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

## **FORM 40-F**

(Check One)

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

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

For the fiscal year ended November 30, 2022

Commission file number: 001-35203

# THERATECHNOLOGIES INC.

(Exact name of registrant as specified in its charter)

**Québec, Canada** (Province or other jurisdiction of incorporation or organization) 2834
(Primary
Standard
Industrial
Classification
Code Number
(if applicable)

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

2015 Peel Street, 11<sup>th</sup> Floor Montreal, Québec, Canada H3A 1T8 (514) 336-7800

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

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

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

Copies to:

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

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

Title Of Each Class

Common Shares

Trading Symbol **THTX** 

Name Of Exchange On Which Registered
The NASDAQ Stock Market LLC

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

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

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

☑ Annual Information Form ☑ Audited Annual Financial Statements				
Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period cov by the annual report: <b>96,806,299</b>	ered			
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been sult to such filing requirements for the past 90 days.				
Yes ☑No □				
Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted purs to Rule 405 of Regulations S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Regis was required to submit such files).	uant trant			
Yes ☑No □				
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act.				
Emerging Growth Corporation ☑				
If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark it registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standar provided pursuant to Section 13(a) of the Exchange Act.				
† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board Accounting Standards Codification after April 5, 2012.	to its			
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: Montreal, Canada Auditor Firm ID:	85			
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registincluded in the filing reflect the correction of an error to previously issued financial statements. $\Box$	trant			
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-bacompensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).	ased			

## **EXPLANATORY NOTE**

Theratechnologies Inc. ("we", "us", "our", the "Corporation" 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, (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 (the "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®, despite new market entrants:
- 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;
- the filing of a supplemental biologic application ("sBLA") for an intramuscular method of administration of Trogarzo®;
- the approval of an intramuscular method of administration of Trogarzo® by the United States Food and Drug Administration ("FDA");
- the filing of a sBLA with the FDA for a new formulation of tesamorelin ("F8 Formulation");
- the approval of the F8 Formulation by the FDA;
- our ability to successfully complete the human factors validation study ("HFS") and to resubmit a CBE supplement with the FDA for EGRIFTA SV<sup>®</sup> in the 2023 fiscal year;
- our capacity to meet the undertakings, covenants and obligations contained in the credit agreement entered into with Marathon's affiliates and not be in default thereof;
- our capacity to find a partner to conduct a Phase 2b/3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- the filing of an amendment to our protocol to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our capacity to find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed:

- our capacity to pursue the development of other peptide-drug conjugates ("PDC") in the field of oncology;
- our capacity to acquire, in-license, or copromote new products;
- 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:

- sales of EGRIFTA SV® and Trogarzo® in the United States will increase over time;
- our expenses will remain under control;
- our commercial practices in the United States 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 the United States;
- continuous supply of EGRIFTA SV® and Trogarzo® will be available to meet market demand on a timely basis;
- our relations with third-party suppliers of EGRIFTA SV® and Trogarzo® will be conflict-free;
- the level of product returns and the value of chargebacks and rebates will not exceed our estimates in relation thereto;
- 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;
- we will file a sBLA for the F8 Formulation in the 2023 fiscal year;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- the HFS will be successfully completed and we will resubmit a CBE supplement with the FDA for *EGRIFTA SV*® by the end of the 2023 fiscal year;
- · the FDA will approve the CBE supplement;
- we will not default under the terms and conditions of the credit agreement entered into with Marathon's affiliates, including meeting the minimum liquidity and revenue target covenants therein;
- we will meet all of the conditions set forth under the credit agreement entered into with Marathon's affiliates to draw down the \$20 million second tranche;
- the interest rate on the amount borrowed from Marathon's affiliates under the credit agreement will not materially vary upwards;

- the Corporation will continue as a going concern;
- we will find a partner to conduct a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our protocol allowing us to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate positive efficacy and safety results;
- we will find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;
- our research and development activities will yield positive results;
- the data obtained from our market research on the potential market for EGRIFTA SV® and on the potential market for Trogarzo®
  in the United States are accurate;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise subsequent to the date of this Annual Report;
- our business plan will not be substantially modified; and
- no international event, such as a pandemic or worldwide war, will occur and adversely affect global trade.

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 ("SEC") to prepare this Annual Report in accordance with Canadian disclosure requirements, which differ from those of the United States.

The Corporation'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 Corporation'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, 2022 ("Annual Information Form") 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 Corporation for the years ended November 30, 2022 and 2021, 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 Corporation's management's discussion and analysis for the year ended November 30, 2022 ("2022 MD&A"), is filed as Exhibit 99.3 to this Annual Report and is incorporated by reference herein.

#### **TAX MATTERS**

Purchasing, holding, or disposing of the Corporation'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

The information provided in the section entitled "Disclosure Controls and Procedures and Internal Control over Financial Reporting" contained in the 2022 MD&A filed as Exhibit 99.3 to this Annual Report is incorporated by reference herein.

#### INTERNAL CONTROL OVER FINANCIAL REPORTING

The information provided in the section entitled "Disclosure Controls and Procedures and Internal Control over Financial Reporting" contained in the 2022 MD&A filed as Exhibit 99.3 to this Annual Report is incorporated by reference herein.

#### NO AUDITOR'S ATTESTATION REPORT

As an "emerging growth company" (as such term is defined in Rule 12b-2 under the Exchange Act), the Corporation is not required to include in this Annual Report an attestation report of the Corporation's independent registered public accounting firm relating to the Corporation's internal control over financial reporting. The Corporation 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

Other than the material weakness described in the section entitled "Disclosure Controls and Procedures and Internal Control over Financial Reporting" contained in the 2022 MD&A filed as Exhibit 99.3 to this Annual Report, there were no changes in our internal controls over financial reporting during the period covered by this Annual Report that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

## **AUDIT COMMITTEE**

The Corporation has an audit committee ("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, 2022, 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 Corporation, 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, 2022 and 2021.

#### **AUDITORS FEES**

Fees	Fiscal Year Ended November 30, 2022 (CAD)	Fiscal Year Ended November 30, 2021 (CAD)
Audit Fees <sup>(1)</sup>	\$750,615	\$639,382
Audit-Related Fees <sup>(2)</sup>	\$53,865	\$48,943
Tax Fees <sup>(3)</sup>	\$115,293	\$170,027
All Other Fees		
Total:	\$919,773	\$858,352

- (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.
- (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 Corporation's external auditors and requires the Audit Committee to pre-approve all permitted non-audit services to be provided by the Corporation's external auditors, which pre-approval may be delegated to any member of the Audit Committee. The Corporation also requires pre-approval of all audit services to be provided by its external auditors. All audit and non-audit services performed by the Corporation's external auditors for the fiscal year ended November 30, 2022, 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 Corporation 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 Corporation's website and is available at <a href="https://www.theratech.com">www.theratech.com</a>. On February 18, 2020, the Corporation 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 Corporation's website and is also available at <a href="https://www.theratech.com">www.theratech.com</a>. The Corporation 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 Corporation 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, 2022 information with respect to the Corporation's 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	29,081,000	29,081,000			
Lease Liabilities	2,196,000	595,000	1,145,000	405,000	51,000
Term loan, including interest (1)	57,667,000	5,649,000	28,421,000	23,597,000	_
Purchase Obligations (2)	3,822,000	3,822,000	_	_	_
Total	\$ 92,766,000	\$ 39,147,000	\$ 29,566,000	\$ 24,002,000	\$ 51,000

- (1) Based on SOFR forward rates. The maturities above reflect the fact that the term loan has been amended in the subsequent event period and, as such, the contractual maturities are used.
- (2) 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, 2022, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to \$1,644,000 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 \$1,310,000 in connection with its oncology platform and \$868,000 in connection with the F8 Formulation and a multi-dose pen injector developed for the F8 Formulation.

#### License agreement:

On February 4, 2020, the Corporation entered into an amended and restated license 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.

#### 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, 2022, 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: Is/ Paul Lévesque

Name: Paul Lévesque Title: President and

Chief Executive Officer

Date: February 28, 2023

## **EXHIBIT INDEX**

Exhibit	
99.1	Annual Information Form dated February 27, 2023 for the year ended November 30, 2022
99.2	Audited Consolidated Annual Financial Statements for the years ended November 30, 2022 and 2021
99.3	Management's Discussion and Analysis for the year ended November 30, 2022
99.4	Certificate of CEO dated February 28, 2023 pursuant to Rule 13a-14(a) of the Exchange Act
99.5	Certificate of CFO dated February 28, 2023 pursuant to Rule 13a-14(a) of the Exchange Act
99.6	Certificate of CEO dated February 28, 2023 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 28, 2023 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.INS	XBRL Instance
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase



Exhibit 99.1

ANNUAL INFORMATION FORM Financial Year Ended November 30, 2022



February 27, 2023

## **BASIS OF PRESENTATION**

In this Annual Information Form (the "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 indicated for the reduction of excess abdominal fat in HIV-infected adult 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 adult patients with lipodystrophy.
- tesamorelin refers to the use of our tesamorelin compound for the potential treatment of nonalcoholic steatohepatitis ("NASH") in the general population and for the potential treatment of other diseases;
- Trogarzo® (ibalizumab-uiyk) refers to a recombinant humanized monoclonal antibody. Trogarzo®, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 ("HIV-1") infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current antiretroviral regimen. Trogarzo is a registered trademark of TaiMed Biologics, Inc. ("TaiMed") and is under licence to us for use in the United States and Canada.
- *THERA Patient Support*<sup>®</sup> is our registered trademark in the United States and it refers to our patients and physicians service desk providing support to these people in connection with our commercialized products.
- SORT1+ Technology is our trademark and refers to our licensed platform to develop peptide-drug conjugates ("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 27, 2023, 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®, despite new market entrants;
- 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;
- the filing of a supplemental biologics application ("sBLA") for an intramuscular method of administration of Trogarzo®;
- the approval of an intramuscular method of administration of Trogarzo® by the United States Food and Drug Administration ("FDA");
- the filing of a sBLA with the FDA for a new formulation of tesamorelin ("F8 Formulation");
- the approval of the F8 Formulation by the FDA;
- our ability to successfully complete the human factors validation study ("HFS") and to resubmit a change being effected ("CBE") supplement with the FDA for *EGRIFTA SV*® in the 2023 fiscal year;
- our capacity to meet the undertakings, covenants and obligations contained in the credit agreement entered into with Marathon's affiliates and not be in default thereof;
- our capacity to find a partner to conduct a Phase 2b/3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- the filing of an amendment to our protocol to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our capacity to find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;
- our capacity to pursue the development of other PDCs in the field of oncology;
- our capacity to acquire, in-license, or copromote new products;
- 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:

- sales of *EGRIFTA SV*® and Trogarzo® in the United States will increase over time;
- our expenses will remain under control;
- our commercial practices in the United States 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 the United States;
- continuous supply of *EGRIFTA SV*® and Trogarzo® will be available to meet market demand on a timely basis;
- our relations with third-party suppliers of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> will be conflict-free;
- the level of product returns and the value of chargebacks and rebates will not exceed our estimates in relation thereto;
- 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;
- we will file a sBLA for the F8 Formulation in the 2023 fiscal year;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- the HFS will be successfully completed and we will resubmit a CBE supplement with the FDA for *EGRIFTA SV*® by the end of the 2023 fiscal year;
- the FDA will approve the CBE supplement;
- we will not default under the terms and conditions of the credit agreement entered into with Marathon's affiliates, including meeting the minimum liquidity and revenue target covenants therein;
- we will meet all of the conditions set forth under the credit agreement entered into with Marathon's affiliates to draw down the \$20 million second tranche;
- the interest rate on the amount borrowed from Marathon's affiliates under the credit agreement will not materially vary upwards;
- the Corporation will continue as a going concern;
- we will find a partner to conduct a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our protocol allowing us to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate positive efficacy and safety results;
- we will find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;
- our research and development activities will yield positive results;

- the data obtained from our market research on the potential market for *EGRIFTA SV*® and on the potential market for Trogarzo® in the United States are accurate;
- the timelines set forth herein will not be materially adversely impacted by unforeseen events that could arise subsequent to the date of this AIF;
- our business plan will not be substantially modified; and
- no international event, such as a pandemic or worldwide war, will occur and adversely affect global trade.

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.

## **NON-IFRS AND NON-US GAAP MEASURE**

The information presented in this AIF includes a measure that is not determined in accordance with International Financial Reporting Standards ("IFRS") or U.S. generally accepted accounting principles ("U.S. GAAP"), being the term "Adjusted EBITDA". "Adjusted EBITDA" is used by the Corporation as an indicator of financial performance and is obtained by adding to net profit or loss, finance income and costs, depreciation and amortization, income taxes, share-based compensation from stock options, and certain write-downs (or related reversals) of inventories. "Adjusted EBITDA" excludes the effects of items that primarily reflect the impact of long-term investment and financing decisions rather than the results of day-to-day operations. The Corporation believes that this measure can be a useful indicator of its operational performance and financial condition from one period to another. The Corporation uses this non-IFRS measure to make financial, strategic and operating decisions.

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## SELECTED EVENTS IN FISCAL YEAR 2022 AND 2023 OUTLOOK

The following summary highlights selected events that occurred in the fiscal year 2022 up to the date of this AIF as well as our business objectives described elsewhere in this AIF for the fiscal year 2023. 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**

- Internalization of commercial and medical affairs teams;
- Ceased operation of Trogarzo® in Europe and retuned our commercial rights to TaiMed;
- Conclusion of a credit agreement providing for up to \$100 million term loan;
- Launch of IV Push method of administration of Trogarzo®; and
- Execution of agreement providing for the distribution of *EGRIFTA SV*® in various countries in the regions of Latin America, Middle East, North Africa, Turkey and Central and Eastern Europe.

## **Regulatory Events**

- FDA approval of the IV Push method of administration of Trogarzo®; and
- Suspension of enrollment in connection with our Phase 1 clinical trial studying TH1902 in various types of cancers.

## **Research and Development Events**

Completion of study enrollment for the development of an intramuscular method of administration of Trogarzo®.

## 2023 Business Objectives

- To continue growing our revenues in the United States from sales of *EGRIFTA SV*® and Trogarzo® and to manage our expenses to achieve a positive Adjusted EBITDA by year-end;
- To pursue potential product acquisitions, in-licensing transactions, copromotion, or other opportunities to grow our revenues;
- To file a sBLA with the FDA to seek approval of the intramuscular method of administration of Trogarzo®;
- To file a sBLA with the FDA to seek approval of the F8 Formulation of tesamorelin;
- To resubmit a CBE supplement with the FDA in relation to the HFS for *EGRIFTA SV*® by September 15, 2023;
- To resume our Phase 1 clinical trial studying TH1902 in various types of cancer by filing an amendment to our protocol with the FDA and, once such trial has resumed, to find a partner for TH1902; and
- To continue looking for a partner to initiate a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population.

## 1.1 NAME, ADDRESS AND INCORPORATION

We were incorporated under Part IA of the *Companies Act* (Québec), or CAQ, on October 19, 1993 under the name Theratechnologies Inc. We amended our articles on October 20, 1993 by repealing the restrictions applicable to private companies. On December 6, 1993, we again amended our articles to increase the number of directors and to modify our share capital. On March 26, 1997, we further modified our share capital to consist of an unlimited number of common shares and an unlimited number of preferred shares. Finally, on June 21, 2011, we amended our articles to give the power to our directors to appoint a number of additional directors equal to 33.33% of the number of directors elected at the last shareholders meeting preceding any appointment.

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

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

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

## 1.2 SUBSIDIARIES

As at February 27, 2023, Theratechnologies had the following five wholly-owned subsidiaries:

- **Theratechnologies Europe Limited,** a company governed by the *Companies Act 2014* (Ireland). Theratechnologies Europe Limited provides the services of personnel to Theratechnologies Inc. for its activities in the United States;
- 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.**, 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 Intercontinental Inc. is no longer an active subsidiary;
- **Theratechnologies Europe Inc.**, 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. Theratechnologies Europe Inc. is no longer an active subsidiary; and
- **Pharma-G Inc.**, a company governed by the *Business Corporations Act* (Québec). Pharma-G Inc. is no longer an active subsidiary.

#### 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 and to achieve a positive Adjusted EBITDA from the sale of our existing and potential future assets in North America 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*® and Trogarzo® in the United States.

*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 the first HIV treatment approved with a new mechanism of action in more than 10 years. The treatment is administered every two weeks. It is a long-acting antiretroviral ("ARV") therapy that can lead to an undetectable viral load in combination with other ARVs.

Trogarzo® was also approved by the European Medicines Agency ("EMA") in September 2019 and is no longer under licence to us in Europe further to our decision to terminate and return to TaiMed our commercialization rights to this product in April 2022. The EMA has since withdrawn the marketing approval of Trogarzo® in Europe.

In addition to the sale of our products, we are conducting research and development activities. We have a pipeline of investigational medicines in the areas of NASH and oncology. Tesamorelin, the active ingredient in *EGRIFTA SV®*, is designed to increase endogenous growth hormone secretion and is the foundation for its potential use for the treatment of NASH in the general population. Tesamorelin has a well-established safety profile, with more than 10 years of product history in HIV lipodystrophy. TH1902, a PDC derived from our licensed platform SORT1+ Technology<sup>TM</sup> that attaches to docetaxel, is designed to specifically target Sortilin ("SORT1") receptors expressed in cancer cells of various types of cancer. TH1902 was studied in a Phase 1 clinical trial until we decided to voluntarily pause the recruitment of patients in December 2022. We are also working on the development of other PDCs.

Our plan to initiate a Phase 2b/3 clinical trial to study tesamorelin for the treatment of NASH in the general population has been postponed until we can find a partner.

To date, we have completed the in-house bioequivalence study of the F8 Formulation and have begun assessing the development of a device, such as a pen (the "Pen"), intended to be used eventually with the F8 Formulation. As a result of issues in sourcing bacteriostatic water for injection in the past fiscal year, we have delayed the filing of a sBLA with the FDA seeking the approval of the F8 Formulation until later in fiscal 2023.

We have also completed the enrollment of patients for the development of an intramuscular method of administration of Trogarzo<sup>®</sup> and plan on filing a sBLA with the FDA seeking its approval in the current fiscal year.

