000 at-the-market, or ATM, facility. Such prospectus supplement was filed on December 16, 2021 and the ATM program was renewed.
- *Conclusion of Agreement for the Reimbursement of Trogarzo*® *in Italy.* On October 26, 2021, we announced that we had reached an agreement with the Italian Medicines Agency for the reimbursement of Trogarzo®.
- Pharmacokinetic Results of Trogarzo® similar in IV Push mode of administration of Trogarzo® as those in the intravenous mode of administration. On September 22, 2021, we announced that the pharmacokinetics results of the IV Push mode of administration of Trogarzo® were no different than those of the intravenous mode of administration of Trogarzo®.
- *ATM Facility*. On July 23, 2021, we announced that we had filed a prospectus supplement to our short form base shelf prospectus with the SEC and Canadian securities regulatory authorities establishing an ATM facility entitling us to issue and sell up to US\$50,000,000 common shares from treasury.
- Study of Tesamorelin for the Potential Treatment of NASH in the General Population. On July 15, 2021, we announced that discussions with the FDA ad the EMA on our protocol design were completed and provided details on such study design. We also announced that the costs of conducting such study were higher than expected and we had retained a third party to assist in identifying a potential partner. As a result, we announced that the timelines to initiate such study were no longer applicable.
- *Appointment and Election of New Board Members.* On June 23, 2021, we announced that we had appointed Mr. Frank Holler to the Board of Directors. This announcement followed the election of three

new members, Mr. Joe Arena, Mr. Andrew Molson and Mr. Alain Trudeau, to the Board of Directors of Theratechnologies during the annual meeting of shareholders of Theratechnologies held on May 13, 2021.

- *Strategic Hire Supporting the Human Resources Activities*. On May 31, 2021, we announced the addition of one new senior member to our executive team, namely Mr. André Dupras acting as Vice President, Human Resources.
- *Strategic Hires Supporting the Commercial Activities*. On March 29, 2021, we announced the addition of two new senior members to our executive team, namely Mr. John Leasure and Mr. Peter Kowal. Mr. Leasure acts as Global Commercial Officer, whereas Mr. Kowal acts as Vice President, HIV-US, Commercial Operations.
- *First Patient Dosed with TH1902 in Phase 1 Clinical Trial.* On March 24, 2021, we announced that a patient had received a first dose of TH1902 as part of the dose-escalating part of our Phase 1 clinical trial evaluating TH1902 in various types of cancer.
- *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.

- *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 in-house 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*TM 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®*.
- *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.
- *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).

2.3 <u>OUR 2022 BUSINESS STRATEGY AND OBJECTIVES</u>

Our business strategy in 2022 is focused on: increasing sales of *EGRIFTA SV®* and Trogarzo® in the United States; obtaining commercially attractive pricing and reimbursement of Trogarzo® in key countries of the European Union and launching Trogarzo® therein; launching the F8 Formulation and the IV Push mode of administration in the U.S.; continuing Part 1b of our Phase 1 clinical trial studying TH1902 in various types of cancer; beginning a Phase 3 clinical trial using tesamorelin for the potential treatment of NASH in the general population after having secured additional financing or having found a partner; continuing pursuing potential product acquisitions, in-licensing transactions or other similar opportunities complementary to our business; seeking potential partners for our licensed SORT1+ TechnologyTM platform in countries where we do not intend to develop and conduct clinical trials; retaining and attracting a pool of talent to participate and contribute to the successful execution of our business strategy and objectives; and managing our financial position to ensure we can successfully execute on our 2022 business strategy and objectives.

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



2.4 PRODUCTS

Our Approved Products

EGRIFTA SV® (tesamorelin for injection)

EGRIFTA SV® (tesamorelin for injection) induces the release of growth hormone which causes a reduction in excess abdominal fat (lipohypertrophy) in HIV-infected patients without reducing or interfering with subcutaneous fat, and, as such, has no clinically significant effect on undesired loss of subcutaneous fat (lipoatrophy).

EGRIFTA SV[®] is an improved formulation of the original F1 Formulation 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 original F1 Formulation, therefore resulting in a smaller volume of administration. No filing has been made in any country seeking the approval of *EGRIFTA SV*[®]. *EGRIFTA SV*[®] is injected under the skin into the abdomen once a day.

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 $EGRIFTA\ SV^{\circledR}$. 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.

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. The EMA rejected our request and the PIP must be completed by June 2023. Up to 12 patients will be enrolled in order to complete the PIP and each patient must be treated over a period of 24 weeks with a four-week follow-up.

As part of the approval of Trogarzo®, the EMA requested that we conduct a post-authorisation efficacy study, or PROMISE, according to a protocol to be agreed with the EMA. In July 2020, we agreed on the final terms of this protocol. The PROMISE study 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 PROMISE study should be conducted over a five-year period and the enrollment of patients began in December 2021. We expect the costs of the PROMISE study to be approximately 4,000,000 euros. The costs are to be borne as to 52% by TaiMed and as to 48% by us. As a result of this requirement in Europe, we decided to initiate a similar study in the United States, or PROMISE-US. We believe that data gathered from the PROMISE-US study will form part of the data submitted to the EMA. The costs of the PROMISE-US study will be entirely borne by the Corporation.

Trogarzo® is currently commercially available in Germany and in Italy. It is also available in certain other European countries through access programs. We are working on obtaining pricing and reimbursement conditions 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. See "Item 2.6 – Research and Development Activities – Ibalizumab – IV-Push Form of Administration of Trogarzo" below.

Trogarzo® was developed by TaiMed and we have an exclusive license to distribute this product in Canada, the United States, Europe and certain other additional countries. See "Item 2.5 – Commercialization Activities – *Trogarzo®* – General" below.

Mechanism of Action

Unlike other antiretroviral agents, Trogarzo® binds primarily to the second extracellular domain of the CD4 receptor, away from major histocompatibility complex II molecule binding sites. It potentially prevents the HIV virus from infecting CD4+ 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 ART were noted during the clinical trials.

2.5 <u>COMMERCIALIZATION ACTIVITIES</u>

EGRIFTA SV® - United States

General

 $EGRIFTA\ SV^{\circledR}$ (tesamorelin for injection) is commercialized in the United States. Prior to November 2019, the date on which $EGRIFTA\ SV^{\circledR}$ became commercially available in the United States, $EGRIFTA^{\circledR}$ (tesamorelin for injection) was also commercialized in the United States. However, $EGRIFTA^{\circledR}$ is no longer offered for sale in the United States since being replaced by $EGRIFTA\ SV^{\circledR}$ in the 2020 fiscal year. See "Item 2.5 – Commercialization Activities – Marketing and Sales of our Products" below for a description of our commercial infrastructure.

Manufacturing

We do not own or operate commercial scale manufacturing facilities for the production of *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 $EGRIFTA\ SV^{\circledR}$ in a 2 mg/vial formulation and one vial of $EGRIFTA\ SV^{\circledR}$ is required to administer a dose of 1.4 mg which is bioequivalent to a 2 mg dose of the original F1 Formulation.

Active Pharmaceutical Ingredient

We are currently negotiating the renewal of our manufacture and supply agreement with Bachem, or Bachem Agreement, relating to the manufacture and supply of the active pharmaceutical ingredient of tesamorelin, or API, for *EGRIFTA SV®*. However, despite the ongoing negotiations, Bachem has advised us that it would manufacture lots of API, if needed. 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 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 $EGRIFTA~SV^{\mathbb{R}}$, we provide patients with the necessary devices to administer $EGRIFTA~SV^{\mathbb{R}}$. 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 $EGRIFTA\ SV^{\circledR}$ in the United States, we have entered into various agreements with third-party service providers to distribute our products to patients. The distribution of $EGRIFTA\ SV^{\circledR}$ 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 $EGRIFTA\ SV^{\circledR}$.

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 $EGRIFTA\ SV^{(1)}$, 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 $EGRIFTA\ SV^{\circledR}$ in the United States is comprised of a limited number of wholesalers through which specialty pharmacies we have contracted with can order $EGRIFTA\ SV^{\circledR}$. These wholesalers accept purchase orders from those specialty pharmacies, purchase $EGRIFTA\ SV^{\circledR}$ from RxCrossroads, and resell this product to these specialty pharmacies. Our wholesalers do not handle the physical delivery of $EGRIFTA\ SV^{\circledR}$. The shipping and delivery of $EGRIFTA\ SV^{\circledR}$ to those specialty pharmacies is handled by RxCrossroads. To date, we have agreements in place with the following wholesalers for $EGRIFTA\ SV^{\circledR}$: 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 $EGRIFTA\ SV^{\circledR}$ from our authorized wholesalers and distribute $EGRIFTA\ SV^{\circledR}$ 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 $SV^{\mathbb{R}}$ directly from RxCrossroads for redistribution within their own retail specialty pharmacy stores.

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 have 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 was payable twelve (12) months after the first commercial sale of Trogarzo® in the European Territory and was paid in October 2021. 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-wholesaling 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. 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 $EGRIFTA\ SV^{\circledR}$ and Trogarzo $^{\circledR}$ 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 affairs 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 effective as of December 1, 2021, or Syneos Agreement, pursuant to which Syneos will continue providing us with various services in connection with the commercialization of $EGRIFTA\ SV^{\circledR}$ and Trogarzo $^{\circledR}$ in the United States until November 30, 2024. 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 $EGRIFTA\ SV^{\otimes}$ and Trogarzo $^{\otimes}$, a medical science liaison team solely assigned to our medical activities, a community liaison team educating patient's associations on HIV, a managed market team solely dedicated to the reimbursement of our products with both public and private payors.

Effective March 14, 2022, we will cease relying on Syneos to provide us with a sales force team, a medical science liaison team and a community liaison team. Top performers forming part of these teams will become employees of our U.S. subsidiary and will be managed directly by us. We are currently finalizing our in-house infrastructure to welcome these new employees.

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

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 SV®

EGRIFTA SV® is not approved in Europe and, therefore, is not available in this territory.

<u>Trogarzo®</u>

Trogarzo® became commercially available in Germany in September 2020 and in Italy in December 2021. Our European subsidiary, Theratechnologies Europe Limited, has also retained the services of Syneos in Europe to

assist with the commercialization of Trogarzo[®]. In the European Territory, Syneos provides us with the services of a medical director, medical science liaison personnel for France, Italy and Spain, and one key account manager.

Currently, Trogarzo® can only be promoted in Italy, the only country where we entered into an agreement with regulatory authorities with respect to its pricing and reimbursement conditions, but is available in other countries, such as France and Spain, through access programs. Although Trogarzo® is commercially available in Germany to patients, we can no longer promote it as of September 2021 since no agreement has been reached yet with German regulatory authorities on its pricing and reimbursement conditions. We are continuing our efforts on obtaining pricing and reimbursement conditions 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 obtained pricing and reimbursement conditions for Trogarzo® in Israel and are still in negotiation with Norwegian regulatory authorities in relation to the pricing and reimbursement conditions of Trogarzo® in this territory.

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 in-house bioequivalence study of the F8 Formulation. The F8 Formulation is eight times more concentrated than the F1 Formulation and twice as concentrated as the current $EGRIFTA\ SV^{(8)}$ 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 is expected to be stable at room temperature, even once reconstituted; and (3) the volume of administration will be smaller, approximately 0.2 ml. The fill and finish form of the F8 Formulation will be manufactured by a third party. To date, one process validation batch has been manufactured.

We intend to file an 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 intended to be used in conjunction with the F8 Formulation. To date, its development is not completed and we are still working on the Pen. As a result, no timeline has been set for the filing of an sBLA with the FDA in relation to the Pen.

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. In November 2020, we filed an Investigational New Drug Application, or IND, with the FDA for a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH

and we received a "Study May Proceed" letter for such Phase 3 clinical trial from the FDA in December 2020. 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 followed up on the FDA's recommendation and requested a meeting with the agency. On July 15, 2021, we announced that we had completed discussions with the FDA following an end of Phase 2 meeting and with the EMA following a scientific advice meeting regarding the Phase 3 clinical trial in NASH.

The finalized Phase 3 trial design is planned for a multicenter, randomized, double-blind, placebo-controlled two-part study designed to evaluate the safety and efficacy of tesamorelin in liver-biopsy confirmed patients with NAS score of at least 4 and stage 2 or 3 fibrosis. Part 1 of the study will include a total of approximately 1,100 patients (1:1, tesamorelin:placebo), including approximately 75 to 100 people living with HIV. A second liver biopsy will be performed after the first approximately 1,100 participants have completed 18 months of treatment. This should form the basis for filing an sBLA with the FDA. The clinical trial will also include a futility analysis that would be conducted after the first approximately 400 patients have completed 18 months of treatment and have received a second liver biopsy. The futility analysis will provide a perfunctory review indicating if an early treatment effect with tesamorelin has been observed and will determine if the study should proceed as planned. Following a potential sBLA approval, Part 2 of the trial will continue to enroll an additional approximately 1,800 patients (3:1, tesamorelin:placebo) to continue to measure clinical outcomes over a period of five years. A total of approximately 2,900 patients are expected to be enrolled.

We have already entered into an agreement with Worldwide Clinical Trials, Inc., or WCT, a contract research organization with experience in implementing large and late-stage clinical trials, to assist with the potential conduct of our Phase 3 clinical trial, or WCT Agreement. See "ITEM 9 – Material Contracts – WCT Agreement" below.

On July 15, 2021, we also announced that the final Phase 3 clinical trial design would result in higher costs than what we had expected and, as a result, we were assessing our options to best execute this program, including seeking a potential partner. An external U.S.-based biopharma advisory firm was retained for that purpose. To date, we are still continuing to seek a partner and to assess additional options, such as certain forms of financing.

In order to further de-risk the Phase 3 trial, the Corporation intends to submit an amended protocol to the FDA. The new protocol will include a Phase 2b/3 seamless study design where the first 350 or so patients' data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. A decision will then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. This will not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it will inform the continuation of enrollment while providing an indication of benefit to patients.

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.

VAMOS Study

The Company has decided to conduct an observational study in the United States titled "The Visceral Adiposity Measurement and Observation Study", or VAMOS. VAMOS is an epidemiologic cross-sectional study to answer the unknown associations between visceral fat and cardiovascular disease risk, liver fat, liver fibrosis, pericardial fat, and muscle fat in today's HIV patients. These associations will be measured across a diversity of weights, BMIs, genders, and races so that the impact of visceral fat can be understood with external validity to the results. Additionally, the performance of anthropometric measurements like waist circumference, or WC, and hip circumference will be assessed in a modern HIV population. The aims of this study are two-fold: (1) to determine the utility of WC's ability to predict cardiovascular risk scores, liver fat, liver fibrosis, and abnormal glucose homeostasis across the full VAMOS population and subgroups; and (2) to identify common clinical data points in today's standard of care that can be used to assess a patient's risk of having excess visceral fat. The VAMOS results are expected to direct clinicians on why and which patients in their practice should be screened for excess visceral fat.

Ibalizumab

IV-Push Form of Administration of Trogarzo®

TaiMed has completed the research and development activities of the IV Push mode of administration of Trogarzo® and, in December 2021, we filed an sBLA with the FDA in relation thereto. The FDA has accepted our filing and has provided a target action date of October 3, 2022 in accordance with the *Prescription Drug User Fee Act* (PDUFA). The IV Push mode of administration of Trogarzo® is a more convenient form of administration. It can be infused within 30 seconds without dilution compared to the 15-minute infusion time of the current intravenous mode of administration. We believe this mode of administration will represent a marked improvement for patients. Under the terms of the TaiMed Agreement, we are entitled to commercialize this new form of administration of Trogarzo® if, and when, approved. We expect launching this new mode of administration in 2022.

Intra-Muscular Administration of Trogarzo®

In addition to the development of the IV-Push mode of administration of Trogarzo®, we began enrolling patients to study an intramuscular mode of 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 began enrolling patients for the conduct of the PROMISE study requested by the EMA and have decided to initiate the PROMISE-US study in the United States. We will also conduct the PIP as per the requirements of the EMA. See "Item 2 – Our Business – Products – Trogarzo" above for a description of these programs.

TH1902

Acquisition of SORT1+ TechnologyTM Platform

The research and development activities carried out on our TH1902 PDC and other PDCs 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+ TechnologyTM) 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, was payable on the date that a Phase 1 clinical trial is initiated using one of the peptides developed through the oncology platform, whereas 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.

On March 23, 2021, we paid the Second Installment to the former shareholders of Katana through the issuance of 481,928 common shares.

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

We are currently developing a platform of new proprietary peptides for cancer drug development targeting SORT1 receptors called SORT1+ TechnologyTM. SORT1 is a receptor that plays a significant role in protein internalization, sorting and trafficking. It is highly expressed in cancer cells compared to healthy tissue making it an attractive target for cancer drug development. Expression has been demonstrated in, but not limited to, ovarian, triple-negative breast, endometrial, skin, small cell and non-small cell lung, colorectal and pancreatic cancers. Expression of SORT1 is associated with aggressive disease, poor prognosis and decreased survival. Preliminary assessments have demonstrated that the SORT1 receptor is expressed in 40% to 90% of cases of endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

The Corporation's innovative PDCs generated through our SORT1+ TechnologyTM demonstrate 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 anti-cancer drugs within the tumor microenvironment, and more importantly, directly inside SORT1 cancer cells. Commercially available anticancer drugs, like docetaxel, doxorubicin or tyrosine kinase inhibitors are conjugated to our peptide to specifically target SORT1 receptors. This could potentially improve the efficacy and safety of those agents.

In preclinical data, the Corporation's lead investigational PDC, TH1902, derived from our SORT1+ TechnologyTM, has shown to improve anti-tumor activity and reduce neutropenia and systemic toxicity compared to traditional chemotherapy. Additionally, in preclinical models, TH1902 has shown to bypass the multidrug resistance protein 1 (MDR1; also known as P-glycoprotein) and inhibit the formation of vasculogenic mimicry -

two key resistance mechanisms to chemotherapy treatment. TH1902 combines our proprietary peptide and the cytotoxic drug, docetaxel.

In December 2020, we 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 FDA granted fast track designation to TH1902 as a single agent for the treatment of all 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.

In March 2021, a Phase 1 clinical trial was initiated evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design includes a Part 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.