## 2.2 THREE-YEAR HISTORY

## 2022

- 2023 Fiscal Year Guidance and Key Objectives. On January 4, 2023, we announced, among other things, revenue guidance between \$90 million and \$95 million for the fiscal year 2023, our key objectives for the fiscal year 2023 consisting of achieving positive Adjusted EBITDA and the creation of an advisory scientific committee whose mandate is to optimize the protocol amendments for the development of TH1902.
- *Voluntary Pause of Phase 1 Clinical Trial Studying TH1902*. On December 1, 2022, we announced our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 and to revisit the study design of this clinical trial.
- *FDA Approval of 30-Second Intravenous Push Method of Administration of Trogarzo*<sup>®</sup>. On October 3, 2022, we announced that the FDA approved the 30-Second Intravenous Push Method of Administration of Trogarzo<sup>®</sup>.
- *Closing of Funding of \$40 million Under Credit Agreement.* On July 27, 2022, we announced that we received \$40 million under the terms of a credit agreement with affiliated funds of Marathon Asset Management.
- Conclusion of Non-Dilutive Term Loan of Up to \$100 million. On July 13, 2022, we announced that we had entered into a binding commitment with affiliated funds of Marathon Asset Management providing for a non-dilutive term loan of up to \$100 million (the "Marathon Credit Facility"). On February 27, 2023, we entered into a first amendment to the Marathon Credit Facility (the "First Amendment to the Marathon Credit Facility"). The First Amendment to the Marathon Credit Facility and the Marathon Credit Facility are collectively referred to as the "Marathon Credit Facility". See "Item 9 Material Contracts Marathon Credit Facility" below for a description of the Marathon Credit Facility.
- Strategic Hire Supporting Investor Relations. On May 31, 2022, we announced the hiring of a new Head of Investor Relations.
- *Initiation of Basket Trial in Phase 1 Clinical Trial Studying TH1902*. On May 10, 2022, we announced the initiation of the recruitment of patients in the basket portion of the first-in-human study of TH1902. The dose of TH1902 was then established at 300 mg/m<sup>2</sup>.
- Return of European Commercialization Rights of Trogarzo® to TaiMed. On April 27, 2022, we announced that we notified TaiMed of our decision to return the European commercialization rights to Trogarzo® to TaiMed within the next 180 days pursuant to the terms of the TaiMed Agreement.
- Launch of an Internal Sales Force. On February 15, 2022, we announced the launch of our own field force through the hiring of key account managers joining from our long-term contract sales organization. We also announced the hiring of medical science liaison and community liaison personnel as part of the internalization of commercial and medical dedicated personnel.

## 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 (the "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®* (the "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.

## 2.3 OUR 2023 BUSINESS OBJECTIVES

Our business objectives in 2023 is focused on: increasing sales of EGRIFTA SV® and Trogarzo® in the United States and on managing our expenses to achieve a positive Adjusted EBITDA by year-end; continuing pursuing potential product acquisition, in-licensing transactions, copromotion, or other similar opportunities to grow our revenues; filing sBLAs in the United States for both the intramuscular method of administration of Trogarzo® and the F8 Formulation; resubmitting a CBE supplement with the FDA in relation to the HFS for EGRIFTA SV®; filing an amended protocol with the FDA to resume our Phase 1 clinical trial studying TH1902 in various types of cancer; seeking potential partners for our Phase 2b/3 clinical trial in NASH using tesamorelin and, once our Phase 1 clinical trial has resumed, for TH1902; and, managing our financial position to ensure we can successfully execute on our 2023 business objectives.

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



### 2.4 PRODUCTS

## **Our Approved Products**

## EGRIFTA SV® (tesamorelin for injection)

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

EGRIFTA  $SV^{\otimes}$  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  $SV^{\otimes}$  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  $SV^{\otimes}$ . EGRIFTA  $SV^{\otimes}$  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), presence of hormonal imbalance (growth hormone) and/or microbiome alteration and chronic inflammation. 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 EGRIFTASV. 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 in Europe by the EMA on September 26, 2019, 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.

In connection with our decision to stop the commercialization of Trogarzo® in Europe in the fiscal year 2022, we filed a request with the EMA seeking the withdrawal of the marketing authorisation for Trogarzo® as an approved product in Europe as of January 1, 2023 and such request was granted by the EMA. A similar request was also filed with the Medecines and Healthcare products Regulatory Agency in the United Kingdom and such request was granted.

As a result of the withdrawal of Trogarzo® as an approved product in Europe, our obligation to conduct a pediatric study and any other post-approval studies related to this product have ceased.

However, we are continuing the conduct of our efficacy study in the United States, the PROMISE-US study, as we believe data generated through this study will help the medical community to acknowledge the value of Trogarzo® in the United States. The costs of the PROMISE-US study are entirely borne by the Corporation. The PROMISE-US 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®.

Trogarzo® is available as a single dose, 2 mL vial containing 150 mg/mL of ibalizumab-uiyk. Each vial delivers approximately 1.33 mL 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. This maintenance dose is either administrated intravenously or through the new intravenous push method of administration approved by the FDA in October 2022. The new intravenous push method administers the same drug product, as an undiluted maintenance dose over 30 seconds, eliminating the need for infusion supplies, reducing duration time of dosing and improving convenience for patients and physicians. Further, many HIV clinics previously unable to administer infusions due to State regulation or institutional policies will now be able to administer Trogarzo® using this new method.See "Item 2.6 – Research and Development Activities – Ibalizumab – Intramuscular Method of Administration of Trogarzo" below.

Trogarzo® was developed by TaiMed and we have an exclusive license to distribute this product in Canada and in the United States. Effective December 15, 2022, we no longer have the commercial rights to distribute Trogarzo® in Europe. 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 nor are expected.

## 2.5 COMMERCIALIZATION ACTIVITIES

## EGRIFTA SV® - United States

#### General

 $EGRIFTA\ SV^{\$}$  (tesamorelin for injection) is commercialized in the United States. Prior to November 2019, the date on which  $EGRIFTA\ SV^{\$}$  became commercially available in the United States,  $EGRIFTA^{\$}$  (tesamorelin for injection) was also commercialized in the United States and Canada. However,  $EGRIFTA^{\$}$  is no longer offered for sale in the United States since being replaced by  $EGRIFTA\ SV^{\$}$  in the 2020 fiscal year. We have also discontinued the sale of  $EGRIFTA^{\$}$  in Canada in October 2022. 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  $EGRIFTASV^{\otimes}$ , 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. ("Bachem") and Jubilant HollisterStier, General Partnership, ("Jubilant"), for all of our required raw materials, drug substance and finished product for commercial sale and clinical trials.

We currently manufacture  $EGRIFTA\ SV^{\otimes}$  in a 2 mg/vial formulation and one vial of  $EGRIFTA\ SV^{\otimes}$  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 (the "Bachem Agreement") relating to the manufacture and supply of the active pharmaceutical ingredient of tesamorelin (the "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.

#### 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 (the "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.

We have an agreement with Lyophilization Services of New England, Inc. ("LSNE") providing for the manufacture and supply of the finished form of the F8 Formulation pursuant to the terms of a commercial supply agreement with an effective date of May 11, 2020.

#### Injection Kit

In connection with the sale of  $EGRIFTA\ SV^{\otimes}$ , we provide patients with the necessary devices to administer  $EGRIFTA\ SV^{\otimes}$ . These devices are comprised of syringes, needles and water for injection. In the United States, we have an agreement with Hospira Worldwide, Inc. ("Hospira") pursuant to which Hospira provides us with sterile water for injection. The packaging of those devices is done through Sharp Clinical Services Inc. ('Sharp") a third-party service provider. The packaging agreement with Sharp was entered into in August 2017 (the "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 1<sup>st</sup>, 2017, we entered into an amended and restated master services agreement with RxC Acquisition Company, LLC ("RxCrossroads") along with two amended and restated statements of work (the "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 principal wholesalers for  $EGRIFTA\ SV^{\circledR}$ : Cardinal Health, McKesson Corporation, 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  $EGRIFTA\ SV^{\circledR}$  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 (the "TaiMed Agreement") and, on March 6, 2017, we amended and restated the TaiMed Agreement, as further

amended. 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 (collectively, the "European Territory"). TaiMed has kept all rights related to the further development of ibalizumab.

On April 27, 2022, we notified TaiMed pursuant to the terms of the TaiMed Agreement that we were terminating our rights to commercialize Trogarzo<sup>®</sup> in the European Territory. Such notice of termination became effective on December 15, 2022.

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 to date, it is unlikely that a filing seeking the approval of Trogarzo® in Canada will be made.

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 is payable in two annual equal installments of US\$1,500,000 each, with the first one expected to be paid in the first half of the 2023 fiscal year, while the second one will be paid 12 months after the date of payment of the first installment.

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. We are not aware of any development plan for an injection formulation.

## Manufacturing

TaiMed is responsible to manufacture and supply Trogarzo<sup>®</sup> to us for each country forming part of the North American Territory. TaiMed has subcontracted the manufacture of Trogarzo<sup>®</sup> to WuXi Apptec Biologics, Inc., ("WuXi") in China, and to Samsung Biologics Laboratories, in South Korea.

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

## Specialty Pharmacies and Distributors

We have entered into agreements with specialty pharmacies, a specialty distributor, 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 Caremark, LLC ("Caremark"), Accredo Health Group, Inc. ("Accredo"), Option Care Enterprises, Inc. ("Option Care"), Priority Healthcare Distribution, Inc. ("Curascript"), and Walgreen Co. ("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 distributor that can deliver Trogarzo® to physicians and Caremark and Walgreen are specialty pharmacies.

In the European Territory, Trogarzo® was approved by the EMA on September 26, 2019. Pursuant to the TaiMed Agreement, we were responsible for all regulatory activities, including regulatory filings and communications with the EMA, in addition to all commercialization activities. Since December 15, 2022, we are no longer involved in the commercialization of Trogarzo® in the European Territory.

## Marketing and Sales of Our Products

North American Territory

Our marketing and sales activities in the United States for  $EGRIFTA\ SV^{\circledR}$  and Trogarzo $^{\circledR}$  are conducted from our head office in Montreal, Québec, Canada. We have also retained the services of Syneos Health ("Syneos") to assist us with market access and reimbursement activities in the United States. The market access and reimbursement teams provided by Syneos are solely dedicated to our products. Syneos is a recognized provider of 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 (the "Syneos Agreement") pursuant to which Syneos will continue providing us with certain services in connection with the commercialization of  $EGRIFTA\ SV^{\circledR}$  and Trogarzo $^{\circledR}$  in the United States until November 30, 2024. The Syneos Agreement contains customary representations and warranties, indemnification, confidentiality, intellectual property and termination provisions.