Part A of the Corporation's Phase 1 study evaluating its novel investigational proprietary PDC TH1902 for the treatment of sortilin positive cancers is progressing as planned. The Corporation is in the final stages of such Phase 1/Part A dose escalation study. As per the study protocol, the MTD is established once a significant adverse event is observed in two or more patients. In total, four patients in the trial have been administered significant doses of TH1902 at 420 mg/m², equivalent to nearly two times the indicated therapeutic dose of docetaxel. To date, we have observed a dose limiting toxicity, or DLT, (grade 4 neutropenia lasting more than 7 days) in one patient, as well as other adverse events after more than one cycle at 420 mg/m². As a result, we have decided to pursue the study at a lower dose of 300 mg/m² (or approximately 1.5 times the usual dose of docetaxel). We currently are enrolling patients at the 300 mg/m² dose to confirm the absence of DLTs following the first cycle. Once MTD has been established, the study protocol allows for immediate initiation of enrollment of a larger open label basket trial. The basket trial will further assess the safety and tolerability of TH1902. Additionally, the preliminary anti-tumor activity of TH1902 will be evaluated for all patients as per the response evaluation criteria in solid tumors. Based on additional research we have conducted on the Sortilin receptor, we have submitted an amendment to the Phase 1 protocol to the FDA to include the following solid tumor types: Hormone Receptor-Positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, and Melanoma with approximately 10 patients per tumor type. In addition, one arm will be added to include a mix of tumor types including Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers with 15 patients in total. The original trial design consisted of 40 patients across a selection of solid tumors, including colorectal and pancreatic cancer. The plan is now to enroll a total of approximately 70 patients in the basket trial to evaluate the potential anti-tumor activity of TH1902.

The research and development work using TH1904 (peptide-drug conjugated to doxorubicin) has slowed down. However, we have begun working on other PDCs, primarily to advance a PDC using SN38.

Partnership Activities

We are exploring the possibility of out-licensing development and commercialization rights for TH1902 in Greater China. As of the date of this AIF, there has been solid interest on the part of Chinese companies and discussions are ongoing with a number of different pharmaceutical and biotech companies.

2.7 <u>COMPETITION</u>

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 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. We are aware that a NDA and a marketing authorization application have been filed with the FDA and the EMA, respectively, for Lenacapavir.

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+ TechnologyTM 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 need 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 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 $SV^{\mathbb{R}}$ and $Trogarzo^{\mathbb{R}}$ 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 may also be subject to various federal and state laws pertaining to health care "fraud and abuse," including but not limited to the federal Anti-kickback Statute, Civil Monetary Penalties Law, and False Claims Act and analogous state laws. The federal Anti-kickback Statute prohibits a person from knowingly and willfully offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referring or recommending an individual to another person to receive items or services or to purchase, lease, order, or arrange for any good, facility, item or service payable in whole or in part under a Federal health care program. The Civil Monetary Penalties Law prohibits, among other things, a person from offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. 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 $EGRIFTA\ SV^{(g)}$ and/or $Trogarzo^{(g)}$), 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. The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly makes a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. 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. Also, the federal Physician Payments Sunshine Act, also known as the Open Payments Act, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to record and disclose to the federal government certain transfers of value to physicians and teaching hospitals and ownership and investment interests held by physicians and their immediate family members. 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.

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 SV®*, as well as WuXi, the manufacturer of Trogarzo®, must adhere to GMPs in connection with the manufacture, labeling, packaging, and any other quality-related functions for these products. If a company wants to make certain changes in its manufacturing equipment, location or process, FDA 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 privately 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 products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of $EGRIFTA\ SV^{\circledR}$ and Trogarzo $^{\circledR}$ and Trogarzo $^{\circledR}$ 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 $EGRIFTA\ SV^{\circledR}$ and/or Trogarzo $^{\circledR}$ on a competitive and profitable basis.

United States

The U.S. Congress, state legislatures, and federal and state agencies from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our drug products profitably. For example, in March 2010, the Patient Protection and Affordable Care Act, and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law was enacted, and was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements (inclusive of price increases) for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of all Medicaid drug rebates. On January 21, 2016, the Centers for Medicare and Medicaid Services, 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 U.S. territories in the calculation of "average manufacturer price" and "best price" effective April 1, 2017. Further, the new law imposed a significant annual fee on companies that manufacture or import certain branded prescription drug products and biologic agents. On December 31, 2020, CMS issued a final rule to support state flexibility to enter into value-based purchasing arrangements, or VBPs, with manufacturers for prescription drugs and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. This final rule is intended in part to further value-based payment arrangements. Implementation of certain aspects of this final rule has been delayed pursuant to a final rule issued by CMS on November 19, 2021. 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 was blocked by a temporary restraining order and preliminary injunctions through various court actions, and on December 29, 2021, CMS formally rescinded the interim final rule, effective February 28, 2022. 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. 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.

The HTA process in the EU Member States was previously solely governed by the national laws of these countries. However, in November 2021, the EU Parliament adopted Regulation (EU) 2021/2282) on HTA, or HTA Regulation. The HTA Regulation came into force in January 2022 and will become applicable from January 2025. The purpose of the HTA Regulation is to create a more harmonised mandatory approach to HTA, involving permanent co-operation between national HTA authorities. The three-year delayed application period aims to ensure that there is enough time to set up the organisational framework of the HTA Regulation and to adopt the implementing and delegated acts and methodological guidance documents provided for by the HTA Regulation. The delayed application will also give Member States time to adjust their national HTA legislation and processes to the new HTA Regulation as needed, and stakeholder organisations, in particular health technology developers, will have time to familiarise and comply with the requirements of the new framework.

2.10 <u>INTELLECTUAL PROPERTY</u>

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

Our PDCs stemming from our licensed SORT1+ TechnologyTM platform are also patent protected in the United States and patent applications have been filed in additional countries.

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

Our current patent portfolio is comprised of the following material patents for tesamorelin:

- 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 the United States, we have the exclusive right to two patents that claim a method for the treatment of NAFLD or NASH in a patient via the administration of tesamorelin. These patents are scheduled to expire in 2040;
- In the United States and in certain major European countries, we own patents relating to the F8 Formulation, which are scheduled to expire in 2033 and 2034, respectively; and

• We have also filed additional patent applications related to the bioequivalence of certain formulation of tesamorelin to the original formulation of *EGRIFTA®*.

SORT1+ TechnologyTM

Our currently licensed patent portfolio related to the SORT1+ TechnologyTM platform is comprised of the following material patents:

- In the United States, we have the exclusive rights to a patent relating to conjugates in respect of the SORT1+ TechnologyTM platform, which is scheduled to expire in 2037;
- In Europe, we have the exclusive rights to a patent relating to peptides and conjugates in respect of the SORT1+ TechnologyTM platform. This patent is scheduled to expire in 2036 and is being validated in certain major European countries;
- We also have exclusive rights to patent applications filed in other countries relating to peptides and conjugates in respect of the SORT1+ TechnologyTM platform, some of which have already been granted and are scheduled to expire in 2036;
- We also have exclusive rights to patent applications filed in several countries relating to the use of peptides and conjugates in respect of the SORT1+ TechnologyTM platform for the treatment of cancers involving vascular mimicry, which are typically associated with poor prognosis. Such applications, if granted, would be scheduled to expire in 2039; and
- We own a PCT patent application filed in December 2020 that relates to formulations made with peptides and conjugates in respect of the SORT1+ TechnologyTM platform, from which patent applications may be pursued in numerous jurisdictions. Such applications, if granted, would be scheduled to expire in 2040.

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 SV is our registered 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®.

*SORT1+ Technology*TM is our trademark and we have filed various trademark registration applications for this mark in various 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:

- 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 <u>EMPLOYEES</u>

As at November 30, 2021, we had 70 employees in Canada, four employees in the United States and 13 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, 2021, we had an additional 48 persons dedicated to the commercialization of $EGRIFTA\ SV^{(8)}$ and $Trogarzo^{(8)}$ in the United States and seven persons dedicated to the commercialization of $Trogarzo^{(8)}$ 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 ongoing COVID-19 pandemic could have a material adverse effect on our 2022 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 2022 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, increased border and port controls and closures, and shutdowns. Although most industrialized countries are relaxing some of the restrictive measures, there remains considerable uncertainty regarding the consequences such relaxed measures may have on the pandemic and the population worldwide as well as on the reimplementation of potential future measures.

As COVID-19 continues to be present and spread around the globe, the Corporation may experience disruptions that could severely impact its business and clinical trials, including:

- patients' limited access to the Corporation's treatments and products;
- diversion of healthcare resources prioritizing the treatment of patients suffering from COVID-19;
- delays or difficulties in enrolling patients in the Corporation's clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities;
- risk that participants enrolled in the Corporation's clinical trials will acquire COVID-19 while the clinical trial is ongoing;
- limitations in employee resources that would otherwise be focused on the commercialization of the Corporation's products and the conduct its clinical trials;
- delays in receiving authorizations from regulatory authorities to approve a drug candidate or to initiate the Corporation's planned clinical trials;

- delays in clinical sites receiving the supplies and materials needed to conduct the Corporation's clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require the Corporation to change the ways in which its clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- interruptions or delays in efforts to acquire data needed to support patent claims or otherwise expand the Corporation's intellectual property portfolio; and
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

The COVID-19 pandemic has significantly increased economic and demand uncertainty throughout North America and Europe. The COVID-19 pandemic has caused disruption and volatility in the global capital markets, which, depending on further developments, could impact the Corporation's 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 the Corporation's operations, financial condition, liquidity, results of operations, and cash flows is still highly uncertain and will depend on future developments. Such developments may include the geographic spread and duration of COVID-19, the severity of the disease and the actions that may be taken by various governmental authorities and other third parties in response to the pandemic.

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 $EGRIFTA\ SV^{\otimes}$ and $Trogarzo^{\otimes}$ in the United States and from $Trogarzo^{\otimes}$ in Europe 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 commercially attractive pricing for Trogarzo® and obtain reimbursement therefor 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^{\otimes} and $Trogarzo^{\otimes}$ 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 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 SV[®]. Our agreement with Bachem has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. Although we are in discussions with Bachem, 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 Bachem yet. Also, we have not qualified 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 potential Phase 3 clinical trial in NASH. Despite our current level of inventory of tesamorelin, we could incur a shortage of 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 $EGRIFTA~SV^{\circledR}$, Trogarzo $^{\circledR}$ 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 $EGRIFTA~SV^{\circledR}$ and Trogarzo $^{\circledR}$ 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 $EGRIFTA~SV^{\circledR}$ and Trogarzo $^{\circledR}$, 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.

Part of our commercial team in the United States and in the European Territory dedicated to the commercialization of our products in these territories is provided by Syneos. In the United States, after March 14, 2022, Syneos will continue to provide us with services related to managed market and certain functions supporting our medical team

in connection with the commercialization of our products. In Europe, Syneos provides us with medical science liaison personnel. 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 retain contract research organizations, or CROs, to support us with the conduct of our clinical trials from time to time. 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 $EGRIFTA\ SV^{\circledR}$ and $Trogarzo^{\circledR}$ in the United States, or of $Trogarzo^{\circledR}$ 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 $EGRIFTASV^{\circledR}$ and Trogarzo $^{\circledR}$ 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.

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 $EGRIFTA~SV^{\circledR}$ and Trogarzo $^{\circledR}$ 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 agreeing on a commercially attractive pricing with regulatory authorities and obtaining reimbursement for Trogarzo®. 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 or that we will be able to negotiate a pricing that will be commercially attractive to us in any of the EU Member States.

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 pricing and reimbursement status in any EU Member States.

Even though 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 $EGRIFTA\ SV^{\mathbb{R}}$ 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 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+ TechnologyTM 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 conduct of the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population will be costly and the Corporation has decided to secure additional resources, including finding a partner, prior to initiating such clinical trial, all of which will result in a postponement of the initiation of such trial. Although the Corporation has begun the search for a potential partner, there can be no assurance that a partner will be found or that a partnership agreement will be entered into on terms satisfactory to the Corporation. If a partner is not found, the Corporation will need to look for alternatives to secure additional resources but there can be no quarantee that the Corporation will secure such resources in an amount sufficient to initiate or complete its Phase 3 clinical trial. Moreover, the Corporation has no meaningful Phase 2 clinical data evaluating tesamorelin for the treatment of NASH in the general population and any result obtained from the conduct of one Phase 3 clinical trial will have to show substantial evidence that tesamorelin is safe and effective for the treatment of NASH in the general population. Finally, the Corporation's decision to design its Phase 3 clinical trial to meet the FDA's primary endpoints may prevent the Corporation from seeking approval of tesamorelin for the treatment of NASH in the general population from the EMA since the primary endpoint for this agency is different from that of the FDA. If the Corporation is unable to secure additional resources to initiate its Phase 3 clinical trial, or find alternatives to pursue this trial, the conduct of such trial could be cancelled. If the Corporation is unable to meet the endpoints of its Phase 3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. And, even if the Corporation meets the endpoints of Part 1 of the Phase 3 clinical trial and obtains a conditional approval letter from the FDA, the Corporation could lose such approval if Part 2 of the Phase 3 clinical trial is unable to show evidence on the resolution of certain clinical outcomes. If the conduct of the clinical trial is cancelled, or if the Corporation does not receive approval for tesamorelin for the treatment of NASH in the general population, its potential long-term revenues, growth and prospects will be materially adversely affected.

The Corporation held discussions with the FDA and the EMA to finalize its Phase 3 clinical trial design, which discussions concluded in July 2021. As a result of such discussions, the trial design will result in higher costs than what the Corporation had previously estimated. The Corporation has decided to postpone the initiation of its Phase

3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population until it can secure additional resources to execute its program and has initiated a search to find a partner for that purpose.

There can be no guarantee that the Corporation will be able to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH if it is unable to secure substantial additional resources, either from a financing, a partnership or other means that it could resort to. In addition, the Corporation may not be able to find a partner to help with securing additional resources. Even if the Corporation finds a partner, the terms and conditions pursuant to which such partner may be interested in assisting the Corporation may not be suitable to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the search of a partner and turn to alternative sources of financing. If the Corporation is unable to secure additional resources, it may further postpone the initiation of its Phase 3 clinical trial until it can secure additional resources, review and amend its current protocol to reduce the costs associated with the study of tesamorelin for the potential treatment of NASH, or may cancel its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. If the Corporation is unable to, or does not proceed with, the development of tesamorelin for the treatment of NASH in the general population, it could have a material adverse effect on its potential long-term revenues, growth and prospects.

Even if the Corporation secures additional resources to initiate its Phase 3 clinical trial, there can be no guarantee that the FDA will approve tesamorelin for the treatment of NASH in the general population since the FDA recommended the Corporation to conduct a Phase 2 clinical trial to generate data resulting from the use of tesamorelin in patients suffering from NASH and since the Corporation must meet the primary endpoints set forth by the FDA in its guidelines. Given the lack of Phase 2 data resulting from the use of tesamorelin in patients suffering from NASH, the data from the Phase 3 clinical trial will have to demonstrate substantial evidence of the safety and effectiveness of tesamorelin for the treatment of NASH in the general population. In addition, even if the Corporation meets the FDA's primary endpoints of the clinical trial and receives approval from the FDA, such approval will be conditional upon completing Part 2 of the Phase 3 clinical trial. If Part 2 of the Phase 3 clinical trial does not show positive evidence on certain clinical outcomes, the FDA could withdraw its approval on the use of tesamorelin for the treatment of NASH in the general population. Finally, if the Corporation is unable to show substantial evidence that tesamorelin is safe and effective for the treatment of NASH in the general population through the conduct of one Phase 3 clinical trial, the FDA could require the Corporation to conduct an additional study.

The Corporation has decided to design its Phase 3 clinical trial based on the FDA guidelines requiring it to demonstrate "NASH resolution and no worsening of fibrosis" as primary endpoints. This trial design does not follow the current EMA guidelines which require a sponsor to demonstrate both (i) NASH resolution and no worsening of fibrosis and (ii) improvement of fibrosis by one stage without worsening of NASH as primary endpoints. Therefore, even if the Corporation meets the primary endpoints for FDA purposes, the EMA may not approve tesamorelin for the treatment of NASH in this territory since the trial was not designed to demonstrate both endpoints.

If the Corporation is unable to obtain approval of tesamorelin for the treatment of NASH in the United States, this would have material adverse effects on its revenues, financial results and long-term growth and prospects. In addition, even if the FDA approves tesamorelin for the treatment of NASH, the lack of an approval in Europe will limit the Corporation's ability to maximize its revenue growth potential, therefore potentially hampering its long-term growth and prospects.

The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain since results obtained from preclinical in vivo development work may not translate into human subjects. The goal of the Phase 1 clinical trial evaluating TH1902 is to determine the MTD that can be administered to human subjects and determine if any adverse side effects will be observed from the injection of TH1902 in human subjects. If the Corporation is unable to demonstrate similar results as 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+ TechnologyTM 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 patient deaths.

TH1902 is being developed as a potential treatment for severe, various life-threatening cancers that express SORT1 receptor. The Phase 1 clinical trial is being conducted with patients that are more prone than healthy subjects to exhibit certain diseases or adverse events. Some of these patients face life-threatening situations and may die during our Phase 1 clinical trial. If patients have serious adverse side effects from the administration of TH1902, it may become difficult to discern whether certain events or symptoms observed in those 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 need to 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 continuation of the 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 associated with the Corporation's current 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+ TechnologyTM platform. The abandonment of the development of the Corporation's SORT1+ TechnologyTM platform would reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospec

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 other sources of financing, such as public offerings, private placements or the conclusion of partnerships. 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 or private 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, do not have access to public or private financing, or are unable to conclude partnerships 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 conduct of clinical trials is subject to a variety of risks, many of which can be beyond the control of the Corporation forcing it to delay the initiation or conduct of clinical trials or forego same.

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

- negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its 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 with the conduct of our clinical trials;
- inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials;
- challenges in recruiting and enrolling patients to participate in clinical trials, such as the proximity of patients to study sites, eligibility criteria to be included in a clinical trial, the nature of a clinical trial and the competition from other clinical study programs for the treatment of similar diseases as those the Corporation may seek to treat;
- severe or unexpected adverse drug effects experienced by patients;
- regulatory agencies requiring a sponsor to conduct additional clinical studies prior to approving a new drug application, a sBLA, or the equivalent thereof in other jurisdictions after review of Phase 3 clinical trial results;
- regulatory agencies may disagree with a sponsor's interpretation of data resulting from its Phase 3 clinical trials, or may change the requirements for approval even after they have approved the sponsor's Phase 3 clinical trial design; and
- difficulties in retaining patients who have enrolled in a sponsor'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.

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

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

If the Corporation incurs any delay in the conduct of a clinical trial or decides to suspend or terminate such trial, this could materially adversely affect the business prospects of the Corporation and its potential long-term revenues derived from the potential sale of its drug candidates. Any delay or suspension of a clinical trial may also adversely impact the duration of the protection afforded by the issuance of patents covering the drug candidate subject to such clinical trial and lead to earlier entries of competitors in the market.

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

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the original 1 mg/vial formulation of *EGRIFTA*®. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not yet filed an sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for the first half of calendar year 2022.

In addition, the Corporation has manufactured one process validation batch of the F8 Formulation only 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 original formulation.

If the FDA does not approve the F8 Formulation as being bioequivalent to the original 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 SV® or Trogarzo®.

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

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 $EGRIFTA\ SV^{\circledR}$ and $Trogarzo^{\circledR}$ 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.

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 SV^{\otimes} and Trogarzo $^{\otimes}$. 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, 2021. Our profitability will mainly depend on our capacity to maintain the commercialization of $EGRIFTA\ SV^{\circledR}$ and $Trogarzo^{\circledR}$ successfully in the United States and $Trogarzo^{\circledR}$ 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 $EGRIFTA\ SV^{\circledR}$ and $Trogarzo^{\circledR}$ under U.S. Medicare and Medicaid programs and under private-health insurers programs in the United States. The obtaining of reimbursement of $Trogarzo^{\circledR}$ 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. In addition, if our share price remains below the conversion price of the Notes, the Notes are unlikely to be converted and we will have to pay all accrued interest thereon and their principal on their maturity date (June 30, 2023).

As at November 30, 2021, we had negative operating cash flow of US\$14,477,000. 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 commercial, managerial and scientific personnel. We have entered into employment agreements with our executive officers and provided them, as well as to other key employees, with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers and other key employees 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 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 $SV^{\mathbb{R}}$ and $Trogarzo^{\mathbb{R}}$, 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, 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, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorisations and thus subject to future negotiations. 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 quidance, 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.

ITEM 4 DIRECTORS AND EXECUTIVE OFFICERS

4.1 <u>DIRECTORS</u>

The table below sets forth the following information about our directors as of February 23, 2022: his/her name, age, city/province/state of residence, principal occupation, the date 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, common share purchase warrants, or Warrants, 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.



Joseph P. Arena Age: 67 Norristown, Pennsylvania, USA

Independent

Director since: May 13, 2021

Areas of Expertise:

- Regulatory Affairs
- Drug Development
- Medical Education
- Management

Other Directorship: None

Principal Occupation

Corporate Director

Joseph Arena was elected to the Board of Directors of Theratechnologies in May 2021.

Joseph Arena was Vice President, Oncology Products, Global Regulatory Affairs at Pfizer, Inc. ("Pfizer") between 2018 and 2021. In such a role, he managed a team that provided strategic global leadership to Medicine Teams for Pfizer's portfolio in oncology. The group was responsible for regulatory strategy and registration of products globally. His tasks included providing guidance on the worldwide regulatory requirements for registration of new chemical entities and new claims, identification of pharmaceutical, toxicological and clinical developmental issues and problem resolution, overseeing the preparation of high quality, effective regulatory submissions, providing oversight and input for all communications agencies and leading scientific teams in direct negotiations with agencies on all issues of product development, product registration and labeling (including post-marketing surveillance).

Prior to acting as Vice President, Oncology Products, Global Regulatory Affairs, he acted as Vice President, Cardiovascular and Metabolic Products, between 2016 and 2018 when he joined the Pfizer Worldwide Safety and Regulatory organization. In such a role, he managed a team that provided strategic global leadership to Medicine Teams for Pfizer's portfolio in Cardiovascular and Metabolic Diseases. The group was responsible for regulatory strategy and registration of products globally.

Prior to joining Pfizer, he was at Merck and Co. Inc. ("Merck") where he held the role of Vice President, Therapeutic Area Lead Oncology, Immunology and in vitro Diagnostics from 2015 to 2016. His team provided global leadership to development teams for oncology and immunology products and in vitro diagnostics across the portfolio. The group was responsible for regulatory strategy and registration of Merck's products globally with a focus on the United States, European Union, China and Japan.

Mr. Arena began his career as a research scientist in 1989 at Merck Research Laboratories in Rahway, New Jersey. In 1996, he moved to a position in Regulatory Affairs International focusing primarily on Merck's cardiovascular products. He eventually assumed management and leadership roles with Regulatory Affairs International, including management of therapeutic areas in Diabetes, Neuroscience, Atherosclerosis and Cardiovascular.

Mr. Arena received his B.S. in Pharmacy from St. John's University in Queens, New York. After four (4) years in community and hospital settings, he attended the University of Medicine and Dentistry of New Jersey and received a Ph.D. in Pharmacology, followed by a post-doctoral fellowship in the Physiology Department at the University of Rochester in New York.

Securities Held or Controlled						
Common Shares DSU Options Warrants Notes						
(#)	(#)	(#)	(#)	(US\$)		
7,500	Nil	14,170	Nil	Nil		

Committees of the Board of Directors

Nil



Frank A. Holler Age: 65 Summerland, B.C., Canada

Independent

Director since:

June 23, 2021

Areas of Expertise:

- Corporate Finance
- Life Sciences
- Management

Other Directorship:

Sernova Corp.; and Harvest One Cannabis Inc.

Principal Occupation

President and CEO, Ponderosa Capital Inc.

Frank A. Holler was appointed to the Board of Directors in June 2021.

He is currently the President & CEO of Ponderosa Capital Inc. He previously served as Chairman & CEO of BC Advantage Funds (VCC) Ltd., a venture capital firm investing in emerging technology companies in British Columbia.

He also served as President and CEO of Xenon Pharmaceuticals Inc. from 1999 to 2003 after having been President and CEO of ID Biomedical Corporation from 1991 to 1998. In addition, he was a founding director of Angiotech Pharmaceuticals.

Prior to working in biotechnology and healthcare, Mr. Holler was a Vice-President of Investment Banking with Merrill Lynch Canada and Wood Gundy Inc. (now CIBC World Markets).

Mr. Holler is a member of the board of directors of two additional public companies: Sernova Corp. in Ontario, Canada, and Harvest One Cannabis Inc. in British Columbia, Canada.

Mr. Holler holds an MBA and BA (Economics) from the University of British Columbia.

Securities Held or Controlled

Common Shares	DSU	Options	Warrants	Notes
(#)	(#)	(#)	(#)	(US\$)
Nil	Nil	14,170	Nil	Nil

Committees of the Board of Directors

Member of Audit Committee



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 Autorité des marchés financiers) 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.

Gérald A. Lacoste Age: 78 Ste-Adèle, Québec, Canada

Independent

Director since: February 8, 2006

Areas of Expertise:

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

Other Directorship:

None

Securities Held or Controlled						
	Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)	
	100,000	21,936	84.174	Nil	45,000	

Committees of the Board of Directors

Chair of Nominating and Corporate Governance Committee Member of Audit Committee



Paul Lévesque Age: 58 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

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.

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.

He also assumed the role of Global President and General Manager for the Rare Disease Unit until he joined Theratechnologies on April 6, 2020.

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.

Paul holds a BSc in biochemistry from Laval University and a Diploma in Management from McGill University.

Securities Held or Controlled						
Common Shares DSU Options Warrants Notes						
(#)	(#)	(#)	(#)	(US\$)		
111,200	Nil	1,134,728	20,000	Nil		

Committees of the Board of Directors

N.A.



Gary Littlejohn Age: 66 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

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. He held the position of Interim CEO at Helix BioPharma from October 2015 to January 2016. 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.

Securities Held or Controlled						
Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)		
19,060	6,850	46,928	Nil	Nil		
Committees of the Board of Directors						

Chair of Compensation Committee Member of Audit Committee



Dale MacCandlish Weil Age: 66 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

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's in business administration from McGill University and has obtained her certification as a certified director after successfully completing the ICD Directors Education Program.

Securities Held or Controlled					
Common Shares DSU Options Warrants Notes					
(#)	(#)	(#)	(#)	(US\$)	
31,840	5,531	69,174	Nil	2,000	

Committees of the Board of Directors

Member of Nominating and Corporate Governance Committee



Andrew Molson Age: 54 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

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.

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. 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.

Mr. Molson holds a Bachelor of Laws from Laval University (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).

Securities Held or Controlled						
Common Shares	DSU	Options		Notes		
(#)	(#)	(#)	(#)	(US\$)		
30,000	Nil	27,428	Nil	Nil		

Committees of the Board of Directors

Nil



Dawn Svoronos Age: 68 Hudson, Québec, Canada

Director since: April 8, 2013

Independent

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 (#)	Warrants (#)	Notes (US\$)		
273,600	855	134,174	Nil	Nil		

Committees of the Board of Directors

Member of Compensation Committee

Member of Nominating and Corporate Governance Committee



Alain Trudeau Age: 62 Montréal, Québec, Canada

Independent

Director since: October 15, 2020

Areas of Expertise:

- Accounting
- Finance
- Governance

Other Directorship:

None

Principal Occupation Corporate Director

A fellow of the Quebec Chartered Professional Accountant 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.

He currently serves on the board of directors of the Montréal Inc. Foundation, the Institut de médiation et d'arbitrage du Québec (IMAQ) and Blue Bridge Trust Company Inc.

From 2008 to 2019, Mr. Trudeau was a lecturer at the Collège des administrateurs de sociétés de l'Université Laval in Quebec City.

Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal.

Securities Held or Controlled							
Common Shares	DSU	Options	Warrants	Notes			
(#)	(#)	(#)	(#)	(US\$)			
19,300	14,131	27,428	2,500	Nil			

Committees of the Board of Directors

Chair of Audit Committee Member of Compensation Committee

4.2 <u>AUDIT COMMITTEE</u>

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, 2021, the Audit Committee was composed of four members: Alain Trudeau, its Chair, Gary Littlejohn, Gérald A. Lacoste and Frank Holler. 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.

Alain Trudeau. Mr. Trudeau holds a Bachelor of Arts in Accounting from HEC Montréal and is a fellow of the Quebec CPA order. 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.

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 and Chief Financial Officer 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.

Frank Holler. Mr. Holler holds an MBA and BA (Economics) from the University of British Columbia. Prior to joining the Corporation, Mr. Holler was President and CEO of Xenon Pharmaceuticals Inc. from 1999 to 2003 after having been President and CEO of ID Biomedical Corporation from 1991 to 1998. In addition, he was a founding director of Angiotech Pharmaceuticals. Mr. Holler also acted as Vice-President of Investment Banking with Merrill Lynch Canada and Wood Gundy Inc. (now CIBC World Markets).

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 23, 2022: his/her name, age, city/province/state of residence, his/her principal occupation, the date each Executive Officer joined the Corporation, his/her biography and the number of common shares (the only voting securities of the Corporation), DSUs, options, Warrants 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.



Principal Occupation Vice President, Finance

Ms. Marie-Noël Colussi is a graduate of the *Université du Québec à Montréal* in business administration and is a member of the Quebec Chartered Professional Accountant Order. Prior to joining us, Ms. Colussi worked for eight years with KPMG, an international 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, she held the position of Director, Accounting and Internal Control and Controller.

	Securities Held or Controlled					
Marie-Noël Colussi	Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)	
Age: 53	11,075	3,182	238,092	Nil	10,000	
Executive since:						
May 9, 2002						
Laval, Québec, Canada						



Philippe Dubuc Age: 55

Executive since: February 24, 2016

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	Warrants	Notes	
	(#)	(#)	(#)	(#)	(US\$)	
	31,000	Nil	558,414	1,500	25,000	
6						
,						



André Dupras Age: 58

Executive since: May 31, 2021

Mont-Tremblant, Québec, Canada

Principal Occupation

Vice President, Human Resources

Mr. André Dupras joined Theratechnologies as Vice President, Human Resources in May 2021.

Mr. Dupras brings more than 25 years of experience in Human Resources. Most recently, Mr. Dupras was Vice President, Human Resources at Clementia Pharmaceuticals. Previously, he spent close to 15 years at Pfizer Canada in various leadership roles in Human Resources and Commercialization. He also worked at Bombardier Aerospace as Director of Human Resources and Director of Global Compensation, at Aon Hewitt as a consultant in Compensation and Organizational Effectiveness and at Réno-Dépôt as Director of Human Resources.

Mr. Dupras holds a Master's Degree in Management Science (Human Resources) and a Bachelor's Degree in Administration (Marketing and Human Resources). He is a member of the Order of Certified Human Resources Professionals (CHRP, CHRA).

	Securities Held or Controlled				
Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)	
Nil	Nil	141,404	Nil	Nil	



Jocelyn Lafond Age: 54

Executive since: April 16, 2007

Montreal, Québec, Canada

Principal Occupation

General Counsel 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 *Université Laval* and a Masters Degree in Law from the University of Toronto. He has been a member of the *Barreau du Québec* since 1992. Prior to joining us in 2007, Mr. Lafond was a partner with the international law firm of Fasken Martineau DuMoulin LLP.

	Securities Held or C	ontrolled		
Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)
18,000	5,000	434,857	Nil	8,000



John Leasure Age: 57

Executive since: March 29, 2021

Underhill, Vermont, USA

Principal Occupation

Global Commercial Officer

John Leasure was hired as Global Commercial Officer in March 2021. He brings extensive experience in Sales, Marketing, Operations and General Management both in the U.S and internationally. He has expertise managing brands across multiple stages of the product life cycle and has launched numerous products in a variety of therapeutic areas.

Prior to joining Theratechnologies, John spent 30 years at Pfizer where he led teams in Anti-infectives, Inflammation, Immunology and Oncology. Most recently, John led the Oncology business in Canada where, under his leadership, the business experienced unprecedented growth and launched over 10 new products.

He holds a B.A., Business from Gettysburg College in Pennsylvania.

	Securities Held or C	ontrolled		
Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)
5,000	Nil	154,848	Nil	Nil



Christian Marsolais Age: 59

Executive since: May 7, 2007

Town of Mount Royal, Québec, Canada

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 *EGRIFTA*® 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 Con	itrolled		
Common Shares	DSU	Options	Warrants	Notes
(#)	(#)	(#)	(#)	(US\$)
59,297	6,312	680,373	Nil	15,000



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.

Conor Walshe
Age: 48
Executive since: March 19, 2019
Rathmines, Ireland

	Securities Held or Co	ntrolled		
Common Shares	DSU	Options	Warrants	Notes
(#)	(#)	(#)	(#)	(US\$)
Nil	Nil	223,333	Nil	Nil

4.4 CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS

To our knowledge, except with respect to Mr. Frank Holler, no director and executive officer (a) is, as at February 23, 2022, or has been within the ten (10) years before February 23, 2022, 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 23, 2022, 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.

Mr. Frank Holler was previously the Chair and the Chief Executive Officer of BC Advantage Funds, or BCAF, a venture capital fund investing in emerging technology companies. On July 5, 2013, Allon Therapeutics Inc., or Allon, one of BCAF's publicly traded portfolio companies in which Mr. Holler acted as a director, made a proposal to its creditors under the *Bankruptcy and Insolvency Act* (Canada) and a reorganization of its share structure was approved by the Supreme Court of British Columbia. Following this approval, all of Allon's common shares were acquired by a third party and Allon's common shares were delisted from the Toronto Stock Exchange on June 28, 2013. Mr. Holler ceased acting as a director of Allon effective July 16, 2013.

Mr. Frank Holler was also a director of Contech Enterprises Inc., or Contech, one of the privately held emerging technology companies forming part of the BCAF portfolio. On December 23, 2013, Contech made a proposal to its creditors under the *Bankruptcy and Insolvency Act* (Canada) and a reorganization of its share structure was approved by the Supreme Court of British Columbia on January 26, 2015. The proposal was intended to facilitate a financing by a new lender and a debt restructuring that, taken together, would enable Contech to carry on its business for the foreseeable future. On March 6, 2015, the Court of Appeal of British Columbia overturned the approval of the proposal by the Supreme Court and placed Contech into bankruptcy. Mr. Holler ceased acting as a director of Contech effective March 6, 2015.

4.5 <u>SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS</u>

As at February 23, 2022, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 716,872, which represented 0.75% of our outstanding common shares.

ITEM 5 INTERESTS OF EXPERTS

KPMG LLP, our auditors, is the only person or company named as having prepared or certified a statement, report or evaluation, included or mentioned in a filing under securities regulations during our most recently completed financial year.

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

External Auditors Service Fees

KPMG LLP have been acting as our auditors since 1993. In addition to performing the audit of our consolidated financial statements, KPMG LLP provided other services to us that were billed or payable in respect of each of our fiscal years ended November 30, 2021 and 2020:

Fees	Fiscal Year Ended November 30, 2021 (CA\$)	Fiscal Year Ended November 30, 2020 (CA\$)
Audit Fees(1)	639,382	497,667
Audit-Related Fees(2)	48,943	89,175
Tax Fees(3)	170,027	54,563
Total:	858,352	641,405

- (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.
- (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.

ITEM 6 SECURITIES OF THE COMPANY

6.1 <u>AUTHORIZED SHARE CAPITAL</u>

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 <u>DIVIDEND POLICY</u>

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.

	TSX		NASDAQ			
Period(1)	High (CA\$)	Low (CA\$)	Volume	High (US\$)	Low (US\$)	Volume
2020						
December	3.23	2.68	1,780,000	2.54	2.09	2,810,000
2021						
January	4.16	2.72	4,910,000	3.25	2.13	7,880,000
February	4.13	2.82	6,660,000	3.25	2.20	25,200,000
March	4.98	3.67	3,670,000	3.99	2.92	7,490,000
April	5.34	4.18	1,590,000	4.25	3.35	3,670,000
May	4.60	4.02	775,359	3.82	3.27	2,140,000
June	4.83	4.18	744,182	3.95	3.4834	1,950,000
July	4.85	4.12	1,220,000	3.9599	3.2181	3,730,000
August	4.60	4.00	721,528	3.68	3.18	2,930,000
September	5.61	4.45	905,298	4.46	3.46	5,130,000
October	4.79	4.24	399,290	3.79	3.36	1,890,000
November	4.62	4.01	766,060	3.65	3.16	2,160,000
December	4.30	3.77	604,435	3.37	2.90	2,460,000
2022						
January	3.95	3.47	683,135	3.10	2.77	2,070,000
February (to February 22)	4.14	3.61	313,887	3.26	2.85	1,260,000

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

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.