We have contracted with Asembia, LLC ("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, to date, we do not expect seeking its approval for sale in Canada.

Other Territories

#### EGRIFTA SV®

*EGRIFTA SV*® is not approved in any country outside of the United States.

In November 2022, we entered into an agreement with foreign distributors providing them with the exclusive right to distribute EGRIFTA  $SV^{(g)}$  under named patient programs only in various countries based in the regions of Latin America, Middle East, North Africa and Turkey and Central and Eastern Europe. This agreement has a five-year term. The exclusive distributors have no minimum purchase obligations but have to buy and pay EGRIFTA  $SV^{(g)}$  in U.S. denominated dollars at a discount to the current list price in the United States or at a discount to the price at which they are entitled to sell it in a country under the named patient program of such country. This agreement does not impose annual minimum purchases on the distributors but contains restrictive covenants regarding the sale of competitive products to EGRIFTA  $SV^{(g)}$ .

## <u>Trogarzo®</u>

Trogarzo® was commercially available in the European Territory through our European subsidiary, Theratechnologies Europe Limited, until December 15, 2022, the effective date on which all of our commercialization rights to Trogarzo® were returned to TaiMed under the TaiMed Agreement.

Since our decision to return to TaiMed our commercial rights to Trogarzo® in the European Territory, we have ceased all activities related to pricing and reimbursement of this product in the various European countries in which such activities were ongoing.

## 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**

EGRIFTA SV® Human Factors Study

Following complaints received from patients relating to the reconstitution of *EGRIFTA SV*® after its launch in 2019, we have submitted in March 2021 to the FDA a Changes Being Effected ("CBE") supplement to the Instructions For Use ("IFU") included in the *EGRIFTA SV*® product labeling and, per the timelines set forth in the regulation, we implemented these changes, which included an amended IFU. We also provided patients with detailed training through our call center, *THERA Patient Support*®, related to the changes and the number of complaints has since been significantly reduced. The FDA responded to our CBE supplement with a complete response letter asking us to carry out a HFS to ensure that patients reconstitute the product in the proper manner. We had one year to complete and resubmit the supplemental application including the HFS to the FDA and the FDA has recently granted until September 15, 2023, a six-month extension period, to submit the response to the FDA complete response letter. The first part of the HFS, the formative study, has now been completed and the Company filed its proposed HFS protocol with the FDA for its review prior to initiate the summative study. The Company has yet to receive a response from the FDA on its proposed protocol.

#### 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  $EGRIFTA\ SV^{\otimes}$  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. To date, all process validation batches have been manufactured.

The F8 Formulation requires the use of bacteriostatic water for injection ("BWFI") since the reconstituted product will be used for seven daily injections. In the spring of 2022, we were informed by the sole global supplier of BWFI that its manufacturing plant had been the subject of an FDA inspection that resulted in this supplier having to make modifications to its facilities before being able to resume manufacturing and shipment of its BWFI. As a result, our plan to file a sBLA by the end of the first quarter of 2022 had to be delayed until this supplier could resume the manufacture of BWFI and the shipment thereof or until we could find an alternate supplier to source BWFI. We have entered into a development agreement with a third party supplier for the manufacture of our own supply of BWFI and, to date, the engineering and validation batches of BWFI have been manufactured. We have initiated discussions with this third party supplier with the aim of entering into a long term supply agreement for BWFI. In addition, with the requirement of the FDA to conduct a HFS for *EGRIFTA SV*®, we have proactively decided to conduct one for the F8 Formulation as well prior to submitting a sBLA seeking the approval of the F8 Formulation. This study is expected to be completed after the *EGRIFTA SV*® HFS. We now plan on filing an sBLA with the FDA seeking the approval of the F8 Formulation in the fourth quarter of 2023 for the treatment of lipodystrophy in people living with HIV.

The F8 Formulation is also intended to be used in our Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population. See "Tesamorelin for NASH in the General Population" below.

## Multi-Dose Pen Injector

In the fiscal year 2021, 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 assessing the feasibility. As a result, no timeline has been set for the development of 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 ("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.

In July 2021, we 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. To date, we are still continuing to seek a partner and discussions are still ongoing.

In order to de-risk the Phase 3 trial, in February 2022, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address these with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes 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. The amended protocol would allow us to generate hard endpoint data on NAS score and fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

NAFLD includes nonalcoholic fatty liver ("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.

#### **Ibalizumab**

Intramuscular Method of Administration of Trogarzo®

The Corporation has now completed the enrollment of all patients for this study and the study is completed. We are presently completing the analysis of the data related thereto. The study consisted of assessing the safety and pharmacokinetic levels of Trogarzo® when administered intramuscularly using a syringe. We expect to file a sBLA with the FDA seeking the approval of the intramuscular method of administration in the course of the 2023 fiscal year.

#### TH1902

Phase 1 Clinical Trial

In December 2020, we filed an IND application with the FDA for the initiation of a 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, we initiated our Phase 1 clinical trial evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design included a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose (the "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 B of the Phase 1 clinical trial, also known as the "basket trial" consisted in recruiting a total of approximately 70 patients to study the safety and tolerability of TH1902 in the following various solid tumor types, including HR+ breast cancer, triple negative breast cancer, ovarian cancer, endometrial cancer, melanoma, thyroid cancer, small cell lung cancer, and prostate cancer.

As per the study protocol, the MTD is established once a significant adverse event is observed in two or more patients.

Part A of the Phase 1 clinical trial was completed in the summer of 2022. We then reported that a total of 18 heavily pre-treated patients, who received an average of eight prior cancer treatments, were enrolled in the dose escalation portion of the study. Following the safety observations at 420 mg/m2 including grade 3 neuropathy, grade 4 neutropenia, grade 3 ocular changes (visual acuity, keratitis and ocular surface dryness) and grade 2 skin toxicities (rash, pruritis and inflammation), the dose of TH1902 was decreased to 300 mg/m2 for the next dose level and was expanded to a total of six patients. No dose limiting toxicities ("DLTs") were observed during the first cycle, therefore, the dose of 300 mg/m2 was selected for continuation of the basket trial.

In addition, we reported that the levels of free docetaxel were low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m2. 300 mg/m2 appeared to be a well-tolerated dose level.

We further reported the observation of signs of efficacy in three heavily pretreated patients and the recorded results included:

- confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m2, although the prostate specific antigen ("PSA") continued to progress;
- stabilized disease in a prostate cancer patient with measurable reduction in target lesion sizes (single digit percentages), including one PSA response (the patient was treated with mixed cycles of TH1902 from 420 mg/m2 to 300 mg/m2); and
- stabilized disease in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages) after receiving a total of 11 cycles (the patient's dose was escalated from 60 mg/m2 to 360 mg/m2).

Following the determination of the MTD, we began enrolling patients in the basket trial and, in December 2022, we decided to voluntarily pause the enrollment of patients and revisit the study design of our clinical trial studying TH1902 in various types of cancer. The decision was made after consulting with our investigators. The efficacy results observed were not convincing enough to pursue the enrollment of patients and did not outweigh the adverse events seen in some patients.

The Corporation is currently studying the data from its Phase 1 clinical trial and has formed a scientific advisory committee ("SAC") comprised of the study's principal investigator, and several medical oncologists from across the United States who are leading experts in the end-to-end lifecycle of oncology drug development to help determine the best developmental path forward for TH1902. The meeting of the SAC is scheduled to take place in the latter half of March 2023.

Further to our decision to voluntarily pause the enrollment of patients, we have had discussions with the FDA. Following such discussions, we received a letter from the FDA indicating that our Phase 1 clinical trial was placed

on a partial clinical hold subject to our responses to a list of questions. We intend to respond to the FDA's questions along with the filing of the amended protocol. Questions raised by the FDA were already being addressed by our team as part of our analysis of the data accumulated so far in the Phase 1 clinical trial and we are confident that we will be able to address all of the FDA's questions. The FDA indicated that their review of the protocol amendment would be completed within thirty days of submission.

Consistent with our 2023 objectives of achieving a positive Adjusted EBITDA, any new investment in the development of TH1902 will be stage-gated. Once the Phase 1 clinical trial has resumed, we plan on evaluating potential partnerships for TH1902.

## SORT1+ Technology<sup>TM</sup> Platform

### Description

SORT1+ Technology<sup>TM</sup> is the name we gave our platform that provides for the development of new proprietary peptides for cancer drug development targeting SORT1 receptors. 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 the SORT1+ Technology<sup>TM</sup> 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, SN38 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+ Technology<sup>TM</sup>, 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.

We are no longer conducting research and development work on TH1904, one of our other investigational PDCs. However, we continue the conduct of research and development activities on other PDCs, primarily to advance a PDC using SN38.

Since announcing our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 in various types of cancer, partnership discussions in Greater China regarding the development and commercialization of TH1902 have been paused as well.

## Acquisition of SORT1+ Technology™ Platform

We acquired the SORT1+ Technology  $^{TM}$  platform following the acquisition of all of the issued and outstanding shares of Katana BioPharma Inc. ("Katana") on February 25, 2019 (the "Katana Agreement"). Katana had the exclusive worldwide rights, through a royalty-bearing licence agreement entered into with Transfert Plus, LP

("Transfert Plus"), to a technology platform using peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells (the "Transfert Plus License Agreement"). Katana has since been wound up into Theratechnologies and we became a party to the Transfer Plus License Agreement.