		5.75% Debentures(1)		
Period(2)	High (US\$)	Low (US\$)	Volume	
2020				
December	75.00	61.10	223,000	
2021				
January	83.00	80.00	52,000	
February	89.00	80.00	175,000	
March	91.00	82.00	338,000	
April	90.50	82.00	165,000	
May	91.00	88.00	344,000	
June	91.00	87.50	11,000	
July	92.00	91.00	221,000	
August	96.00	91.00	48,000	
September	92.00	88.00	91,000	
October	91.50	87.50	55,000	
November	91.75	87.50	51,000	
December	92.00	88.50	63,000	
2022				
January	88.50	85.10	43,000	
February (to February 22)	85.00	85.00	19,000	

⁽¹⁾ Price per US\$100.00 principal amount of the 5.75% Notes.

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
January 19, 2021	Warrants(1)	US\$3.18	8,363,950
February 26, 2021	Stock Options	CA\$3.93	1,019,331
February 26, 2021	Stock Options	US\$3.10	81,093
February 26, 2021	Deferred Stock Units(2)	CA\$3.89	5,784
July 27, 2021	Stock Options	US\$3.48	21,515
July 27, 2021	Stock Options	CA\$4.32	38,500
July 27, 2021	Deferred Stock Units	CA\$4.38	10,275
October 15, 2021	Deferred Stock Units	CA\$4.38	6,850

⁽²⁾ High and low price based on intraday high and low trading prices. Sources for data in the above table is Bloomberg.

- (1) The Warrants were issued on January 19, 2021 and formed part of units issued by way of prospectus. Each unit was comprised of one common share and one-half of one common share purchase warrant, each whole warrant entitling the holder thereof to purchase one common share at a price of US\$3.18 at any time until January 19, 2024.
- (2) 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 material legal proceedings and, as at February 23, 2022, we are not subject to any such material 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 $SV^{\textcircled{\tiny{18}}}$ 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 Loxxes 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 $EGRIFTA SV^{\otimes}$ ($EGRIFTA^{\otimes}$ 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 gensral population. The agreement provides for 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 Licence Agreement is scheduled to expire on the latest of (i) February 2039, and (ii) the date of expiry of the last patents to be issued under the agreement or of any of the patents related to any improvements made under the licensed technology, unless earlier terminated pursuant to certain customary termination provisions.

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, 2021.

Additional information regarding our Company is available on SEDAR at www.sedar.com, or upon written request addressed to Jocelyn Lafond, General Counsel 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.

AUDIT COMMITTEE CHARTER

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. <u>Obligations and Duties</u>

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 significant or 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 forward-looking information and use of non-GAAP financial measures).
- 4. Review and discuss reports from the external auditor on:
 - a. all critical accounting policies and practices used by the Company;
 - 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 auditor's report to the Committee on the planning of external auditing; and
 - d. the external auditor's 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.
- 4. 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.
- 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. Authorize the Chair of the Committee to pre-approve all engagements for permitted non-audit services provided by the external auditor to the Company and any consolidated subsidiary where such engagements have not been pre-approved by the Committee as set forth above under paragraph 4; *provided*, *however*, that the upper limit of the amount of such approval shall be determined annually by the Committee; and *provided*, *further*, that the Chair reports any approval to the Committee at the next meeting of the Committee following the date on which the approval was given by the Chair.
 - 6. 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.
- 7. 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.
- 8. Resolve any disagreement between management and the external auditor regarding financial reporting.
- 9. Review the audit process with the external auditor.
- 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. <u>External Advisors</u>

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. <u>Composition of the Committee</u>

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. <u>Term of the Mandate</u>

Committee members are appointed by Board resolution to carry out their mandate extending from the date of the appointment to the next annual general meeting of the shareholders or until their successors are so appointed.

VI. <u>Vacancy</u>

The Board may fill vacancies at any time by resolution. Subject to the constitution of the quorum, the Committee's members can continue to act even if there is one or many vacancies on the Committee.

VII. Chair

The Board appoints the Committee Chair who will call and chair the meetings. The Chair reports to the Board the deliberations of the Committee and its recommendations.

VIII. <u>Secretary</u>

Unless otherwise determined by resolution of the Board, the Secretary of the Company shall act as Committee Secretary. The Secretary must attend Committee meetings and prepare the minutes. He/she must provide notification of meetings as directed by the Committee Chair. The Secretary is the guardian of the Committee's records, books and archives.

IX. <u>Meeting Proceedings</u>

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 Chair, 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, as and when applicable, 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. <u>Annual Review</u>

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

XIII. <u>Effective Date</u>

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, August 7, 2019 and May 13, 2021 Board meetings.



MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEAR ENDED NOVEMBER 30, 2021

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 year ended November 30, 2021, or Fiscal 2021, compared to the year ended November 30, 2020, or Fiscal 2020. 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 23, 2022, was approved by our Board of Directors on February 23, 2022 and should be read in conjunction with our audited annual consolidated financial statements and the notes thereto as at November 30, 2021, 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 with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB).

The Company's functional and presentation currency is the United States dollar (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® and 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 (NASH) in the general population and in people living with HIV.

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:

- 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 pricing and reimbursement conditions of other competing drugs or therapies that are or may become available;
- our ability to protect and maintain our intellectual property rights in tesamorelin;
- our success in obtaining commercially attractive pricing and 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 the intravenous push, or IV Push, mode of administration of Trogarzo® by the United States Food and Drug Administration, or FDA:
- the approval of a new formulation of tesamorelin, or F8 Formulation by the FDA;
- our capacity to develop a multi-dose pen injector, or Pen, for use with the F8 Formulation;
- the approval of our amended protocol by the FDA regarding our planned Phase 3 trial in NASH using tesamorelin;
- our capacity to finance or finding a partner to conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- our capacity to pursue the conduct of our Phase 1 clinical trial using our TH1902 PDC in various types of cancers;
- our capacity to enter into a partnership agreement with a third party regarding our TH1902 PDC for Greater China;
- our capacity to pursue the development of our other PDCs 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, including our commercial regular practice associated with the sale of our products;
- 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 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 SV® and Trogarzo® will not change their respective current safety profile;
- no recall or market withdrawal of 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 SV® and Trogarzo® will be available;
- our relations with third-party suppliers of *EGRIFTA SV®* and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *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 integration of U.S. employees into our U.S. subsidiary will not be disruptive to our business and will strengthen our commercial capabilities in the United States;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- we will succeed in developing the Pen or any other device for use with the F8 Formulation and the FDA will approve
 the use of such device for the F8 Formulation;
- we will have the financial means or will find a partner to conduct a Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our current Phase 3 trial protocol evaluating the use tesamorelin for the
 potential 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;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate strong efficacy results;
- we will succeed in entering into a partnership agreement with a third party for TH1902 in Greater China;
- 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 subsequent to 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 a promising pipeline of investigational medicines in oncology and NASH and two approved medicines ($EGRIFTA\ SV^{(g)}$) and Trogarzo (for people living with HIV. The Company has a sales and marketing infrastructure to commercialize its products in the U.S. and Europe. We continue to assess the market for potential product acquisitions or in-licensing transactions that would be complementary to our business and further drive future sustainable growth and value creation.

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 in Italy, and the Company expects to launch Trogarzo® in key additional European countries later 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, Trogarzo® was approved in Israel in January 2022 and is now commercially available.

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.

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The Company's commercial product strategy for the 2022 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 additional European countries and launch Trogarzo® in those key European countries.

IMPACT OF THE COVID-19 PANDEMIC

In Fiscal 2021, 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 Fiscal 2021, we continued to offer virtual interactions 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. While these efforts have helped support our goal to increase U.S. sales of Trogarzo® and EGRIFTA SV® new rounds of closures related to the Omicron variant of the virus have slowed some of these initiatives. 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.

To date, our on-going Phase 1 clinical trial of TH1902 for the treatment of various cancers and preparations for 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 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 $EGRIFTA\ SV^{\circledR}$. 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 $EGRIFTA\ SV^{\circledR}$, the F8 Formulation is stable at room temperature, even once reconstituted. We intend to file a sBLA with the FDA to seek approval of the bioequivalence of the F8 Formulation in the first half of calendar 2022 for the treatment of lipodystrophy in people living with HIV.

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 issued two U.S. patents to Massachusetts General Hospital, or MGH, relating to the treatment of hepatic disease using growth hormone related hormone, or GHRH, or analogues thereof which are scheduled to expire in 2040. We have an exclusive worldwide license with MGH for these patents.

The Company is currently working on the development of the Pen to be used in conjunction with the F8 Formulation. To date, its development is not completed, and we

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are still working on the Pen. As a result, no timeline has been set for the filing of an sBLA with the FDA in relation to the Pen.

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 (TGFß1) 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, we filed an Investigational New Drug Application, or IND, with the FDA for a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH and we received a "Study May Proceed" letter for such Phase 3 clinical trial from the FDA in December 2020. The letter contained a recommendation that the Corporation request 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 followed up on the FDA's recommendation and requested a meeting with the agency. On July 15, 2021, we announced that we had completed discussions with the FDA following an end of Phase 2 meeting and with the EMA following a scientific advice meeting regarding the Phase 3 clinical trial in NASH.

The finalized Phase 3 trial design is planned for a multicenter, randomized, double-blind, placebo-controlled two-part study designed to evaluate the safety and efficacy of tesamorelin in liver-biopsy confirmed patients with NAS score of at least 4 and stage 2 or 3 fibrosis. Part 1 of the study will include a total of approximately 1,100 patients (1:1, tesamorelin:placebo), including approximately 75 to 100 people living with HIV. A second liver biopsy will be performed after the first approximately 1,100 participants have completed 18 months of treatment. This should form the basis for filing an sBLA with the FDA. The clinical trial will also include a futility analysis that would be conducted after the first approximately 400 patients have completed 18 months of treatment and have received a second liver biopsy. The futility analysis will provide a perfunctory review indicating if an early treatment effect with tesamorelin has been observed and will determine if the study should proceed as planned. Following a potential sBLA approval, Part 2 of the trial will continue to enroll an additional approximately 1,800 patients (3:1, tesamorelin:placebo) to continue to measure clinical outcomes over a period of five years. A total of approximately 2,900 patients are expected to be enrolled.

On July 15, 2021, we also announced that the final Phase 3 clinical trial design would result in higher costs than what we had expected and, as a result, we were assessing our options to best execute this program, including seeking a potential partner. An external

U.S.-based biopharma advisory firm was retained for that purpose. To date, we are still continuing to seek a partner and to assess additional options, such as certain forms of financing.

In order to further de-risk the Phase 3 trial, the Company intends to submit an amended protocol to the FDA. The new protocol will include a Phase 2b/3 seamless study design where the first 350 or so patients' data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. A decision will then be made whether to continue the study until full number of patients (1,094) have completed 18 months of treatment. This does not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH.

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.

The Company has retained the services of a 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.

The Company is also conducting a study titled Visceral Adiposity Measurement and Observation Study, or VAMOS, to reflect our commitment to improve the health outcomes of people living with HIV. VAMOS is an epidemiologic cross-sectional study to answer the unknown associations between visceral fat and cardiovascular disease risk, liver fat, liver fibrosis, pericardial fat, and muscle fat in today's HIV patient. These associations will be measured across a diversity of weights, BMIs, genders, and races so that the impact of visceral fat can be understood with external validity to the results. Additionally, the performance of anthropometric measurements like waist circumference (WC) and hip circumference (HC) will be assessed in a modern HIV population. The aims of this study are two-fold: (1) To determine the utility of WC's ability to predict cardiovascular risk scores, liver fat, liver fibrosis, and abnormal glucose homeostasis across the full VAMOS population and subgroups (2) Identify common clinical data points in today's standard of care that can be used to assess a patient's risk of having excess visceral fat. The VAMOS results is expected to direct clinicians on why and which patients in their practice should be screened for excess visceral fat and treatment.

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 2022.

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.

In March 2021, a Phase 1 clinical trial was initiated evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design includes a Part 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.

The Corporation's Phase 1 study evaluating its novel investigational proprietary PDC TH1902 for the treatment of sortilin positive cancers is progressing as planned. The Company is in the final stages of a Phase 1/Part A dose escalation study evaluating its lead investigational peptide-drug conjugate (PDC) TH1902 for the treatment of sortilin-positive cancers. As previously mentioned, we are currently evaluating patients in order to establish the safety of TH1902 as well as establish the maximum tolerated dose (MTD). As per study protocol, the MTD is established once a significant adverse event is observed in two or more patients. In total, 4 patients in the trial have been administered significant doses of TH1902 at 420 mg/m² doses of TH1902, equivalent to nearly two times the indicated therapeutic dose of docetaxel. To date, Theratechnologies has observed a dose limiting toxicity (DLT) (grade 4 neutropenia lasting more than 7 days) in one patient, as well as other adverse events after more than one cycle at 420 mg/m². As a result, we have decided to pursue the study at a lower dose of 300 mg/m² (or approximately 1.5 times the usual dose of docetaxel). We currently are enrolling patients at the 300 mg/m² dose to confirm the absence of DLTs following the first cycle. Once MTD has been established, the study protocol allows for immediate initiation of enrollment of a larger open label basket trial. The basket trial will further assess the safety and tolerability of TH1902. The preliminary anti-tumor activity of TH1902 will be evaluated for all patients as per the response evaluation criteria in solid tumors. Based on additional research we have conducted on the Sortilin receptor, we have

submitted an amendment to the Phase 1 protocol to the FDA to include the following solid tumor types: Hormone Receptor-Positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, Melanoma (10 patients per tumor type). In addition, one arm will be added to include Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers (15 patients in total). The original trial design consisted of 40 patients across a selection of solid tumors, including colorectal and pancreatic cancers. The plan is now to enroll a total of approximately 70 patients in the basket trial to evaluate the potential anti-tumor activity of TH1902.

We are exploring the possibility of out-licensing development and commercialization rights for TH1902 in Greater China. We are pleased to report that there has been solid interest on the part of Chinese companies, and that discussions are ongoing with a number of different pharmaceutical and biotech companies.

Ibalizumab for HIV

An sBLA was filed with the FDA in the fourth quarter of 2021 for the Company's Intravenous (IV) Push method of administration of Trogarzo® for the treatment of human immunodeficiency virus type 1, or HIV-1. The FDA has accepted our filing and has provided a target action date of October 3, 2022 in accordance with the Prescription Drug User Fee Act (PDUFA).

Theratechnologies and TaiMed are also evaluating an intramuscular (IM) method of administration for Trogarzo® within the TMB-302 study. Patient screening for the IM study is in progress and we expect completion in the second half of 2022.

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 Company has initiated enrolment in this post-authorization study evaluating the real-world long-term efficacy and durability of Trogarzo® in combination with other antiretrovirals in Europe. The study, named Prospective and Retrospective, Observational Multicenter Ibalizumab Study of Efficacy (PROMISE). We are also conducting a similar trial in the United States, (PROMISE-US). PROMISE-US is a Prospective and Retrospective Observational study of Multidrugresistant patient outcomes with and without Ibalizumab in a real-world SEtting. We intend to use the PROMISE-US data as part of the PROMISE trial.

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 latter part of 2022.

JANUARY 2021 OFFERING Use of Proceeds

In its prospectus supplement dated January 13, 2021 relating to the January 2021 offering, the Company indicated that it intended to use the net proceeds from such offering primarily to fund research and development activities, commercialization initiatives, general and administrative expenses, working capital needs and other general corporate purposes. More specifically, out of net proceeds of the offering then estimated to be \$42,500,000, an amount of \$30,500,000 was earmarked for the NASH Phase 3 clinical trial and \$7,000,000 for oncology research and development (including the TH1902 Phase 1 clinical trial), with the remainder left for commercial and marketing activities and other uses.

In the months following the January 2021 offering, the Company was able to complete its discussions with the FDA and the EMA regarding the design and protocol for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH. As part of its announcement on July 15, 2021 regarding the finalization of the trial design, the Company also announced that the changes made to the design pursuant to the discussions held with the FDA and the EMA would result in higher costs than previously estimated, and that the Company was evaluating its options to best execute its late-stage development program for tesamorelin, including seeking a potential partner. As a result of the delay in the initiation of the NASH Phase 3 clinical trial, the funds raised in the January 2021 offering earmarked for such trial have been added to the Company's available cash balance. The Company's ability to execute its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH will be dependent on its ability to secure additional financial resources.

The following table shows the estimated use of proceeds, compared with the actual use of proceeds as at November 30, 2021:

In millions	Estimated Use of Proceeds	Actual Use of Proceeds	Variance
Nash Phase 3 clinical trial	\$30.5	\$2.4	\$(28.1)
Oncology R&D	7.0	\$ 2.9	(4.1)
Commercial and marketing activities	3.5		(3.5)
Other	1.5		(1.5)
Net Proceeds	\$42.5	\$5.3	\$(37.2)

As at November 30, 2021, approximately \$2,418,000 had been used in connection with the NASH Phase 3 clinical trial.

As at November 30, 2021, approximately \$2,886,000 had been used in connection with oncology research and development activities and the variance between the amount reserved and the amount used as at November 30, 2021 represents funds held in cash pending their planned allocation as costs are incurred.

Finally, the Company has not implemented new initiatives in terms of commercial and marketing activities, such that the funds earmarked for such use have been added to the Company's working capital.

2022 BUSINESS STRATEGY AND OBJECTIVES

Our 2022 Business Strategies and Objectives are as follows:

- Continue to grow sales of *EGRIFTA SV®* in North America and Trogarzo® in the United States and in the European Countries where it has obtained reimbursement:
- Seek commercially attractive pricing and reimbursement of Trogarzo® in additional countries of the European Union, including France, Spain and the United Kingdom and launch Trogarzo® therein;

10

- Launch the F8 Formulation of tesamorelin and the IV Push mode of administration of ibalizumab in the U.S.;
- Initiate Part B of our Phase 1 clinical trial studying TH1902 in various types of cancer;
- Begin a Phase 3 clinical trial using tesamorelin for the potential treatment of NASH in the general population after having secured additional financing or having found a partner;
- Pursue potential product acquisitions and in-licensing transactions or other similar opportunities complementary to our business;,
- Seek potential partners for our licensed SORT1+ TechnologyTM platform in countries where we do not intend to develop and conduct clinical trials;
- We plan on retaining and attracting a pool of diverse talents at all levels to participate and contribute to the successful
 execution of our business strategy and objectives; and
- Manage our financial position to ensure we can successfully execute on our 2022 business strategy and objectives.