In consideration of the acquisition of all of the issued and outstanding shares of Katana, the Corporation agreed to pay a purchase price aggregating CAD 6.9 million in various tranches. To date, there remains a balance of CAD 2,880,000 payable through the issuance of common shares upon our decision to pursue the development of TH1902, or any other PDCs studied in a Phase 1 clinical trial, that warrant the pursuit of its development beyond the completion of such Phase 1 clinical trial.

Description of the Transfert Plus License 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.

### 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 proven nor approved by the FDA. Other approaches to reduce excess abdominal fat include coping mechanisms such as lifestyle modification (diet and exercise), switching antiretroviral therapy, or liposuction.

## **Trogarzo®**

Fostemsavir and Lenacapavir are direct competitors to Trogarzo<sup>®</sup>. Contrary to Fostemsavir which is administered orally twice per day, Trogarzo<sup>®</sup> is a long-acting ARV that only needs to be administered intravenously every two weeks. Lenacapavir has been approved by the FDA in December 2022. Like Fostemsavir, Lenacapavir's indication for use targets the same patient population as that of Trogarzo<sup>®</sup>. Lenacapavir is administrated subcutaneously once every six months. In addition, we are aware of other agents including, but not limited to, dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens for the treatment of heavily treatment-experienced patients with MDR HIV-1.

### Tesamorelin for the Treatment of NASH in the General Population

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

## SORT1+ Technology<sup>TM</sup> 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 PDCs, could be used in various types of cancers. Our Phase 1 clinical trial studying TH1902 in various types of cancer has been voluntarily paused and there can be no guarantee that our Phase 1 clinical trial will resume and, to the extent it resumes, that we will observe positive signs of safety and efficacy. Even if successful, by the time we enter the market, there may be approved medicines that would directly compete with TH1902 or any other PDCs we may develop.

### 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, 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  $SV^{\otimes}$  and  $Trogarzo^{\otimes}$  in the United States.

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®* and/or Trogarzo®), and criminal penalties, including imprisonment; further, an alleged violation of the Anti-kickback Statute could be used as a basis for a federal or state false claims law challenge. 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, medical 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. There are a number of states that have similar reporting and disclosure requirements, and failure to comply with these laws could have adverse consequences.

#### **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.

## **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.

### 2.9 PHARMACEUTICAL PRICING AND REIMBURSEMENT

In the United States and in other countries, sales of  $EGRIFTA~SV^{\circledR}$  and Trogarzo $^{\circledR}$  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  $EGRIFTA\ SV^{\$}$  and  $Trogarzo^{\$}$ .  $EGRIFTA\ SV^{\$}$  and/or  $Trogarzo^{\$}$  may not be considered cost-effective. It is time consuming and expensive for us, and our commercial partners, to seek reimbursement from

third-party payors. Reimbursement may not be available or sufficient to allow us, or our commercial partners, to sell EGRIFTA SV<sup>®</sup> and/or Trogarzo<sup>®</sup> 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 were delayed until July 1, 2022. 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.

The passage of the Inflation Reduction Act (IRA) of 2022 shall further impact Medicare reimbursement. The IRA has three key elements reforming Medicare drug pricing policy. The implementation of these changes under the IRA are still forthcoming, so the specific implications for pharmaceutical pricing and reimbursement are yet to be determined. Likewise, we are unable to predict potential modification, amendment, or repeal of the IRA, though some predict that challenges may be made to the Act in 2023 or beyond as different provisions are enacted.

As the first key element, the IRA created a Medicare drug price negotiation program enabling the Secretary of the U.S. Department of Health and Human Services to negotiate the prices of certain costly, single-source drugs or biologics within the Medicare program. Certain drugs are excluded from this negotiation process, such as drugs that are less than 9 years, or biologics less than 13 years, from their FDA-approval or licensure date, and drugs with an orphan designation as their only FDA-approved indication. The first set of these negotiated prices will not take effect until 2026.

Second, the IRA requires drug manufacturers to pay rebates to the federal government for price increases above the rate of inflation for single-source drugs or biologics covered under Medicare Part B and most drugs under Medicare Part D, which already occurs under the Medicaid program. This inflation rebate provision for Medicare Part B took effect at the start of 2023, and such provision for Medicare Part D took effect in 2022 as the starting point for measuring drug price increases, with rebate payments required beginning in 2023.

Third, the IRA restructures the Medicare Part D benefit to limit patients' out-of-pocket costs and rebalance the bearing of risk for Part D plans and manufacturers. Some of these changes are set to take effect in 2024, while other aspects of this provision will take effect in 2025.

As mentioned previously, industry is still waiting to understand the full implications of these changes and the practical impact on pharmaceutical pricing and reimbursement.

# 2.10 <u>INTELLECTUAL PROPERTY</u>

As further described below, tesamorelin, the active ingredient of  $EGRIFTASV^{\otimes}$ , is protected by patents in the United States and in certain European countries.

Our PDCs stemming from our licensed SORT1+ Technology $^{\text{TM}}$  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. 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 August 2023;
- We also own patents in several other countries relating to the use of tesamorelin in the treatment of HIV--associated lipodystrophy, which are scheduled to expire from May 2023 to October 2025;
- In the United States, we have the exclusive rights to two patients that claim methods for the treatment of NAFL or NASH in a patient, as well as for reducing liver fibrosis and the risk of liver cancer in such patients, via the administration of tesamorelin. These patents are scheduled to expire in 2040;
- In the United States, we also have the exclusive rights to an additional patent application that claims a method for preventing or delaying the onset of cirrhosis or for treating cirrhosis, in a patient suffering from NAFL or NASH, via the administration of tesamorelin. This application, if granted, would be scheduled to expire in 2040;
- We also have the exclusive rights to patent applications in several other countries relating to the treatment of NAFL or NASH in a patient. These applications, if granted, would be 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;
- We have also filed patent applications in the US and Canada related to the use of the F4 formulation in a treatment regimen bioequivalent to the original formulation of EGRIFTA®. These applications, if granted, would be scheduled to expire in 2039; and
- We have also filed a PCT patent application in June 2021 and are currently filing corresponding patent applications in the US and several other jurisdictions, relating to the use of the F8 formulation in a treatment regimen bioequivalent to the original formulation of EGRIFTA®. These applications, if granted, would be scheduled to expire in 2041.

SORT1+ Technology™

Our currently licensed patent portfolio related to the SORT1+ Technology<sup>™</sup> 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+ Technology™ platform, which is scheduled to expire in 2037;
- In the United States, we also have the exclusive rights to a patent application relating to peptides in respect of the SORT1+ Technology™ platform. This application, if granted, would be scheduled to expire in 2036;
- In Europe, we have the exclusive rights to a patent relating to peptides and conjugates in respect of the SORT1+ Technology™ platform. This patent is scheduled to expire in 2036 and is validated in certain major European countries;

- In Europe, we also have the exclusive rights to a patent application relating to additional peptides and conjugates in respect of the SORT1+ Technology™ platform. This application, if granted, would be scheduled to expire in 2036 and may be 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+ Technology™ 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+ Technology™ 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;
- We own patent applications filed in several countries relating to formulations of conjugates in respect of the SORT1+ Technology™ platform. Such applications, if granted, would be scheduled to expire in 2040; and
- We also have exclusive rights to a PCT patent application filed in February 2022 relating to the use of peptides and conjugates in respect of the SORT1+ Technology™ platform for the treatment of cancers comprising Sortilin-expressing cancer stem cells (CSCs), which are typically associated with poor prognosis and often exhibit resistance to common chemotherapeutic approaches. Patent applications may be pursued in numerous jurisdictions stemming from this PCT application. Such applications, if granted, would be scheduled to expire in 2042.

### 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.

### **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 license 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*<sup>TM</sup> 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 EMPLOYEES

As at November 30, 2022, we had 89 employees in Canada, 47 employees in the United States and 8 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, 2022, we had an additional 13 persons dedicated to the commercialization of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States.

## 2.12 <u>FACILITIES</u>

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 have a place of business in the United States located at 101 Hudson Street, 21st Floor, in the City of Jersey City, New Jersey, where we lease an office space. We also moved our place of business in Ireland to 12 Duke Street, 1st Floor, Royal Hibernian Way, Dublin 2 where we lease a 1,765 square-foot office space.

We also conduct our research and development activities in laboratories leased from the Université du Québec à Montréal, in Montreal, Canada, and in laboratories subleased from Repare Therapeutics Inc., in Montréal, Canada.

# 2.13 <u>ENVIRONMENT</u>

To our knowledge, in the last financial year, environmental issues did 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 CORPORATION'S CASH POSITION

The Corporation's report of independent registered public accounting firm (the "Auditors Report") to shareholders and the Board of Directors of the Corporation, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022 contains a going concern note about the Corporation's ability to continue as a going concern and its capacity to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. The going concern note casts substantial doubt about the capacity of the Corporation to meet its monetary obligations. The inclusion of a going concern note in the Corporation's Auditors Report triggers an event of default under the Marathon Credit Facility. However, in connection with the issuance of the Auditors Report for the fiscal year ended November 30, 2022, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that additional amendments or waivers of such event of default will be obtained from Marathon in future years if the yearly Auditors Report of the Corporation contains a going concern note. In the event there occurs an event of default under the Marathon Credit facility, the interest rate payable on the loaned amount increases by 300 basis points and Marathon has the right to declare all amounts outstanding under the loan immediately due and payable and not fund any additional tranches under the Marathon Credit Facility. If Marathon was to declare all loaned amounts due and payable under the Marathon Credit Facility, the Corporation would not currently be able to repay such amount unless it secures additional financings. Therefore, the Corporation would have to issue additional equity or secure access to alternative funding enabling it to repay wholly the loaned amounts under the Marathon Credit Facility. The issuance of additional equity would dilute current shareholders and such dilution could be substantial depending on the amount of money the Corporation would have to raise and the price at which such equity offering would be made. In the event the Corporation is unable to implement measures allowing it to secure the repayment of its debt, the Corporation could also have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

The Corporation's Auditors Report to the shareholders and Board of Directors, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022, contains a going concern note about the Corporation's ability to continue as a going concern and the capacity of the Corporation to realize its assets and discharge its liabilities and commitments in the normal course of business. The going concern note casts doubt about the capacity of the Corporation to meet its monetary obligations. For the year ended November 30, 2022, the Company incurred a net loss of \$47.2 million and had negative operating cash flows of \$14.7 million. The Corporation's total current liabilities exceeded total current assets at November 30, 2022. The Corporation's outstanding \$27.5 million convertible unsecured senior notes mature on June 30, 2023 (the "Notes") requiring the Corporation to use its cash balance to repay the principal of the Notes.