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Fourth-Quarter and Fiscal 2021 Revenue Highlights						
(in thousands of dollars)	Three-month periods ended November 30,		% Years ended change November 30,			% change
	<u>2021</u>	<u>2020</u>		<u>2021</u>	<u>2020</u>	
EGRIFTA®, EGRIFTA SV® net sales	12,753	10,751	18.6%	43,009	35,399	21.5%
Trogarzo® net sales	6,001	8,372	-28.3%	26,814	30,654	-12.5%
Revenue	\$18,754	\$19,123	-1.9%	\$69,823	\$66,053	5.7%

Fourth-Quarter Fiscal 2021 Financial Results

Revenue

Consolidated revenue for the three months ended November 30, 2021 amounted to \$18,754,000 compared to \$19,123,000 for the same period last year, representing a decrease of 1.9%.

For the fourth quarter of Fiscal 2021, sales of *EGRIFTA SV*[®] reached \$12,753,000 compared to \$10,751,000 in the fourth quarter of the prior year, representing an increase of 18.6%. Strong sales of *EGRIFTA SV*[®] were mostly the result a higher selling price and lower government rebates and chargebacks.

In the fourth quarter of Fiscal 2021, Trogarzo® sales amounted to \$6,001,000 compared to \$8,372,000 for the same quarter of 2020, representing a decrease of 28.3%. During the fourth quarter of Fiscal 2021, Trogarzo® net sales were impacted by a provision related to greater than anticipated clawbacks on units sold in France prior to finalization of reimbursement terms, pursuant to temporary use authorizations ("ATU" and "AAP"). Negotiations are still ongoing with the Economic Committee for Health Products ("CEPS") to finalize pricing and reimbursement terms in France. Sales were also affected by lower unit sales as a result of lower patient access to hospitals and clinics because of COVID-19 and the impact of a new competitor.

Cost of Sales

For the three-month period ended November 30, 2021, cost of sales was \$6,411,000 compared to \$6,650,000 in the comparable period of Fiscal 2020. Cost of goods sold were stable at \$5,191,000 compared to \$5,190,000 for the same period last year.

Cost of sales included an amortization of \$1,220,000 in the fourth quarter of 2021 and 2020 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, 2021 amounted to \$8,678,000 compared to \$6,795,000 in the comparable period of Fiscal 2020. The

increase during the fourth quarter of Fiscal 2020 was largely due to the development of our oncology platform, including the Phase 1 trial for TH1902, 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.

Out of the foregoing R&D expenses, expenses relating specifically to the Company's program evaluating TH1902 for the treatment of sortilin-positive cancers (currently in Phase 1) reached approximately \$782,000 in the three-month period ended November 30, 2021, and those relating to its program evaluating tesamorelin for the treatment of NASH (currently at Phase 3 preparation stage) totaled \$460,000 for the same period. As explained previously, the Phase 1 study involving TH1902 is progressing as planned, while the initiation of the Phase 3 clinical trial for tesamorelin has been delayed pending assessment of our options to best execute this program, including seeking additional resources or potential partnership.

Selling Expenses

Selling expenses in the three-month period ended November 30, 2021 amounted to \$8,193,000 compared to \$6,532,000 in the comparable period of Fiscal 2020.

The increase in selling expenses is largely associated with the addition of senior personnel in North America to build a stronger sales organization, as well as increased activities in Europe ahead of the launch of Trogarzo in key markets.

General and Administrative Expenses

General and administrative expenses in the fourth quarter of Fiscal 2021 amounted to \$3,537,000, compared to \$3,255,000 reported in the same period of Fiscal 2020. The increased is due to an overall increase in activity to reflect the growth of our business.

Net Finance Costs

Net finance costs for the three-month period ended November 30, 2021 were \$1,817,000 compared to \$1,424,000 in the same period last year.

Adjusted EBITDA1

Adjusted EBITDA for the fourth quarter of Fiscal 2021 was \$(5,501,000) compared to \$(1,417,000) in same period of Fiscal 2020.

The increase in Adjusted EBITDA loss from Q4 2020 to Q4 2021 was mainly due to higher selling expenses and increased spending on research and development activities in the fourth quarter of 2021.

Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$9,901,000, or \$0.10 per share, in the fourth quarter of Fiscal 2021 compared to a net loss of \$5,549,000, or \$0.07 per share, in the fourth quarter of Fiscal 2020.

 $^{^1}$ Adjusted EBITDA is a Non-GAAP Financial Measure. See the "Non-IFRS Financial Measures" section of the MD&A for a description of the composition and reconciliation of this measure.

Quarterly Financial Information

The following table is a summary of our unaudited consolidated operating results for the last 8 quarters of Fiscal 2021 and Fiscal 2020.

(in thousands of dollars, except per share amounts)

	2021			2020				
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Revenue	18,754	17,852	17,787	15,430	19,123	14,049	17,162	15,719
Operating expenses								
Cost of sales								
Cost of goods sold	5,191	4,283	4,714	4,190	5,190	4,611	5,769	5,400
Other production-related costs	-	-	-	-	240	280	391	140
Amortization of other asset	1,220	1,221	1,220	1,221	1,220	1,220	1,220	1,221
R&D	8,678	8,296	6,417	4,883	6,795	4,183	3,622	3,419
Selling	8,193	7,657	6,901	6,158	6,532	7,025	6,941	6,361
General and administrative	3,537	3,633	3,884	3,562	3,255	2,699	3,706	2,570
Total operating expenses	26,819	25,090	23,136	20,014	23,232	20,018	21,649	19,111
Net finance costs	(1,817)	(2,254)	(1,023)	(1,332)	(1,424)	(799)	(1,319)	(1,152)
Income taxes	(19)	(18)	(20)	(6)	(16)	-	-	-
Net loss	(9,901)	(9,510)	(6,392)	(5,922)	(5,549)	(6,768)	(5,806)	(4,544)
Basic and diluted loss per share	(0.10)	(0.10)	(0.07)	(0.07)	(0.07)	(0.09)	(0.08)	(0.06)

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 2021 were associated with the development of our product pipeline.

Fiscal Year 2021 Financial Results

Revenue

Consolidated revenue for Fiscal 2021 was \$69,823,000 compared to \$66,053,000 for the same period last year, representing an increase of 5.7%.

For Fiscal 2021, sales of *EGRIFTA SV®* reached \$43,009,000 compared to \$35,399,000 for the same period last year (which also included sales of *EGRIFTA®*) representing growth of 21.5%. Strong sales of *EGRIFTA SV®* were mostly the result a higher number of units sold compared to the previous year, as well as higher selling price and lower government rebates and chargebacks. In addition, COVID-19 had a lesser impact on new prescriptions in Fiscal 2021 compared to Fiscal 2020.

In Fiscal 2021, Trogarzo® sales were \$26,814,000 compared to \$30,654,000 last year. During Fiscal 2021, Trogarzo® net sales were impacted by a provision taken in the fourth quarter related to greater than anticipated clawbacks on units sold in France prior to finalization of reimbursement terms, pursuant to temporary use authorizations ("ATU" and "AAP"). Negotiations are still ongoing with the Economic Committee for Health Products ("CEPS") to finalize pricing and reimbursement terms in France. Sales were also affected by lower unit sales as a result of lower patient access to hospitals and clinics because of COVID-19 and the impact of a new competitor.

Cost of Sales

For Fiscal 2021, cost of sales was \$23,260,000 compared to \$26,902,000 in the comparable period of Fiscal 2020. Cost of sales included cost of goods sold that amounted to \$18,378,000 in Fiscal 2021 compared to \$20,970,000 in Fiscal 2020. The decrease in cost of goods sold was mainly due to a higher proportion of $EGRIFTA\ SV^{\circledR}$ sales, which carry lower cost of goods sold, and a lower transfer price for Trogarzo $^{\circledR}$ since the fourth quarter of Fiscal 2020 given the achievement of a predetermined amount of net sales of the product on the U.S. market. In addition, cost of sales in Fiscal 2020 included other production-related costs of \$1,051,000 compared to nil in 2021.

R&D Expenses

R&D expenses were \$28,274,000 for Fiscal 2021 compared to \$18,019,000 for Fiscal 2020. The increase in R&D expenses was largely due to the development of our oncology platform, including the Phase 1 study, spending on the development of the F8 formulation and multi-dose pen injector, costs associated to the preparation Phase 3 trial 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.

Out of the foregoing R&D expenses, expenses relating specifically to the Company's program evaluating TH1902 for the treatment of sortilin-positive cancers (currently in Phase 1) reached approximately \$2,686,000 in Fiscal 2021, and those relating to its

program evaluating tesamorelin for the treatment of NASH (currently in the Phase 3 preparation stage) totaled \$2,983,000 for the same period. As explained previously, the Phase 1 study involving TH1902 is progressing as planned, while the initiation of the Phase 3 clinical trial for tesamorelin has been delayed pending assessment of our options to best execute this program, including seeking additional resources or potential partnership.

Selling Expenses

Selling expenses for Fiscal 2021 were \$28,909,000 compared to \$26,859,000 for the same period in Fiscal 2020. The increase is mainly due to the addition of senior personnel and an increase in promotional activities related to our commercial products in the United States, as well as additional spending in Europe, in anticipation of the launch of Trogarzo® in key markets.

General and Administrative Expenses

General and administrative expenses for Fiscal 2021 were \$14,616,000 compared to \$12,230,000 for the same period in Fiscal 2020. The increase in general and administrative expenses was mainly associated with an overall increase in business activities, senior hires to support our corporate initiatives in North America and increased overall activity in Europe.

Net Finance Costs

Net finance costs for the Fiscal 2021 were \$6,426,000 compared to \$4,694,000 in Fiscal 2020. The increase in net finance costs in 2021 versus the comparable period in 2020 was mostly due to foreign currency variations. We recorded a net foreign currency loss of \$320,000 in Fiscal 2021, versus a net foreign currency gain of \$418,000 in 2020. We also recorded higher accretion expense in Fiscal 2021 (\$2,358,000) than in Fiscal 2020 (\$2,056,000).

Adjusted EBITDA²

Adjusted EBITDA for Fiscal 2021 was \$(14,586,000) compared to \$(7,093,000) in Fiscal 2020, reflecting increased R&D expenses and higher selling, general and administrative expenses, as well as investments towards building our infrastructure in Europe. These higher expenses were partially offset by higher revenues and gross margins mostly due to increasing *EGRIFTA SV* sales.

Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$31,725,000, or \$0.34 per share, in Fiscal 2021 compared to \$22,667,000, or \$0.29 per share, in Fiscal 2020.

16

 $^{^2}$ Adjusted EBITDA is a Non-GAAP Financial Measure. See the "Non-IFRS Financial Measures" section of the MD&A for a description of the composition and reconciliation of this measure.

Selected Annual Information

(in thousands of dollars, except per share amounts)

Years ended November 30	2021	2020	2019
Revenue	69,823	66,053	63,216
Selling expenses	28,909	26,859	26,482
Research and development expenses	28,274	18,019	10,841
General and administrative expenses	14,616	12,230	8,330
Adjusted EBITDA 3	(14,586)	(7,093)	323
Net loss	(31,725)	(22,667)	(12,496)
Loss per share: Basic and diluted	(0.34)	(0.29)	(0.16)
Cash, bonds and money market funds	40,354	20,768	41,244
Total assets	119,212	100,142	117,555
Long-term obligations (including current portion)		4,666	7,987
Lease liabilities	2,518	2,980	
Convertible unsecured senior notes	54,227	52,403	50,741

³ Adjusted EBITDA is a Non-GAAP Financial Measure. See the "Non-IFRS Financial Measures" section of the MD&A for a description of the composition and reconciliation of this measure.

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 Europe, 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.

As at November 30, 2021, cash, bonds and money market funds amounted to \$40,354,000 compared to \$20,768,000 at November 30, 2020. Available cash is invested in highly liquid fixed income instruments including governmental, municipal and paragovernmental organizations, high-grade corporate bonds and money market funds.

For Fiscal 2021, cash flow used in operating activities was \$14,477,000 compared to \$13,554,000 in Fiscal 2020. Changes in operating assets and liabilities for Fiscal 2021 had a positive impact on cash flow of \$242,000. These changes included an increase of \$4,187,000 in inventories, an increase in prepaid expenses and deposits of \$5,569,000, and were offset by a decrease in trade and other receivables of \$1,852,000, by an increase in accounts payable and accrued liabilities of \$5,549,000, and by an increase in provisions of \$2,226,000. These changes are mostly related to an increase in our commercial activities.

During Fiscal 2021, the Company realized net proceeds from the issue of common shares and warrants of \$42,608,000 and recorded net proceeds from the exercise of warrants of \$742,000 and stock options of \$545,000. Significant uses of cash included the payment of a \$5,000,000 milestone related to the launch of Trogarzo in Europe, as well as \$3,306,000 in interest on the convertible unsecured senior notes.

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 of \$3,394,000 resulted in net proceeds of \$42,608,000.

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. The Company has also announced that it will evaluate its options in funding late-stage development programs, which may include seeking a potential partner or additional financing. The Company is also evaluating its options with respect to the convertible debentures which become due in June 2023. During the year, the Company entered into an ATM program (see note 21(c) to the Audited Financial Statements) under which it may sell, from time to time, up to \$50 million of its common shares.

Commitments

Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

Subsequent events

On December 1, 2021, the Company granted 2,099,651 stock options at an exercise price of CA \$4.21 and 269,170 stock options at an exercise price of \$3.30.

On November 23, 2021, the Company filed a short form base shelf prospectus with the Securities and Exchange Commission and Canadian securities regulatory authorities with the intent of filing a prospectus supplement to renew the prospectus supplement of July 23, 2021 relating to the \$50,000 ATM facility. Such prospectus supplement was filed on December 16, 2021 and the ATM was renewed (see Note 21 (c) to the Audited Financial Statements).

Contractual obligations

The following table lists as of November 30, 2021 information with respect to the Company's contractual obligations.

	Less than 1				
Contractual Obligations	Total	Year	1 to 3 Years	3 to 5 Years	5 years
Convertible unsecured senior notes, including interest	64,113,000	3,306,000	60,807,000		
Lease Liabilities	2,973,000	624,000	1,275,000	1,074,000	_
Purchase Obligations (1)	8,575,000	8,575,000		<u></u>	
Total	\$75,661,000	\$12,505,000	\$62,082,000	\$ 1,074,000	\$ —

(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, 2021, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to \$6,598,000 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 \$1,253,000 in connection with its oncology platform and \$724,000 in connection with the F8 Formulation and the Pen developed for the F8 Formulation.

Long-term obligations are contingent upon occurrence of certain stated events in commercialization rights and license agreements.

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, 2021 and 2020, 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 13 (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.

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The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 28 to the Audited Financial Statements), 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 \$9,261,000 (2020 – \$10,947,000), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the years ended November 30, 2021 and 2020. 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, paragovernmental, municipal and high-grade corporate bodies and money market funds (2021 – \$19,955,000; 2020 – \$8,031,000). As at November 30, 2021, 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 to the Audited Financial Statements, 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, 2021 and 2020.

(in thousands)

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		2021		2020
	CA\$	EURO	CA\$	EURO
Cash	589	61	871	36
Bonds and money market funds	16,298	-	821	-
Trade and other receivables	331	1,553	522	1,052
Tax credits and grants receivable	385	123	942	25
Accounts payables and accrued liabilities	(6,819)	(7,256)	(4,937)	(4,496)
Lease liabilities	(1,755)	(1,010)	(2,109)	(1,138)
Provisions	-	(1,970)	-	-
Total exposure	9,029	(8,499)	(3,890)	(4,521)

The following exchange rates are those applicable as at November 30, 2021 and 2020 to:

		2021		2020
	Average rate	Reporting date rate	Average rate	Reporting date rate
CA\$ – US\$	0.7979	0.7822	0.7445	0.7695
Euro – US\$	1.1906	1.1338	1.1325	1.1928

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)

	2021		2020
CA\$	EURO	CA\$	EURO

Positive impact 451 (425) (195) (226)

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, 2021, 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 \$141,000 (2020: nil); 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, 2021 of \$41,491,000 (2020: \$28,124,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately \$207,000 (2020: \$141,000); 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, 2021 was approximately \$52,756,000 (\$43,125,000 at November 30, 2020) 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 29 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.

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 13 to the Audited Financial Statements) 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, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorizations and thus subject to further negotiation. 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 from the effects of technological change or new product introductions, 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

Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after December 1, 2021 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these consolidated financial statements.

Onerous contracts - Cost of Fulfilling a Contract (Amendments to IAS 37)

The amendments specify which costs an entity includes in determining the cost of fulfilling a contract for the purpose of assessing whether the contract is onerous. The amendments apply for annual reporting periods beginning on or after January 1, 2022 to contracts existing at the date when the amendments are first applied. At the date of initial application, the cumulative effect of applying the amendments is recognised as an opening balance adjustment to retained earnings or other components of equity, as appropriate. The comparatives are not restated. The Company is currently evaluating the impact of the amendments on its financial statements.

Outstanding Securities Data

As at February 23, 2022, the number of common shares issued and outstanding was 95,121,639 while outstanding options granted under our stock option plan were 5,126,564. 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.

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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, 2021. 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, 2021, 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 November 30, 2021 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, 2021, 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, 2021 to November 30, 2021 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 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. Stock-option 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. Management believes this non-GAAP financial measure, in addition to conventional measures prepared in accordance with IFRS, enable investors to

evaluate the Company's operating results, underlying performance and future prospects in a manner similar to management.

Our method for calculating Adjusted EBITDA may differ from that used by other companies and, accordingly, our definition of this non-GAAP financial measure may not be comparable to similar measures presented by other issuers. Although Adjusted EBITDA is frequently used by securities analysts, lenders and others in their evaluation of companies, it has limitations as an analytical tool. Investors are cautioned that non-GAAP financial measures should not be construed as an alternative to net income determined in accordance with IFRS as indicators of our performance or to cash flows from operating activities as measures of liquidity and cash flows.

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Adjusted EBITDA

(in thousands of dollars)

	Three-month periods ended November 30		Years ended November 30		
	2021	2020	2021	2020	2019(1)
Net loss	(9,901)	(5,549)	(31,725)	(22,667)	(12,496)
Add (deduct):					
Depreciation and amortization	2,189	2,192	8,748	8,520	7,495
Lease inducement and amortization	-	-	-	-	238
Net finance costs	1,817	1,424	6,426	4,694	3,983
Income taxes	19	16	63	16	-
Share-based compensation for stock option plan	405	259	1,932	1,427	1,087
(Reversal) write-down of inventories	(30)	241	(30)	917	16
Adjusted EBITDA	(5,501)	(1,417)	(14,586)	(7,093)	323

⁽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.

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 ongoing COVID-19 pandemic could have a material adverse effect on our 2022 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 2022 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, increased border and port controls and closures, and shutdowns. Although most industrialized countries are relaxing some of the restrictive measures, there remains considerable uncertainty regarding the consequences such relaxed measures may have on the pandemic and the population worldwide as well as on the reimplementation of potential future measures.

As COVID-19 continues to be present and spread around the globe, the Corporation may experience disruptions that could severely impact its business and clinical trials, including:

- patients' limited access to the Corporation's treatments and products;
- diversion of healthcare resources prioritizing the treatment of patients suffering from COVID-19;
- delays or difficulties in enrolling patients in the Corporation's clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities;
- risk that participants enrolled in the Corporation's clinical trials will acquire COVID-19 while the clinical trial is ongoing;
- limitations in employee resources that would otherwise be focused on the commercialization of the Corporation's products and the conduct its clinical trials;
- delays in receiving authorizations from regulatory authorities to approve a drug candidate or to initiate the Corporation's planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct the Corporation's clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require the Corporation to change the ways in which its clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether:
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;

- interruptions or delays in efforts to acquire data needed to support patent claims or otherwise expand the Corporation's intellectual property portfolio; and
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors
 due to limitations in employee resources or forced furlough of government employees.

The COVID-19 pandemic has significantly increased economic and demand uncertainty throughout North America and Europe. The COVID-19 pandemic has caused disruption and volatility in the global capital markets, which, depending on further developments, could impact the Corporation's 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 the Corporation's operations, financial condition, liquidity, results of operations, and cash flows is still highly uncertain and will depend on future developments. Such developments may include the geographic spread and duration of COVID-19, the severity of the disease and the actions that may be taken by various governmental authorities and other third parties in response to the pandemic.

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^{\otimes} and $Trogarzo^{\otimes}$ in the United States and on $Trogarzo^{\otimes}$ 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 commercially attractive pricing for Trogarzo® and obtain reimbursement therefor 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;

32

- 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 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 SV®. Our agreement with Bachem has expired and we are currently renegotiating the terms and conditions of a new manufacturing agreement. Although we are in discussions with Bachem, 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 Bachem yet. Also, we have not qualified 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 potential Phase 3 clinical trial in NASH. Despite our current level of inventory of tesamorelin, we could incur a shortage of 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.

Part of our commercial team in the United States and in the European Territory dedicated to the commercialization of our products in these territories is provided by Syneos. In the United States, after March 14, 2022, Syneos will continue to provide us with services related to managed market and certain functions supporting our medical team in connection with the commercialization of our products. In Europe, Syneos provides us with medical science liaison personnel. 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 retain contract research organizations, or CROs, to support us with the conduct of our clinical trials from time to time. 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^{\otimes} and $Trogarzo^{\otimes}$ in the United States, or of $Trogarzo^{\otimes}$ 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.

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^{\otimes} and $Trogarzo^{\otimes}$.

Market acceptance and sales of $EGRIFTA\ SV^{\circledR}$ and Trogarzo $^{\circledR}$ 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 $EGRIFTA\ SV^{\circledR}$ and Trogarzo $^{\circledR}$.

Sales of $EGRIFTA\ SV^{\circledR}$ and Trogarzo $^{\circledR}$ 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 agreeing on a commercially attractive pricing with regulatory authorities and obtaining reimbursement for Trogarzo®. 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, or that we will be able to negotiate a pricing that will be commercially attractive to us in any or all of the EU Member States.

Even if Trogarzo® is reimbursed, in EU Member States, legislators, policymakers and healthcare insurance funds continue to propose and implement cost-containing measures

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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 pricing and reimbursement status in any EU Member States.

Even though 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 $EGRIFTA\ SV^{\circledR}$ and $Trogarzo^{\circledR}$ 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

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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 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 peptide-drug conjugates resulting from our SORT1+ TechnologyTM 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 conduct of the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population will be costly and the Corporation has decided to

secure additional resources, including finding a partner, prior to initiating such clinical trial, all of which will result in a postponement of the initiation of such trial. Although the Corporation has begun the search for a potential partner, there can be no assurance that a partner will be found or that a partnership agreement will be entered into on terms satisfactory to the Corporation. If a partner is not found, the Corporation will need to look for alternatives to secure additional resources but there can be no guarantee that the Corporation will secure such resources in an amount sufficient to initiate or complete its Phase 3 clinical trial. Moreover, the Corporation has no meaningful Phase 2 clinical data evaluating tesamorelin for the treatment of NASH in the general population and any result obtained from the conduct of one Phase 3 clinical trial will have to show substantial evidence that tesamorelin is safe and effective for the treatment of NASH in the general population. Finally, the Corporation's decision to design its Phase 3 clinical trial to meet the FDA's primary endpoints may prevent the Corporation from seeking approval of tesamorelin for the treatment of NASH in the general population from the EMA since the primary endpoint for this agency is different from that of the FDA. If the Corporation is unable to secure additional resources to initiate its Phase 3 clinical trial, or find alternatives to pursue this trial, the conduct of such trial could be cancelled. If the Corporation is unable to meet the endpoints of its Phase 3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. And, even if the Corporation meets the endpoints of Part 1 of the Phase 3 clinical trial and obtains a conditional approval letter from the FDA, the Corporation could lose such approval if Part 2 of the Phase 3 clinical trial is unable to show evidence on the resolution of certain clinical outcomes. If the conduct of the clinical trial is cancelled, or if the Corporation does not receive approval for tesamorelin for the treatment of NASH in the general population, its potential long-term revenues, growth and prospects will be materially adversely affected.

The Corporation held discussions with the FDA and the EMA to finalize its Phase 3 clinical trial design, which discussions concluded in July 2021. As a result of such discussions, the trial design will result in higher costs than what the Corporation had previously estimated. The Corporation has decided to postpone the initiation of its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population until it can secure additional resources to execute its program and has initiated a search to find a partner for that purpose.

There can be no guarantee that the Corporation will be able to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH if it is unable to secure substantial additional resources, either from a financing, a partnership or other means that it could resort to. In addition, the Corporation may not be able to find a partner to help with securing additional resources. Even if the Corporation finds a partner, the terms and conditions pursuant to which such partner may be interested in assisting the Corporation may not be suitable to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the search of a partner and turn to alternative sources of financing. If the Corporation is unable to secure additional resources, it may further

postpone the initiation of its Phase 3 clinical trial until it can secure additional resources, review and amend its current protocol to reduce the costs associated with the study of tesamorelin for the potential treatment of NASH, or may cancel its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. If the Corporation is unable to, or does not proceed with, the development of tesamorelin for the treatment of NASH in the general population, it could have a material adverse effect on its potential long-term revenues, growth and prospects.

Even if the Corporation secures additional resources to initiate its Phase 3 clinical trial, there can be no guarantee that the FDA will approve tesamorelin for the treatment of NASH in the general population since the FDA recommended the Corporation to conduct a Phase 2 clinical trial to generate data resulting from the use of tesamorelin in patients suffering from NASH and since the Corporation must meet the primary endpoints set forth by the FDA in its guidelines. Given the lack of Phase 2 data resulting from the use of tesamorelin in patients suffering from NASH, the data from the Phase 3 clinical trial will have to demonstrate substantial evidence of the safety and effectiveness of tesamorelin for the treatment of NASH in the general population. In addition, even if the Corporation meets the FDA's primary endpoints of the clinical trial and receives approval from the FDA, such approval will be conditional upon completing Part 2 of the Phase 3 clinical trial. If Part 2 of the Phase 3 clinical trial does not show positive evidence on certain clinical outcomes, the FDA could withdraw its approval on the use of tesamorelin for the treatment of NASH in the general population. Finally, if the Corporation is unable to show substantial evidence that tesamorelin is safe and effective for the treatment of NASH in the general population through the conduct of one Phase 3 clinical trial, the FDA could require the Corporation to conduct an additional study.

The Corporation has decided to design its Phase 3 clinical trial based on the FDA guidelines requiring it to demonstrate "NASH resolution and no worsening of fibrosis" as primary endpoints. This trial design does not follow the current EMA guidelines which require a sponsor to demonstrate both (i) NASH resolution and no worsening of fibrosis and (ii) improvement of fibrosis by one stage without worsening of NASH as primary endpoints. Therefore, even if the Corporation meets the primary endpoints for FDA purposes, the EMA may not approve tesamorelin for the treatment of NASH in this territory since the trial was not designed to demonstrate both endpoints.

If the Corporation is unable to obtain approval of tesamorelin for the treatment of NASH in the United States, this would have material adverse effects on its revenues, financial results and long-term growth and prospects. In addition, even if the FDA approves tesamorelin for the treatment of NASH, the lack of an approval in Europe will limit the Corporation's ability to maximize its revenue growth potential, therefore potentially hampering its long-term growth and prospects.

The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain since results obtained from preclinical in vivo development work may not translate into human subjects. The goal of the Phase 1 clinical trial evaluating TH1902 is to determine the MTD that can be administered to

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human subjects and determine if any adverse side effects will be observed from the injection of TH1902 in human subjects. If the Corporation is unable to demonstrate similar results as 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+ TechnologyTM 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 patient deaths.

TH1902 is being developed as a potential treatment for severe, various life-threatening cancers that express SORT1 receptor. The Phase 1 clinical trial is being conducted with patients that are more prone than healthy subjects to exhibit certain diseases or adverse events. Some of these patients face life-threatening situations and may die during our Phase 1 clinical trial. If patients have serious adverse side effects from the administration of TH1902, it may become difficult to discern whether certain events or symptoms observed in those 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 need to 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 continuation of the 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 associated with the Corporation's current 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+ TechnologyTM platform. The abandonment of the development of the Corporation's SORT1+ TechnologyTM platform would reduce its pipeline of drug candidates and could materially adversely affect its long-term growth and prospects.

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 other sources of financing, such as public offerings, private placements or the conclusion of partnerships. 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 or private 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, do not have access to public or private financing, or are unable to conclude partnerships 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 conduct of clinical trials is subject to a variety of risks, many of which can be beyond the control of the Corporation forcing it to delay the initiation or conduct of clinical trials or forego same.

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

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The conduct of clinical trials is subject to a variety of risks, many of which can be beyond the control of the Corporation forcing it to delay the initiation or conduct of clinical trials or forego same.

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

- negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its 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 with the conduct of our clinical trials;
- inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials;
- challenges in recruiting and enrolling patients to participate in clinical trials, such as the proximity of patients to study sites, eligibility criteria to be included in a clinical trial, the nature of a clinical trial and the competition from other clinical study programs for the treatment of similar diseases as those the Corporation may seek to treat;
- severe or unexpected adverse drug effects experienced by patients;
- regulatory agencies requiring a sponsor to conduct additional clinical studies prior to approving a new drug application, a sBLA, or the equivalent thereof in other jurisdictions after review of Phase 3 clinical trial results;
- regulatory agencies may disagree with a sponsor's interpretation of data resulting from its Phase 3 clinical trials, or may change the requirements for approval even after they have approved the sponsor's Phase 3 clinical trial design; and
- difficulties in retaining patients who have enrolled in a sponsor'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.

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

• failure to conduct the clinical trial in accordance with the regulatory requirements of a sponsor's study protocol; and

• inspections of the clinical study operations or study sites by regulatory agencies that would reveal deficiencies or violations requiring a sponsor to undertake corrective actions (to the extent any are available).

If the Corporation incurs any delay in the conduct of a clinical trial or decides to suspend or terminate such trial, this could materially adversely affect the business prospects of the Corporation and its potential long-term revenues derived from the potential sale of its drug candidates. Any delay or suspension of a clinical trial may also adversely impact the duration of the protection afforded by the issuance of patents covering the drug candidate subject to such clinical trial and lead to earlier entries of competitors in the market.

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

The Corporation has conducted studies to assess the bioequivalence of the F8 Formulation against the original 1 mg/vial formulation of *EGRIFTA®*. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not yet filed an sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for the first half of calendar year 2022.

In addition, the Corporation has manufactured one process validation batch of the F8 Formulation only 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 original formulation.

If the FDA does not approve the F8 Formulation as being bioequivalent to the original 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.

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

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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.

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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 SV® or Trogarzo®.

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

49

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.

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.

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 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, 2021. 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. In addition, if our share price remains below the conversion price of the Notes, the Notes are unlikely to be converted and we will have to pay all accrued interest thereon and their principal on their maturity date (June 30, 2023).

As at November 30, 2021, we had negative operating cash flow of \$14,477,000. 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 commercial, managerial and scientific personnel. We have entered into employment agreements with our executive officers and provided them, as well as to other key employees, with long-term incentives as a retention mechanism, but such agreements and incentives do not guarantee that our executive officers and other key employees 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 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, 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 including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorizations and thus subject to future negotiations. 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.

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.

Theratechnologies Inc. 2015 Peel Street, 11th Floor Montreal, Québec H3A 1T8

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, 2021 and 2020

THERATECHNOLOGIES INC.

Table of Contents

(In thousands of United States dollars)

	Page
Consolidated Statements of Financial Position	1
Consolidated Statements of Net Loss and Comprehensive Loss	2
Consolidated Statements of Changes in Equity	3
Consolidated Statements of Cash Flows	4
Notes to Consolidated Financial Statements	5 - 63

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. ("Company") as of November 30, 2021 and 2020, the related consolidated statements of net loss and comprehensive loss, changes in equity, and cash flows for the years ended November 30, 2021 and 2020 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, 2021 and 2020, and the financial performance and its cash flows for the years ended November 30, 2021 and 2020, in conformity with International Reporting Standards ("IFRS") as issued by the International Accounting Standards Board.

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 of 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.

(signed) KPMG LLP

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

Montréal, Canada February 23, 2022

THERATECHNOLOGIES INC.

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

As at November 30, 2021 and 2020

	Note	November 30, 2021	November 30 2020
Assets			
Current assets			
Cash	\$		\$ 12,737
Bonds and money market funds	6	19,955	8,031
Trade and other receivables	7	10,487	12,430
Tax credits and grants receivable	8	441	755
Inventories	9	29,141	25,145
Prepaid expenses and deposits	10	10,745	5,189
Derivative financial assets	21(d)	740	520
Total current assets		91,908	64,807
Non-current assets			
Property and equipment	11	743	865
Right-of-use-assets	12	2,111	2,618
Intangible assets	13	21,388	24,529
Deferred financing costs	21(c)	621	-
Other asset	14	2,441	7,323
Total non-current assets		27,304	35,335
Total assets	\$	119,212	\$ 100,142
Liabilities			
Current liabilities			
Accounts payable and accrued liabilities	15 \$	40,376	\$ 34,815
Provisions	16	4,123	1,947
- Provisions Other obligations	17	4,123	4,666
Current portion of lease liabilities	19	463	425
Income taxes payable	19	60	16
Deferred revenue		54	50
Total current liabilities		45,076	41,919
Non-current liabilities			
Convertible unsecured senior notes	18	54,227	52,403
Lease liabilities	19	2,055	2,555
Cetase idunities Other liabilities	20	94	41
Total non-current liabilities		56,376	54,999
Total liabilities		101,452	96,918
		,	
Equity			
Share capital and warrants	21	335,752	287,312
Equity component of convertible unsecured senior notes		4,457	4,457
Contributed surplus		12,843	12,065
Deficit	01.0	(335,248)	(300,129)
Accumulated other comprehensive loss	21(i)	(44)	(481)
Total equity		17,760	3,224
Commitments	27		
Subsequent events	30		

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

Approved by the Board of Directors

(signed) Alain Trudeau 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, 2021 and 2020

	Note	2021	2020
Revenue	3	\$ 69,823	\$ 66,053
Operating expenses			
Cost of sales			
Cost of goods sold		18,378	20,970
Other production-related costs		=	1,051
Amortization of other asset	14	4,882	4,881
Research and development expenses net of tax credits of \$277 (2020 – \$296)		28,274	18,019
Selling expenses		28,909	26,859
General and administrative expenses		14,616	12,230
Total operating expenses		95,059	84,010
Loss from operating activities		(25,236)	(17,957)
Finance income	5	195	717
Finance costs	5	(6,621)	(5,411)
	-	(6,426)	(4,694)
Loss before income taxes		(31,662)	(22,651)
Income taxes		(63)	(16)
Net loss		(31,725)	(22,667)
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 financial assets at fair value through other comprehensive income			
(FVOCI)		(197)	14
Exchange differences on translation of foreign operations		634	(516)
		437	(502)
Total comprehensive loss		\$ (31,288)	\$ (23,169)
Loss per share		 <u>-</u>	
Basic and diluted	21(h)	\$ (0.34)	\$ (0.29)