The Marathon Credit Facility contains various covenants, including a prohibition on the inclusion of a going concern note in the Corporation's Auditors Report. The inclusion of a going concern note in the Corporation's Auditors' Report related to the Corporation's audited consolidated financial statements would trigger an event of default under the Marathon Credit Facility resulting in the interest rate payable on any outstanding loaned amount to be increased by 300 basis points and would allow Marathon to declare such principal amount and interest

thereon immediately due and payable. Marathon would also no longer have the obligation to fund any additional tranches under the Marathon Credit Facility and would have the option to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation.

Subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation for the fiscal year ended November 30, 2022, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that Marathon will agree to amend the Marathon Credit Facility or grant a waiver in future years if the Corporation's future Auditors Report include a going concern note. The failure to amend the Marathon Credit Facility or to obtain a waiver from Marathon in future years in the event additional going concern notes are included in the Corporation's Auditors Reports could have a material adverse effect on the Corporation and its business prospects in the event Marathon declares all principal amounts and interest thereon immediately due and payable and the Corporation is unable to repay the loaned amounts.

An event of default under the Marathon Credit Facility resulting in Marathon declaring all principal amount and interest thereon immediately due and payable would require the Corporation to seek and find alternative sources of financing. Such alternative sources of financing could be the issuance of equity, subject to then prevailing market conditions. The issuance of equity security would dilute shareholders and such dilution could be substantial depending on the price at which the equity offering would be made and the amount to be raised. If the Corporation was unable to secure additional financing to repay any of its outstanding loaned amount, the Corporation could have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

We did not generate a profit from our operations in the fiscal year ended November 30, 2022. In addition, despite announcing our goal to achieve a positive Adjusted EBITDA by the end of the 2023 fiscal year, there can be no guarantee that we will achieve this milestone, nor that we will achieve profitability.

We have a history of net losses, including a net loss of \$47.2 million for the fiscal year ended November 30, 2022. In the future, our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*® and Trogarzo® successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel, 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. Our profitability will also depend on our ability and capacity to control our operating expenses.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*® and Trogarzo® in the United States. 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 obtain or sustain profitability.

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

Our ability to repay the \$27.5 million outstanding Notes due on June 30, 2023 requires that we access the \$20 million second tranche of the loan under the Marathon Credit Facility or obtain alternative equity financing in the near term and also depends on our future financial and operating performance to avoid, among other things, being in default under the Marathon Credit Facility. Future financial and operating performance remain subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to achieve a level of positive cash flows from operating activities sufficient to pay the principal and interest on the loan provided by Marathon or our Notes. Furthermore, 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) and, therefore, we need to ensure we have adequate cash resources available by June 30, 2023, to repay the Notes and to continue our operations.

To mitigate the aforementioned risk, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to remove as a condition to accessing the \$20 million second tranche of the loan, being the filing to the FDA of the results of the HFS the Corporation is currently conducting. Notwithstanding the removal of this condition, access to the \$20 million second tranche remains subject to compliance by June 30, 2023 with a twelve-month revenue target of \$75 million and other covenants. As a result, there remain risks under the Marathon Credit Facility that the Corporation will not be able to access the second tranche for the repayment of the Notes on June 30, 2023 since a default under the Marathon Credit Facility, unless waived by Marathon, prevents the Corporation from borrowing additional money.

For the year ended November 30, 2022, the Corporation had negative operating cash flows of \$14.7 million. In addition, the Corporation had a working capital deficiency (total current liabilities exceed total current assets) at November 30, 2022 of \$40.9 million due in part to the amount borrowed under the Marathon Credit Facility being classified as a current liability as a result of the amendment to the Marathon Credit Facility having been entered into after the fiscal year end of the Corporation. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay expenditures and capital additions, 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 or in the absence of accessing the \$20 million second tranche, we could face substantial liquidity problems and we could have to resort to insolvency laws to seek protection from our creditors.

Interest rate fluctuations may have a material adverse effect on our capacity to reimburse the loaned amounts under the Marathon Credit Facility and on our capacity to execute on our business plan.

The interest rate we have to pay Marathon under the Marathon Credit Facility is based on the Secured Overnight Financing Rate ("SOFR"), plus 9.5%.

SOFR is a broad measure of the cost of borrowing cash overnight collateralized by U.S. Treasury securities. SOFR has a limited history, and the future performance of SOFR cannot be predicted based on its limited historical performance. The level of SOFR may bear little or no relation to historical actual or indicative data. Prior observed patterns, if any, in the behavior of market variables and their relation to SOFR, such as correlations, may change in the future. While some pre-publication historical data have been released by the Federal Reserve Bank of New York, such analysis inherently involves assumptions, estimates and approximations, and hypothetical or historical performance data are not indicative of, and have no bearing on, the potential performance of SOFR. The future performance of SOFR is therefore impossible to predict, and no future performance of SOFR may be inferred from any of the historical actual or indicative data. Changes in the levels of SOFR will affect the interest rate we have to pay to Marathon under the Marathon Credit Facility during the term of the loan and may adversely affect the amount of cash we will have to allocate to the repayment of the loan.

Interest rates are highly sensitive to many factors, including governmental monetary policies, domestic and international economic and political conditions, and other factors beyond our control. If SOFR increases as a result of events over which we have no control, this could have a material adverse effect on our financial condition and results of operations. If SOFR increases, our debt service obligations would increase even if the amount borrowed remained the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease.

The Marathon Credit Facility includes significant operating and financial restrictions on the Corporation, any of which could prevent us from capitalizing on business opportunities. In addition, our failure to comply with such restrictions could trigger an event of default which would increase by 300 basis points the interest payable on any loaned amounts under the Marathon Credit Facility and would allow Marathon to declare the outstanding loaned amounts immediately due and payable in addition to providing Marathon with the right to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation. If we are unable to cure an event of default or obtain a waiver from Marathon in relation to such

event of default, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws.

The Marathon Credit Facility governing our outstanding \$40 million loan and potential additional tranches which may be drawn thereunder impose significant operating and financial restrictions on the Corporation. These restrictions limit our ability and the ability of certain of our subsidiaries to, among other things: (i) incur or guarantee additional debt or issue disqualified stock or preferred stock; (ii) pay dividends and make other distributions on, or redeem or repurchase, capital stock; (iii) make certain investments; (iv) incur additional liens; (v) enter into transactions related to the acquisition, disposition, in-licensing or out-licensing of assets; and (vi) merge or consolidate.

In addition, the Marathon Credit Facility imposes that we maintain a minimum of \$20 million in cash and cash equivalent at all times. This minimum liquidity amount goes up to \$30 million if we do not obtain the approval of the F8 Formulation by March 31, 2024. The minimum liquidity covenant restricts the management of the Corporation's liquidity and could increase the likelihood that the Corporation may not be able to meet its obligations as they become due. The Marathon Credit facility also imposes revenue targets on a quarterly basis. The Marathon Credit Facility further imposes reporting requirements on our business activities on a quarterly basis. These reporting requirements extend beyond those that we have to comply with under securities regulations and add a layer of complexity to our reporting obligations. The minimum liquidity covenant restricts the management of the Corporation's liquidity and increases the likelihood that the Corporation may not be able to meet its obligations as they become due. As a result of the restrictions and obligations described above, we will be limited as to how we conduct our business and we may be unable to enter into transactions that may be accretive to our business to compete effectively or to take advantage of new business opportunities. Debt financing opportunities will also be limited in the event that we are unable to raise capital through the issuance of equity. There can be no assurances that we will be able to maintain compliance with these requirements and covenants in the future and, if we fail to do so, that we will be able to obtain waivers from Marathon and/or amend the covenants contained in the Marathon Credit Facility to remove those obligations.

Our failure to comply with the covenants described above as well as other terms of our indebtedness will result in an event of default under the Marathon Credit Facility which, if not cured or waived, will result in an increase of 300 basis point on the interest payable on the outstanding loaned amount. An event of default under the Marathon Credit Facility would also allow Marathon to declare all loaned amounts immediately due and payable and entitle Marathon to execute on its first ranking security interest on all of our assets and foreclose on our assets. If we were to default under the Marathon Credit Facility and Marathon were to declare all amounts outstanding under the loan immediately due and payable, this would also trigger a default under the terms of the Notes. In the event there occurs an event of default under the Marathon Credit Facility and we are unable to cure such event of default or obtain a waiver from Marathon in relation thereto, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws. Any of those circumstances will have a material adverse effect on shareholders as they will lose the entire value of their investment in the capital of the Corporation.