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, 2021 and 2020

	_	Share capital and warrants		Equity component of convertible unsecured			Accumulated other	
	Note	Number of shares	Amount	senior notes	Contributed surplus	Deficit	comprehensive income (loss)	Total
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		-	-	-	-	-	14	14
Exchange differences on translation of foreign operations		-	-	-	-	-	(516)	(516)
Total comprehensive loss		-	-	-	-	(22,667)	(502)	(23,169)
·								
Share-based compensation plan					1 41 4			1 44 4
Share-based compensation for stock option plan		-	-	-	1,414	-	-	1,414
Exercise of stock options Monetary consideration		60,000	145	_	_			145
Attributed value		-	132	-	(132)	-	-	145
/ Ittibuted value			102		(102)			
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
Total comprehensive loss								
Net loss		-	-	-	-	(31,725)	-	(31,725)
Other comprehensive income:						(-, -,		(, , ,
Net change in fair value of FVOCI financial assets		-	-	-	-	-	(197)	(197)
Exchange differences on translation of foreign operations		-	-	-	-	-	634	634
Total comprehensive loss		_	-	_	-	(31,725)	437	(31,288)
·						(==,:==)		(0-,-00)
Transactions with owners, recorded directly in equity	04()	46 707 066	40.000					40.000
Public issue of common shares and warrants	21(a)	16,727,900	46,002	-	-	(2.20.4)	-	46,002
Share issue costs Exercise of warrants	21(a)	233,400	742	-	-	(3,394)	-	(3,394)
Share issue – Oncology	21(a) 21(b)	481.928	668	-	(668)	-	-	142
Share-based compensation plan:	ZI(I)	401,320	000	-	(000)	_	-	
Share-based compensation for stock option plan	21(g)	_	_	_	1,879	_	_	1,879
Exercise of stock options:	(9)				_,			_,510
Monetary consideration	21(g)	665,000	595	-	-	-	-	595
Attributed value		-	433	-	(433)	-	-	
Total contributions by owners		18,108,228	48,440		778	(3,394)		45,824
		,,	, . 10			(=,== 1)		,321
Balance as at November 30, 2021		95,121,639	\$335,752	\$4,457	\$12,843	\$(335,248)	\$(44)	\$17,760

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, 2021 and 2020

	Note	20	21		20
ash flows from (used in)					
perating					
Net loss		\$ (31,7))E)	\$	(22,6
		Φ (31,77	25)	Ф	(22,0
Adjustments for	11	,	27		:
Depreciation of property and equipment	11		37		
Amortization of intangible assets and other asset	13,14	8,0			7,
Amortization of right-of-use assets	12		49		
Share-based compensation for stock option plan and stock appreciation rights		1,9			1,
(Reversal) write-down of inventories	9		30)		
Change in fair value of derivative financial assets	21(d)		12)		
Change in fair value of liability related to deferred stock unit plan	21(d)		:09		(1
Interest on convertible unsecured senior notes	5	3,3			3
Interest income	5	(19	95)		(2
Foreign exchange		8	90		(;
Accretion expense	5	2,3	58		2
		(14,7)	19)		(7,
Change in operating assets and liabilities		(14,1.	10)		(1,
Trade and other receivables		1,8	52		(2,
Tax credits and grants receivable			23		(
Inventories		(4,18	37)		(4,
Prepaid expenses and deposits		(5,5)			(1,
Accounts payable and accrued liabilities		5.5			3
Provisions		2,2			(
Income taxes payable			44		(-
Deferred revenue			4		
Botomed revenue			42		(6,
tal cash used in operating activities		(14,4			(13,
		(14,4	11)		(10,
nancing activities					
Repayment of long-term obligations		(5,00			(3,
Proceeds from exercise of stock options			95		
Proceeds from exercise of warrants		7	'42		
Proceeds from issue of common shares and warrants		46,0	02		
Share issue costs		(3,3	94)		
Deferred financing costs			47 <u>)</u>		
Interest paid on convertible unsecured senior notes		(3,3)			(3,
Payment of lease liability		(6:			(0,
		,			
al cash from (used in) financing activities		34,5	57		(7,
esting activities					
Acquisition of intangible assets			39)		
Acquisition of property and equipment	11		27)		
Proceeds from sale of bonds and money market funds			40		4
Acquisition of bonds and money market funds		(12,7	56)		
Interest received		(1	72)		
Acquisition of derivative financial assets		,	-		
al cash from (used in) investing activities		(12,4	54)		4
talean a in a sale		7,6	26		(16,
cnange in cash		12,7	37		28
•					
sh, beginning of year			36		
ist change in cash ush, beginning of year fect of foreign exchange on cash ush, end of year		\$ 20,3	36	\$	12

See Note 23 for supplemental cash flow disclosures.

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

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* (Québec) and is domiciled in Québec, Canada. The Company's head office is located at 2015 Peel Street, Suite 1100, Montréal, Québec, Canada, 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 23, 2022.

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, which are measured at fair value,
- derivative financial assets, which are measured at fair value,
- liabilities related to cash-settled share-based arrangements and derivative financial liabilities, which are measured at fair value,
- lease liabilities which are measured at present value of lease payments not paid at commencement date,
- 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 26.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

1. Basis of preparation (continued)

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.

Use of estimates and judgments

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

Judgments in applying accounting policies

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

Milestone payments related to Trogarzo®

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

Contingent consideration related to oncology platform

The purchase consideration for the oncology platform (Note 13) 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

1. Basis of preparation (continued)

Use of estimates and judgments (continued)

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, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorisations and thus subject to future negotiation. The product revenue recognized 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 from the effects of technological changes or new product introductions, 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 some of the impact of the outbreak of the Coronavirus (COVID-19) on its operations, it continued to operate during the current pandemic. During the year ended November 30, 2021, the Company recognized payroll subsidiaries totaling \$325 (2020-\$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. Given the prolonged pandemic, it is not clear what the potential impact may be on the Company's business, financial position and financial performance.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies

The accounting policies have been applied consistently by 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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Revenue recognition

Revenue from contracts with customers - Net sales

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

Some arrangements for the sale of finished goods provide for customer cash discounts for prompt payment, allowances, rights of return, rebates on sales made under governmental and commercial rebate programs, chargebacks on sales made to government agencies and retail pharmacies and distribution fees, including potential clawbacks in certain jurisdictions when pricing terms are based on temporary use authorisations and thus subject to future negotiation, 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.

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 14).

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Employee benefits

Salaries and short-term employee benefits

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

Post-employment benefits

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

Termination benefits

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

Finance income and finance costs

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

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Inventories

Inventories are presented at the lower of cost, determined using the first-in, first-out method, and net realizable value. Inventory costs include the purchase price and other costs directly related to the acquisition of materials and other costs incurred in bringing the inventories to their present location and condition. The Company is responsible for coordinating the production and stability testing and for auditing suppliers at different times during the manufacturing process. Inventory costs also include the costs directly related to the conversion of materials into finished goods. Net realizable value is the estimated selling price in the Company's ordinary course of business less the estimated costs of completion and selling expenses.

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

Property and equipment

Recognition and measurement

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

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

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

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

Subsequent costs

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Property and equipment (continued)

Depreciation

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

Asset	Method	Rate/period
Computer equipment	Declining balance	50%
Laboratory equipment	Declining balance	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.

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, 2021 and 2020, no development expenditures were capitalized.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Intangible assets (continued)

Commercialization rights and oncology platform

Commercialization rights and the oncology platform acquired by the Company have finite useful lives and are measured at cost less accumulated amortization and any accumulated impairment losses. Subsequent changes in the cash-based contingent consideration on the acquisition of intangible assets arising from the attainment of commercial milestones are recorded in the cost of the asset. Commercialization rights – *EGRIFTA SV®* 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 on a straight-line basis. Commercialization rights for the oncology platform will be amortized over the estimated useful life on a straight-line basis when the asset is available for use.

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

Other asset

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

Impairment of non-financial assets

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

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Financial instruments

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

(i) Financial assets measured at amortized cost

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Financial instruments (continued)

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

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Financial instruments (continued)

(iv) Financial liabilities (continued)

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

(v) Compound financial instruments

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

The liability component of a compound financial instrument is recognized initially at the fair value of a similar liability that does not have an equity 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 expected 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, 2021 and 2020

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

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Leases (continued)

Right-of-use assets (continued)

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Deferred Financing Costs

Deferred Financing Costs consists of fees charged by underwriters, attorneys, accountants, and other fees directly attributable to future issuances of shares. Provided these costs are determined to be recoverable, these costs are deferred and charged subsequently against the gross proceeds of the related equity transaction on a proportionate basis when it occurs. If at such time, the Company deems that these costs are no longer recoverable, they will be expensed as a component of finance expenses.

Provisions

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

Chargebacks and rebates

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

Returns

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

Contingent liability

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

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.

Deferred stock unit plan

The deferred stock units ("DSUs") are totally vested on the date of grant and are settled in cash. When DSUs are granted to officers as part of their 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

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.

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, 2021 and earlier application is permitted; however, the Company has not early adopted the new or amended standards in preparing these consolidated financial statements.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

2. Significant accounting policies (continued)

Standards issued but not yet effective (continued)

Onerous contracts - Cost of Fulfilling a Contract (Amendments to IAS 37)

The amendments specify which costs an entity includes in determining the cost of fulfilling a contract for the purpose of assessing whether the contract is onerous. The amendments apply for annual reporting periods beginning on or after January 1, 2022 to contracts existing at the date when the amendments are first applied. At the date of initial application, the cumulative effect of applying the amendments is recognised as an opening balance adjustment to retained earnings or other components of equity, as appropriate. The comparatives are not restated. The Company is currently evaluating the impact of the amendments on its financial statements.

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 28.

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.

Canada

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

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

3. Revenue (continued)

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 (the "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:

	2021	2020
EGRIFTA® and EGRIFTA SV®	\$ 43,009	\$ 35,399
Trogarzo®	26,814	30,654
	\$ 69,823	\$ 66,053
Net sales by geography were as follows:		
	2021	2020
Canada	\$ 2021 269	\$ 2020 354
Canada United States	\$	\$
	\$ 269	\$ 354

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

4. Personnel expenses

	Note		2021		2020
Salaries and short-term employee benefits		\$	11,480	\$	7,564
Post-employment benefits		Ť	644	•	458
Share-based compensation	21(e),(g)		1,651		1,297
Termination benefits			209		876
		\$	13,984	\$	10,19

5. Finance income and finance costs

	Note	2021	2020
Net foreign currency gain		\$ -	\$ 418
Interest income		195	299
Finance income		195	717
Accretion expense	17, 18, 19	(2,358)	(2,056)
Interest on convertible unsecured senior notes		(3,306)	(3,306)
Bank charges		(31)	(40)
Net foreign currency loss		(926)	-
Loss on financial instruments carried at fair value		 -	 (9)
Finance costs		(6,621)	(5,411)
Net finance cost recognized in net profit or loss		\$ (6,426)	\$ (4,694)

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

6. Bonds and money market funds

	2021	2020
Bonds	\$ 12,553	\$ 634
Money market funds	7,402	7,397
	\$ 19,955	\$ 8,031

As at November 30, 2021, bonds were interest-bearing financial assets with stated interest rates ranging from 0.5% to 3.9% (2020 - 2.2% to 4.1%) and had an average maturity of 2.26 years (2020 - 0.06 years).

7. Trade and other receivables

	2021	2020
Trade receivables	\$ 9,261	\$ 10,947
Sales tax receivable	243	407
Other receivables	983	1,076
	\$ 10,487	\$ 12,430

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

8. Tax credits and grants receivable

Balance as at November 30, 2019	\$	-
Tax credits and grants recognized in net loss		749
Effect of change in exchange rates		6
D	•	
Balance as at November 30, 2020	\$	755
Tax credits and grants recognized in net loss	\$	755 602
·	\$	
Tax credits and grants recognized in net loss	\$	602

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	Ф.	450
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		329
2041		330
	\$	12 920

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

9. Inventories		
	2021	2020
Raw materials	\$ 2,142	\$ 2,290
Work in progress	735	488
Finished goods	26,264	22,367
	\$ 29,141	\$ 25,145

Inventories were written down to net realizable value by an amount of \$21 in 2021 (2020 - \$917), and a reversal of inventory write down of \$51 in 2021 (2020-nil) was recorded. An amount of nil (2020 - \$910) was recorded in cost of sales as other production-related costs and \$(30) (2020 - \$7) was recorded in cost of goods sold.

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

10. Prepaid expenses and deposits

	2021	2020
Prepaid expenses	\$7,721	\$4,997
Deposits	3,024	192
	\$10,745	\$5,189

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

11. Property and equipment

	Computer equipment	Laboratory equipment	Office furniture and equipment	Leasehold improvements	Total
Cost					
Balance as at					
November 30, 2019	\$231	\$107	\$334	\$642	\$1,31
Additions	41	-	-	-	4
Balance as at					
November 30, 2020	\$272	\$107	\$334	\$642	\$1,35
Additions	106	-	1	8	11
Disposals	(5)	-	(3)	-	3)
Balance as at					
November 30, 2021	\$373	\$107	\$332	\$650	\$1,46
Accumulated depreciation					
Balance as at					
November 30, 2019	\$87	\$32	\$58	\$66	\$24
Depreciation	75	18	56	98	24
Balance as at					
November 30, 2020	\$162	\$50	\$114	\$164	\$49
Depreciation	72	19	46	100	23
Disposals	(5)	-	(3)	-	(
Balance as at					
November 30, 2021	\$229	\$69	\$157	\$264	\$71
Net carrying amounts					
November 30, 2021	\$144	\$38	\$175	\$386	\$74

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

12. Right-of-use assets

Balance as at November 30, 2019	\$	-
Impact of initial adoption of IFRS 16		2,954
Amortization		(441)
Effect of change in exchange rates		105
Balance as at November 30, 2020	\$	2,618
Amortization		(449)
Effect of change in exchange rates		(58)
D I 00 0004	•	0.111
Balance as at November 30, 2021	\$	2,111

13. Intangible assets

	Commercialization rights – Trogarzo® North American Territory	Commercialization rights – Trogarzo® European Territory	Commercialization rights – <i>EGRIFTA SV</i> ®	Oncology platform	Total
Cost					
Balance as at November 30, 2019 and 2020	\$11,972	\$7,612	\$14,041	\$3,449	\$37,074
Additions	-	-	-	39	39
Balance as at November 30, 2021	\$11,972	\$7,612	\$14,041	\$3,488	\$37,113
Accumulated amortization					
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
Amortization	1,054	615	1,511	-	3,180
Balance as at November 30, 2021	\$3,267	\$999	\$11,459	-	\$15,725
Net carrying amounts					
November 30, 2021	\$8,705	\$6,613	\$2,582	\$3,488	\$21,388
November 30, 2020	\$9,759	\$7,228	\$4,093	\$3,449	\$24,529

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

13. Intangible assets (continued)

The amortization expense of \$3,180 (2020 – \$2,951) is included in selling expenses.

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.

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, 2021 and 2020

13. Intangible assets (continued)

Commercial milestone payments

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

Commercial milestone		Commercial milestone payment		
(i) Achieving aggregate net sales of \$20,000 over four consecutive quarters of the Company's financial year	17	\$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 may also plan 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.

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;

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

13. Intangible assets (continued)

Initial and milestone payments (continued)

- 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.

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 17).

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

13. Intangible assets (continued)

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 consisted in initiating a Phase 1 clinical trial evaluating TH1902 for the treatment of Sortilin positive solid tumors. This milestone was achieved in March 2021 and was satisfied through the issuance of 481,928 common shares (note 21 b)).

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.

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 for the second milestone payment 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.

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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

13. Intangible assets (continued)

Oncology platform (continued)

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 sublicence agreement, it must then pay amounts varying between 5% and 15% of revenues received from such sublicence agreement.

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: \$39 (CA\$50) thousand upon the successful enrolment of the first patient in the first Phase 1 human clinical trial paid in May 2021;
- (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, 2021 and 2020

14.	Other asset	
	Cost	
	Balance as at November 30, 2019, 2020 and 2021	\$ 19,530
	Accumulated amortization	
	Balance as at November 30, 2019	\$ 7,326
	Amortization	4,881
	Balance as at November 30, 2020	\$ 12,207
	Amortization	4,882
	Balance as at November 30, 2021	\$ 17,089
	Net carrying amounts	
	November 30, 2021	\$ 2,441
	November 30, 2020	\$ 7,323

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, 2021 and 2020

15. Accounts payable and accrued liabilities

	Note	2021	2020
Trade payables		\$ 15,526	\$ 17,510
Accrued liabilities and other payables		19,932	13,911
Salaries and benefits due to key management personnel	29	880	776
Employee salaries and benefits payable		1,942	724
Liability related to deferred stock unit plan	21(d)	710	508
Accrued interest payable on convertible unsecured senior notes	18	1,386	1,386
		\$ 40,376	\$ 34,815

16. Provisions

	Chargebacks and rebates	Returns	Other	Total
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
Provisions made	10,655	1,074	-	11,729
Provisions used	(8,570)	(924)	(9)	(9,503)
Effect of change in exchange rate	(50)	-	-	(50)
Balance as at November 30, 2021	\$3,713	\$410	\$-	\$4,123

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

17. Other obligations

The movement in the other obligations is as follows.

	right	mercialization s – Trogarzo® orth American Territory	rights	ercialization – Trogarzo® ean Territory	Total
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
Accretion expense		-		334	334
Payment		-		(5,000)	(5,000)
Current portion as at November 30, 2021	\$	-	\$	- -	\$ -

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. The payment was made in October 2021.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

18. 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:

Convertible unsecured senior notes as at November 30, 2019	\$	50,741
	·	22,1
Accretion expense		1,662
Convertible unsecured senior notes as at November 30, 2020	\$	52,403
Accretion expense		1,824
Convertible unsecured senior notes as at November 30, 2021	\$	54,227

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

19. Leases liabilities

	Carrying valu
	0.10
Balance as at December 1, 2019	\$ 3,19
Accretion expense	21
Lease payments	(568
Effect of change in exchange rates	14
Balance as at November 30, 2020	\$ 2,98
Accretion expense	20
Lease payments	(63
Effect of change in exchange rates	(2
Balance as at November 30, 2021	\$ 2,5
Current portion	(46
Non-current portion	\$ 2,0

20. Other liabilities

	Note	2021		2020
Stock appreciation rights	21(e)	\$ 94	\$	41
		\$ 94	\$	41

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants

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, 2021 and 2020.

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) Public offering

On January 19, 2021, the Company completed a public offering for the sale and issuance of 16,727,900 units at a price of \$2.75 per unit for a gross cash consideration of \$46,002, including the full exercise of the over-allotment option.

Each unit was 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") and is classified in Share Capital and Warrants within equity. Share issuance costs of \$3,394 were recorded against the deficit. As at November 30, 2021, 233,400 Warrants were exercised for proceeds of \$742, and there were 8,130,550 Warrants outstanding. Each Warrant entitles the holder thereof to purchase one common share at an exercise price of \$3.18 at any time until January 19, 2024.