## 3.2 RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS

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

Our ability to generate revenue and sustain growth is currently concentrated solely on the commercialization of EGRIFTA SV® and Trogarzo® in the United States. Our success in generating sales revenue from EGRIFTA SV® and Trogarzo® in the United States will depend on our capacity: (a) to pursue the deployment of a commercialization strategy that will be accepted by patients, healthcare professionals and third-party payors; (b) to maintain reimbursement coverage for EGRIFTA SV® and Trogarzo® by third-party payors; (c) to maintain the registration of EGRIFTA SV® and Trogarzo® on U.S. governmental forms as drugs available for purchase in the

United States; (d) to ensure that adequate supplies of *EGRIFTA SV®* and Trogarzo® are available; (e) to maintain conflict-free relationships with our principal third-party suppliers of services, namely our manufacturers (TaiMed and Jubilant HollisterStier, General Partnership ("Jubilant")), our distributor in the United States (RxC Acquisition Company, LLC ("RxCrossroads")), as well as other specialized third parties; and (f) to defend our intellectual property rights regarding tesamorelin against third parties.

Our success in commercializing our products in the United States will also depend on our capacity 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 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 solely 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 some of our core business activities pertaining to the commercialization of our products, namely their manufacturing and distribution. 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®*. We will also rely on a single third-party supplier, LSNE for the manufacture of the F8 Formulation. 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*®, for the F8 Formulation and for our potential Phase 2b/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 suppliers, WuXi and Samsung. We are not in a contractual relationship with WuXi and Samsung for Trogarzo® and, therefore, we may not be able to interact with any of them 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  $EGRIFTA\ SV^{\otimes}$ , Trogarzo $^{\otimes}$  or any other product we may acquire or in-license and we have not made any application 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  $EGRIFTA\ SV^{\otimes}$  and Trogarzo $^{\otimes}$  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  $EGRIFTA\ SV^{\otimes}$  and Trogarzo $^{\otimes}$ , 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.

Syneos Health, Inc. ("Syneos") continues to provide us with support for the commercialization of  $EGRIFTA\ SV^{\circledR}$  and Trogarzo<sup>®</sup> in the United States through the provision of personnel as part of the managed market and reimbursement teams. Although we are aware that there exist 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 may retain contract research organizations ("CROs") to support us with the conduct of 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 a sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers for some 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  $EGRIFTA\ SV^{\otimes}$ , the

F8 Formulation and Trogarzo® if a third-party manufacturer: (a) becomes unavailable to us, or to TaiMed, for any reason, including as a result of the failure to comply with GMP regulations; (b) 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 (c) fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis or not meeting product specifications.

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA SV*® and Trogarzo® in the United States if: (a) RxCrossroads becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws; (b) RxCrossroads 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 (c) RxCrossroads 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 we may face reimbursement challenges if Syneos (a) 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*<sup>®</sup> and/or Trogarzo<sup>®</sup>; (b) experiences compliance issues with the FDA; or (c) fails to perform its contractual obligations under our agreement.

Significant safety problems may arise with respect to EGRIFTA  $SV^{\otimes}$  and Trogarzo which could result in restrictions in EGRIFTA  $SV^{\otimes}$ 's or Trogarzo is 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® and Trogarzo®.

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. 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  $EGRIFTA\ SV^{\mathbb{R}}$  and Trogarzo $^{\mathbb{R}}$  to patients benefitting from U.S. Government funded reimbursement programs represent a significant part of our sales. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

# Even though EGRIFTA SV® and Trogarzo® are approved for sale in the United States, revenue that we generate from their sales may be limited.

Sales of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup> will continue to depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of these products will depend on a number of factors, including: (a) demonstrated product safety, including the prevalence and severity of side effects, and effectiveness as a treatment that addresses a significant unmet medical need; (b) storage requirements, dosing regimen and ease of administration; (c) the availability of competitive alternatives; (d) 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; (e) the willingness and ability of patients to pay out-of-pocket for medications; (f) the product price; and (g) the effectiveness of sales and marketing efforts.

If our products are not accepted by the marketplace, the revenue generated therefrom will be limited and our capacity to grow our revenue and become profitable will be hampered. Our failure to grow our revenue and to become profitable will adversely impact the value of the Corporation, including the market price of our shares. If we fail to 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 and Lenacapavir in the United States. In addition, we are aware of other agents, including dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens to treat heavily-treatment experienced patients with MDR HIV-1. 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.

The development of new therapies is 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 method or route of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology<sup>TM</sup> 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, a new method or route of administration or a drug product could hamper the future growth of our business and have long-term adverse effects on our potential revenues and operating results.

The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain given that, after consultation with investigators, we have voluntarily paused the enrollment of patients in the Phase 1 clinical trial since efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the Phase 1 clinical trial of TH1902 on partial clinical hold and asked a series of questions to the Corporation requiring satisfactory responses thereto prior to resuming the Phase 1 clinical trial. If the Corporation is unable to answer the questions raised by the FDA to the FDA's satisfaction and if the Corporation is unable to resume its Phase 1 clinical trial with TH1902, the Corporation will have to discontinue its Phase 1 clinical trial. Any halt in the Corporation's Phase 1 clinical trial could materially adversely affect the development of its SORT1+ Technology<sup>TM</sup> platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects.

The enrollment of patients in the Corporation's Phase 1 clinical trial evaluating TH1902 was voluntarily paused by the Corporation after consulting with its investigators. The efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the clinical trial on partial clinical hold and has issued a series of questions to the Corporation that will need to be answered to the satisfaction of the FDA prior to resuming the Phase 1 clinical trial. The Corporation has also formed a SAC to help determine the best developmental path forward for TH1902. The decision made by the Corporation illustrates that, to date, we have not been able to replicate results obtained from our preclinical *in vivo* work and that the conduct of clinical trials is risky as results may adversely vary from those that are expected.

If the Corporation is unable to resume its Phase 1 clinical trial with TH1902 because (i) it is unable to adequately answer to all of the questions raised by the FDA, (ii) the SAC is unable to agree on the best developmental path forward for TH1902, or (iii) the FDA does not accept the terms of an amended protocol, the development program of TH1902 will need to be halted. Any halt in the Corporation's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology<sup>TM</sup> platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects. Even if the Corporation is allowed to resume its Phase 1 clinical trial with TH1902, the Corporation may have difficulty enrolling new patients in the resumed trial. The difficulty in enrolling patients would cause additional delays in advancing the development of TH1902. In addition, there can be no guarantee that the results obtained from the resumed Phase 1 clinical trial would yield positive results. In the event that the resumed clinical trial did not yield positive results, the value associated to the SORT1+ Technology<sup>TM</sup> platform asset would be depreciated, thereby adversely impacting the market value of the Corporation, including the price of its Common Shares.

The conduct of research and development activities is very costly and capital intensive. We have already indicated that the development of tesamorelin for the treatment of NASH in the general population was on pause until we find a partner and that the development of TH1902 would be stage-gated in order to meet our goal of achieving a positive Adjusted EBITDA in the 2023 fiscal year. We have also indicated that we would

assess a partnership for the development of TH1902 once the Phase 1 clinical trial has resumed. If we are unable to find a partner for the development of tesamorelin for the treatment of NASH or for the pursuit of the development of TH1902 once the Phase 1 clinical trial has resumed, we may have to cease the development of those assets, any of which could have a material adverse effect on our long-term potential revenue growth and business prospects.

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

As a result of our assessment of the costs associated with our proposed Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population, we have decided to seek a partner prior to launching such trial. The contemplated development of tesamorelin for the treatment of NASH will require the enrollment of over 2,000 patients and the study will be conducted over many years. Therefore, we expect the development of tesamorelin for the treatment of NASH in the general population to cost multiple millions of dollars.

Consistent with our objective of achieving a positive Adjusted EBITDA by the end of the current fiscal year and beyond, we also announced that the development of TH1902 would be stage-gated and that further to resuming the Phase 1 clinical trial, we would assess partnering the development of TH1902.

There can be no assurance that we will be able to find a partner for either the development of tesamorelin for the potential treatment of NASH or for the further development of TH1902. Finding a partner for those development programs will depend on a variety of factors, including the preclinical and clinical data that we have generated for those drug candidates, the current advancement of the programs and the risk related thereto, the regulatory path to seek approval of those drug candidates, the market environment related to NASH and oncology, competition from other products and general market conditions. In addition, even if we were to find a partner for any of those programs, there can be no assurance that the terms and conditions contained in any partnership agreement would be suitable to us. The failure to find a partner for the development of tesamorelin for the potential treatment of NASH and the further development of TH1902 could lead to a halt in the development of those programs.

A complete halt in the conduct of those programs could adversely impact our long-term growth and business prospect since the Corporation would have a reduced pipeline of product candidates.

The Corporation has not filed a sBLA seeking the approval of the F8 Formulation and, consequently, the FDA has not approved the F8 Formulation as being bioequivalent to the Corporation's original formulation of EGRIFTA®. If the FDA does not approve the F8 Formulation, 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<sup>®</sup>. These studies were conducted based on the current FDA regulation to show the bioequivalence of formulations. The Corporation has not yet filed a sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for 2023.

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 and inventory write-downs, 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 pursuing the assessment of the development of the Pen, or any other device to be used with the F8 Formulation. Finally, the non-approval of the F8 Formulation would expose the Corporation to the entry of biosimilar versions of tesamorelin for the treatment of lipodystrophy given that the patent protection for this product will expire in August 2023. Since the F8 Formulation is patent protected until 2033 in the United States,

the commercialization of tesamorelin for the treatment of lipodystrophy using the F8 Formulation could protect the entry of biosimilar versions until the expiry of this patent in 2033.