(b) Milestone oncology

In March 2021, the Company issued 481,928 common shares under the terms of the acquisition agreement entered into with all of the shareholders of Katana for Katana's in-licensed oncology platform. The purchase price for the oncology platform provided for share-based consideration to be issued upon attainment of two milestones. The first milestone was achieved in March 2021. The estimated fair value of the share-based consideration of \$668 initially recorded in contributed surplus on the date of the acquisition was reclassified to share capital (Note 13).

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(c) ATM program

Under the terms of a sales agreement dated July 23, 2021, the Company may issue and sell from time to time its common shares, having an aggregate offering price of up to \$50,000, through or to the Agent, as agent or principal, in the United States. Sales of the common shares will be made in transactions that are deemed to be "at-the-market distributions" (ATM). No common shares will be sold on the TSX or on other trading markets in Canada as "at-the-market distributions". Subject to the terms and conditions of the sales agreement, the Agent will use its commercially reasonable efforts to sell the common shares from time to time, based upon the Company's instructions. The Common Shares would be issued at market prices prevailing at the time of the sale and, as a result, prices may vary between purchasers and during the period of distribution. The Agent will be entitled to compensation at a fixed commission rate of three percent (3.0%) of the gross sales price per common share sold. The Company has no obligation to sell any of the common shares. Either the Company or the Agent may terminate the sales agreement in their sole discretion at any time by giving written notice. As at November 30, 2021, no common shares were issued. Total costs of \$621 incurred in connection with the ATM program were recorded as deferred financing costs in the Consolidated Statements of Financial Position.

(d) 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(d) DSU plan (continued)

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, 2021, \$78 (2020 – \$33) 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, 2021, a loss of \$209 (2020 – gain of \$157) was recognized within finance costs (Note 5). As at November 30, 2021, the Company had a total 215,508 DSUs outstanding (2020 – 220,171 DSUs) and a liability related to the DSUs of \$710 (2020 – liability of \$508).

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, 2021 and 2020, the cash-settled forward stock contracts outstanding correspond to a total of 220,171 common shares at a price of \$5.84 per share (2020 – \$5.75 per share) expiring on December 21, 2022 (2020 – December 21, 2021). As at November 30, 2021, the fair value of cash-settled forward stock contracts was \$740 (2020 – \$520) and is recorded in derivative financial assets. During the year ended November 30, 2021, a gain of \$212 (2020 – loss of \$166) related to the change in fair value of derivative financial assets was recognized within finance costs.

(e) 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, 2021, \$53 (2020 – \$13) 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(e) Share Appreciation Rights (SARs) (continued)

Granted in 2019	Measurement date as at November 30, 2021	Measurement date as at November 30, 2020
Risk-free interest rate	1.57%	0.67%
Expected volatility	59%	64.6%
Average option life in years	5.2 years	6.25 years
Share price	\$3.29 (CA\$4.21)	\$2.31 (CA\$3.00)
Option exercise price	\$6.30 (CA\$8.05)	\$6.19 (CA\$8.05)_
Granted in 2021		Measurement date as at November 30, 2021
Risk-free interest rate		1.57%
Expected volatility		65.5%
Average option life in years		8.2 years
Share price		\$3.29 (CA\$4.21)
Option exercise price		\$3.38 (CA\$4.32)

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, 2021. No SARs were granted in 2020.

	Number of SARs	Weighted average grant date fair value
2021	75,000	\$ 2.13 (CA\$2.73)

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(f) 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.

(g) 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, 2021, 4,251,404 options could still be granted by the Company under the plan (2020 – 2,379,863).

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, 2021 and 2020

21. Share capital and warrants (continued)

(g) Stock option plan (continued)

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

		Weighted av exercise per o	
	Number of options	CA\$	US
Options outstanding as at November 30, 2019	2,415,784 \$	3.94 \$	2.9
Granted – CA\$	1,077,721	3.06	2.2
Forfeited and expired – CA\$	(229,812)	4.72	3.4
Exercised (share price: CA\$8.65 (US\$6.57))	(60,000)	3.38	2.4
Options outstanding as at November 30, 2020	3,203,693 \$	3.59 \$	2.7
Granted – CA\$	1,057,831	3.94	3.1
Forfeited and expired – CA\$	(406,240)	6.61	5.2
Exercised (share price: CA\$4.18 (US\$3.36))	665,000	1.11	0.8
Options outstanding as at November 30, 2021 – CA\$	3,190,284 \$	3.83 \$	3.0
Options exercisable as at November 30, 2021 – CA\$	1,630,476 \$	3.96 \$	3.1
Options exercisable as at November 30, 2020 – CA\$	2,063,672 \$	3.43 \$	2.6
Options outstanding in US\$			
Options as at November 30, 2020 – US\$	12,500	-	2.3
Granted – US\$	102,608	-	3.2
Forfeited – US\$	(34,375)	-	3.0
Options outstanding as at November 30, 2021 – US\$	80,733 \$	- \$	3.0
Options exercisable as at November 30, 2021 – US\$	4,166 \$	- \$	2.3
Options exercisable as at November 30, 2020 – US\$	- \$	- \$	

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(g) Stock option plan (continued)

The following table provides stock option information as at November 30, 2021 (options outstanding in CA\$).

Price range		Number of options outstanding	Weighted average remaining life		Weighted average exercise price
CA\$	US\$		(years)	CA\$	US\$
0.25 - 1.19	0.19 - 0.92	314,660	1.12	0.36	0.28
2.01 – 3.75	1.55 - 2.89	1,310,453	7.32	2.80	2.19
3.76 – 6.00	2.89 - 4.62	1,108,074	8.84	4.15	3.25
6.01 - 9.00	4.62 - 6.93	318,733	6.95	7.92	6.20
9.01 - 10.00	6.93 – 1.70	138,364	6.35	9.56	7.48
		3,190,284	7.16	3.83	3.00

The following table provides stock option information as at November 30, 2021 (options outstanding in US\$).

Price range	Number of options outstanding	Weighted average remaining life	Weighted average exercise price
US\$		(years)	US\$
2.01 – 3.75	80,733	9.32	3.09

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(g) Stock option plan (continued)

For the year ended November 30, 2021, \$1,879 (2020 – \$1,414) was recorded as share-based compensation expense for the stock option plan. The fair value of options granted in 2021 and 2020 was estimated at the grant date using the Black-Scholes model and the following weighted average assumptions.

Options granted in CA\$	2021	2020
Risk-free interest rate	1.35%	0.95%
Expected volatility	70%	74%
Average option life in years	8.5 years	8.5 years
Grant-date share price	\$3.10 (CA\$3.94)	\$2.25 (CA\$3.06)
Option exercise price	\$3.10 (CA\$3.94)	\$2.25 (CA\$3.06)

Options granted in US\$	2021	2020
Risk-free interest rate	1.37%	0.74%
Expected volatility	72%	78%
Average option life in years	8.5 years	8.5 years
Grant-date share price	\$ 3.18 \$	2.35
Option exercise price	\$ 3.18 \$	2.35

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

21. Share capital and warrants (continued)

(g) 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, 2021 and 2020.

Options granted in CA\$	Number of stock options granted	of stock	
2021	1,057,831	\$	2.13 (CA\$2.72)
 2020	1,077,721	\$	1.71 (CA\$2.22)

Options granted in US\$	Number of stock options granted	Weighted average grant date fair value
2021	102,608	\$ 2.22
2020	12,500	\$ 1.70

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, 2021 and 2020

21. Share capital and warrants (continued)

(h) Loss per share

The calculation of basic loss per share was based on the net loss attributable to common shareholders of the Company of \$31,725 (2020 - \$22,667) and a weighted average number of common shares outstanding of 92,350,198 (2020 - 76,991,635), calculated as follows.

	2021	2020
Issued common shares as at December 1	77,013,411	76,953,411
Effect of share options exercised	374,247	38,224
Effect of public issue common shares	14,816,285	-
Effect of broker warrants exercised	146,255	<u>-</u>
Weighted average number of common shares, basic and diluted	92,350,198	76,991,635

For the year ended November 30, 2021, 3,271,017 (2020 – 3,216,193) share options, 8,130,550 Warrants (2020 – nil) and 3,872,053 common shares potentially issuable from the conversion of the \$57,500 aggregate principal amount of convertible unsecured senior notes (Note 18), 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.

(i) Accumulated other comprehensive income (loss)

		2021		2020
Unrealized losses on FVOCI financial assets, net	Φ.	(4.05)	Φ.	2
of tax	\$	(195)	\$	2
Cumulative exchange difference on translation of foreign operations		151		(483)
	\$	(44)	\$	(481)

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

22. Income taxes

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

	2021	2020
Current tax expense	\$ 63	\$ 16
Deferred tax expense (recovery)		
Origination and reversal of temporary differences	\$ (7,796)	\$ (4,890)
Change in unrecognized deductible temporary differences	7,796	4,890
Total deferred tax expense (recovery)	\$ -	\$ -
Total current and deferred tax expense	\$ 63	\$ 16
Reconciliation between effective and applicable tax amounts		
	2021	2020
Income taxes at domestic tax statutory rate	\$ (8,390)	\$ (6,004)
Change in unrecognized deductible temporary differences	7,796	4,890
Impact of differences in statutory tax rates	64	742
Non-deductible expenses and other	593	388
Total income tax expense	\$ 63	\$ 16

The applicable statutory tax rates were 26.5% in 2021 and 2020. 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, 2021 and 2020

22. Income taxes (continued)

Unrecognized deferred tax assets

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

	2021	2020
Research and development expenses	\$ 26,046	\$ 24,924
Non-capital losses	38,615	31,725
Property and equipment	225	242
Intellectual property and patent fees	3,054	2,952
Available deductions and other	7,535	5,045
	\$ 75,475	\$ 64,888

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, 2021 and 2020

22. Income taxes (continued)

Unrecognized deferred tax assets (continued)

As at November 30, 2021 and 2020, the amounts and expiry dates of Canadian tax attributes for which no deferred tax asset was recognized were as follows:

		2021		2020
	Federal	Provincial	Federal	Provincial
Research and development expenses, without time limitation	\$ 89,740	\$ 109,034	\$ 85,792	\$ 104,822
Losses carried forward				
2027	5,960	5,952	5,760	5,753
2028	36,877	17,949	35,640	17,347
2029	15,513	13,111	14,993	12,672
2030	9,109	9,105	8,803	8,800
2031	18,758	16,651	18,129	16,092
2032	12,709	11,669	12,282	11,278
2033	9,132	9,046	8,826	8,742
2034	8,362	8,289	8,082	8,011
2037	7,462	7,373	7,212	7,126
2038	2,177	2,095	2,104	2,025
2039	1,434	1,394	1,386	1,347
2040	7,832	7,805	6,928	6,921
2041	21,220	21,153	-	-
Other temporary differences, without time limitation				
Excess of tax value of property and equipment over carrying value	869	838	959	870
Excess of tax value of intellectual property and patent fees over carrying value	11,522	11,518	11,136	11,131
Available deductions and other	60,940	16,607	50,470	7,619

As at November 30, 2021 and 2020, 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, 2021 and 2020

23. Supplemental cash flow disclosures

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

	2021	2020
Additions to property and equipment included in accounts payable and accrued liabilities	\$ _	\$ 12
Deferred financing costs included in accounts payable and accrued liabilities	174	-
Initial recognition of right-of-use assets and lease liabilities	-	3,192
Reclassification of other liabilities to right-of-use-assets	-	238

24. 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 28), 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 \$9,261 (2020 – \$10,947), all of which were aged under 60 days. There was no amount recorded as bad debt expense for the years ended November 30, 2021 and 2020. 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, paragovernmental, municipal and high-grade corporate bodies and money market funds (2021 – \$19,955; 2020 – \$8,031). As at November 30, 2021, 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

24. Financial instruments (continued)

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 25, 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.

The following are amounts due on the contractual maturities of financial liabilities as at November 30, 2021 and 2020.

					2021
	Carrying amount	Total contractual amount	Less than 1 year	From 1 to 2 years	More than 3 years
Accounts payable and accrued liabilities	\$40,376	\$40,376	\$40,376	-	-
Convertible unsecured senior notes, including interest	54,227	64,113	3,306	60,807	-
Lease liabilities	2,518	2,973	624	1,275	1,074
	\$97,121	\$107,462	\$44,306	\$62,082	\$1,074

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

24. Financial instruments (continued)

Liquidity risk (continued)

					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	-
ong-term obligations	4,666	5,000	5,000	-	-
ease liabilities	2,980	3,640	621	1,267	1,752
	\$94,864	\$110,874	\$43,742	\$65,380	\$1,752

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, 2021 and 2020.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

24. Financial instruments (continued)

Currency risk (continued)

		2021		2020
	CA\$	EURO	CA\$	EURO
Cash	589	61	871	36
Bonds and money market funds	16,298	-	821	-
Trade and other receivables	331	1,553	522	1,052
Tax credits and grants receivable	385	123	942	25
Accounts payables and accrued liabilities	(6,819)	(7,256)	(4,937)	(4,496)
Lease liabilities	`(1,755)	(1,010)	(2,109)	(1,138)
Provisions	-	(1,970)	-	-
Total exposure	9,029	(8,499)	(3,890)	(4,521)

The following exchange rates are those applicable as at November 30, 2021 and 2020.

		2021		2020
	Average rate	Reporting date rate	Average rate	Reporting date rate
	0.7070	0.7000	0.7445	0.7005
CA\$ – US\$	0,7979	0,7822	0.7445	0.7695
Euro – US\$	1,1906	1,1338	1.1325	1.1928

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

24. Financial instruments (continued)

Currency risk (continued)

Based on the Company's foreign currency exposures noted above, varying the above foreign exchange rates to reflect a 5% strengthening of the CA\$ or the Euro would have an impact on net earnings for CA\$ and in the accumulated other comprehensive loss for Euro as follows, assuming that all other variables remained constant.

		2021		2020
	CA\$	EURO	CA\$	EURO
Positive (negative) impact	451	(425)	(195)	(226)

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, 2021, 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 \$141 (2020 – nil); 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, 2021 of \$41,491 (2020 – \$28,124), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately \$207 (2020 – \$141); an assumed decrease of 0.5% would have had an equal but opposite effect.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

24. Financial instruments (continued)

Interest rate risk (continued)

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.

25. 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 SV*® as well as sales of Trogarzo® in the United States and Europe, and, from time to time, on public offerings of securities in North America to finance its activities. In order to maintain or adjust its capital structure, the Company, upon approval from its Board of Directors, may issue or repay long-term debt, issue shares, repurchase shares, pay dividends or undertake other activities as deemed appropriate under the specific circumstances. The Company has also announced that it will evaluate its options in funding late stage development programs, which may include seeking a potential partner or additional financing. The Company is also evaluating its options with respect to the convertible debentures which becomes due in June 2023. During the year, the Company entered into an ATM program (see note 21(c)) under which it may sell, from time to time, up to \$50 million of its common shares.

The capital management objectives remain the same as for the previous year.

As at November 30, 2021, cash, bonds and money market funds amounted to \$40,354 (2020 – \$20,768). 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.

26. 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.

THERATECHNOLOGIES INC.

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

Years ended November 30, 2021 and 2020

26. Determination of fair values (continued)

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.

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, and accounts payable and accrued liabilities 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, 2021 was approximately \$52,756 (2020–\$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, 2021 and 2020

27. 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, 2021, the Company had outstanding purchase orders and minimum payments required under these agreements amounting to \$6,598 (2020 – \$14,042) for the manufacture of Trogarzo[®], *EGRIFTA SV*[®] and for various services.

As at November 30, 2021, the Company also has research commitments and outstanding clinical material purchase orders amounting to \$1,253 (2020 – \$586) in connection with the oncology platform and \$724 (2020 – \$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, 2021 and 2020, 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, 2021 and 2020

27. 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.

28. 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.

	2021		2020	
RxCrossroads	\$ 68,917	\$	63,909	
Others	906		2,144	
	\$ 69,823	\$	66,053	

All of the Company's non-current assets are located in Canada and Ireland. Of the Company's non-current assets of \$27,304 (2020 – \$35,335), \$26,211 (2020 – \$34,006) are located in Canada and \$1,093 (2020 – \$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, 2021 and 2020

29. 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:

	2021	2020
Short-term employee benefits	\$ 2,690	\$ 2,384
Post-employment benefits	72	97
Share-based compensation	1,243	925
Termination benefits	-	864

As at November 30, 2021, the key management personnel controlled 0.7% (2020 - 1.4%) of the voting shares of the Company and held 0.2% (2020 - 0.2%) of the convertible unsecured senior notes.

30. Subsequent events

On December 1, 2021, the Company granted 2,099,651 stock options at an exercise price of CA \$4.21 and 269,170 stock options at an exercise price of \$3.30.

On November 23, 2021, the Company filed a short form base shelf prospectus with the Securities and Exchange Commission and Canadian securities regulatory authorities with the intent of filing a prospectus supplement to renew the prospectus supplement of July 23, 2021 relating to the \$50,000 ATM facility. Such prospectus supplement was filed on December 16, 2021 and the ATM was renewed (see Note 21 (c)).

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 24, 2022

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 24, 2022

Bv: /s/ Philippe Dubuc

Philippe Dubuc Senior Vice President and Chief Financial Officer (Principal Financial Officer)

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 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, 2021, 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 24, 2022

/s/ Paul Lévesque

Name: Paul Lévesque

Title: President and Chief Executive Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 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, 2021, 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 24, 2022

/s/ Philippe Dubuc
Name: Philippe Dubuc

Title: Senior Vice President and Chief Financial Officer

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors Theratechnologies Inc.

We consent to the incorporation by reference in the Registration Statement (No. 333-261289) on Form F-10 of Theratechnologies Inc. of our report dated February 23, 2022 on the consolidated financial statements of Theratechnologies Inc. which comprise the consolidated statements of financial position as of November 30, 2021 and 2020, the related consolidated statements of net loss and comprehensive loss, changes in equity and cash flows for the years ended November 30, 2021 and 2020, and the related notes, which report appears in the annual report on Form 40-F of Theratechnologies Inc. for the fiscal year ended November 30, 2021, and further consent to the use of such report in such annual report on Form 40-F.

(signed) KPMG LLP

February 24, 2022 Montreal, Canada