The Corporation has decided to seek a partner to conduct a Phase 2b/3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. Although the Corporation has begun the search for a potential partner and preliminary discussions are ongoing, 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 may have to cancel this program unless it has access to substantial financial resources to pursue such development program and there can be no quarantee that the Corporation will secure such substantial resources in an amount sufficient to initiate or complete the Phase 2b/3 clinical trial. Moreover, the FDA has issued comments and asked questions on the revised protocol filed by the Corporation in February 2022 and the Corporation has voluntarily decided not to reply to those comments and questions until it can find a partner. In addition, the Corporation's decision to design its Phase 2b/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 find a partner to develop tesamorelin for the treatment of NASH in the general population or to secure substantial financial resources to do it on its own, the Corporation may cancel this program and the development of tesamorelin for the treatment of NASH may never occur. Even if the Corporation finds a partner, the conduct of the Phase 2b/3 clinical trial may be delayed or never begun if the Corporation is unable to properly address the comments and questions raised by the FDA based on the Corporation's amended protocol. Finally, if the Corporation is unable to meet the endpoints of its Phase 2b/3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. Even if the Corporation meets the endpoints of the clinical trial, the FDA could issue a conditional approval letter such that if the Corporation is unable to meet the conditions contained in such letter, the Corporation could lose such approval. 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.

In July 2021, we 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. There are currently ongoing preliminary discussions with potential partners.

In February 2022, in order to de-risk the Phase 3 trial, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address them with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes 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. The amended protocol would allow us to generate hard endpoint data on NAS score and fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

There can be no guarantee that tesamorelin will be studied for the treatment of NASH in the general population if the Corporation is unable to find a partner to conduct the development program on its own. 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 satisfactory to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the development of tesamorelin for the treatment of NASH in the general population or turn to alternative sources of financing. 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 business prospects.

Even if the Corporation finds a partner to initiate a Phase 2b/3 clinical trial, there can be no guarantee that the FDA will be satisfied with the responses to the questions and comments asked in connection with the amendments to the protocol filed in February 2022 and allow the initiation of such trial. Even if the FDA or any other regulatory agency approves the study of tesamorelin for the treatment of NASH in the general population, there can be no guarantee that the results will meet the endpoints of the study and that tesamorelin will be approved for such treatment. Even if the Corporation meets the FDA's primary endpoints and approval is received from the FDA, such approval may be conditioned on conducting additional studies which, if not conducted or if the results therefrom are not positive on certain clinical outcomes, could result in the FDA withdrawing its approval for the use of tesamorelin for the treatment of NASH in the general population.

The Corporation has decided to design its Phase 2b/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 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: (a) negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its clinical trial; (b) 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; (c) 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; (d) inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials; (e) 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; (f) severe or unexpected adverse drug effects experienced by patients; (g) 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; (h) 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 (i) 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.

### 3.4 RISKS RELATED TO OUR INTELLECTUAL PROPERTY

Our patent protection related to the use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is scheduled to expire in August 2023. Until we can commercialize tesamorelin using the F8 Formulation, the FDA-approved use of tesamorelin for the treatment of lipodystrophy will no longer be patent protected and we may face direct competition from biosimilar versions of EGRIFTA SV®. If we face competition from biosimilar products, our revenues are likely to be reduced thus adversely affecting our revenue growth and results of operations.

The use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is patent protected in the United States until August 2023. Tesamorelin, the composition of matter, is no longer patent protected and the formulation of  $EGRIFTA\ SV^{\otimes}$  is not patent protected. If, and when approved, the Corporation will rely on the use of the F8 Formulation to benefit from patent protection until 2033 in the United States in connection with the sale of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.

Although we are not aware that a company has filed any biosimilar version of tesamorelin with the FDA, nothing prevents a company from filing with the FDA a biosimilar version of tesamorelin using the same formulation as that of *EGRIFTA SV*<sup>®</sup> and to seek the same indication as that of *EGRIFTA SV*<sup>®</sup>.

If such a filing was made and the FDA were to approve a biosimilar version of  $EGRIFTA\ SV^{\$}$ , we would expect the price of that biosimilar to be lower than that of  $EGRIFTA\ SV^{\$}$  and we could have to lower our price in order to be able to compete with such biosimilar. A lower price of  $EGRIFTA\ SV^{\$}$  would reduce our revenue and could have an adverse effect on our goal of achieving a positive Adjusted EBITDA by the end of the 2023 fiscal year. Even if were to introduce the F8 Formulation, such biosimilar version could still be a direct competitor to us, albeit with an older formulation of tesamorelin.

# 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  $EGRIFTASV^{\circledast}$  and Trogarzo $^{\circledast}$  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 the United States and in other jurisdictions does not guarantee that we are not infringing one or more third-party patents in such country or in other 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 ("FFDCA"), as well as with 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 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  $EGRIFTA\ SV^{\otimes}$  and Trogarzo $^{\otimes}$  in Canada and in Europe since none of those products have been approved in this territory. Promotional activities may begin once a drug is approved by the heath authority of a country.

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

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

If our activities are found to be in violation of these laws or any other federal and state fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our activities with regard to the commercialization of our products in the United States, which could harm the commercial sales of our products and materially affect our business, financial condition and results of operations. We cannot guarantee that we will be able to mitigate all operational risks. In addition, we cannot guarantee that we, our employees, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations, laws and/or requirements, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on *EGRIFTA SV*®, Trogarzo® or their respective manufacturing processes, withdrawal of *EGRIFTA SV*® or Trogarzo® from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material adverse effect on our product sales, business and results of operations.

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

#### 3.6 LITIGATION RISKS

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

We rely on third-party service providers for 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 such 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. Additionally, if such third-party service providers do not meet their obligations under agreements and we decide to litigate any breach or dispute any amount owed under our agreements, this might materially adversely affect our relationship with such third-party services providers which, in turn, could adversely affect our capacity and ability to deliver on 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: (a) disruptions of important government services; (b) differing regulatory requirements for drug approvals in foreign countries; (c) potentially reduced protection for intellectual property rights, including unexpected changes in the rules governing patents and their enforcement; (d) potential third-party patent rights in foreign countries; (e) 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; (f) unexpected changes in tariffs, trade barriers and regulatory requirements; (g) economic weakness, including inflation, or political instability, particularly in foreign economies and markets; (h) compliance with tax, employment, immigration and labor laws for employees traveling abroad; (i) foreign taxes; (j) 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; (k) workforce uncertainty in countries where labor unrest is more common than in the United States and Canada; (l) production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and (m) 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 our presence in Canada and Europe, we must comply with privacy laws and regulations of Québec and Europe. Both of those laws and regulations introduced data protection requirements 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. These laws have increased the responsibility of all parties collecting personal data. We are currently reviewing and complementing our in-house policies and related procedures to ensure compliance with those laws. In the United States, there exists no federal laws regarding the protection of personal information and all such laws are State-regulated. With the addition of a sales and medical team in-house, we are in the process of assessing compliance with the privacy laws in each of the States where the bulk of our activities is conducted. However, there can be no guarantee that the Corporation will not be found to violate some of those laws as a result of the combination of our business activities in various jurisdictions and the complexity of those laws and their interpretations.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. More and more businesses are subject to information technology system intrusion for which cyber-terrorists often use ransomware to demand payment of a ransom to allow those businesses to regain access to its data. Despite the measures that we have implemented against unwanted intrusion by third parties, there can be no guarantee that our systems could resist to a cyber-attack. 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 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 in-license or acquire approved products, to meet our compliance obligations with various rules and regulations to which we are subject, and to conduct research and development activities related to our 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, with the consent of Marathon, 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, medical, regulatory 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. We have recently hired a team comprised of key account managers and medical science liaison personnel and the loss of any of those individuals and our inability to attract and retain them could have a material adverse effect on our commercial and medical activities related to *EGRIFTA SV*® and Trogarzo®, and, accordingly, on 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 growth 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 financial, milestones or our commercial objectives on time.

In January 2023, we announced revenue guidance for the fiscal year ended November 30, 2023, in the range of \$90 million to \$95 million. 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 achievement of such guidance or 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 sales allowances and chargebacks, recoverability of inventories, estimation of accruals for clinical trial expenses, measurement and recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements. 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.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022 in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. A material weakness may hamper our ability to meet our reporting obligations and could result in a material misstatement in the Corporation's financial statements. As a result, 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 we are unable to comply with our reporting obligations and/or that the financial information we report contains material errors. Any of those events could materially adversely affect the trading price of our Common Shares. A failure to comply with our reporting requirements could also subject us to sanctions and/or investigations by securities regulatory authorities.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022, in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. This control failure caused ineffective controls over the assessment of going concern uncertainty, including the underlying financial data and assumptions supporting the forecasted financial information utilized to prepare projected cash flows and liquidity requirements to comply with some of the covenants in the Marathon Credit Facility. The Corporation's management team has

initiated and continues to implement remediation measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented and operating efficiently. While the Corporation expects these remediation measures to be completed in the fiscal year 2023, it cannot be certain when the remediation will be completed. If the Corporation fails to fully remediate this material weakness or fails to maintain effective internal controls in the future, it could result in a material misstatement of the Corporation's financial statements, which could cause investors to lose confidence in the Corporation's financial statements and cause the trading price of its Common Shares to decline.

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. We are not currently required, and do not, obtain an audit of our internal controls 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.

## 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.

The Corporation's Common Shares are listed on the TSX and on the Nasdaq. The market price of the Common Shares on the Nasdaq and the TSX has fluctuated significantly in the past and the Corporation expects the market prices to continue to fluctuate in the future, and such prices may decline. For example, since the Corporation's listing of its Common Shares on Nasdaq to December 31, 2022, the Corporation's closing share price on Nasdaq has ranged from a low of \$0.8262 to a high of \$11.23. Consequently, you may not be able to sell your Common Shares at prices equal to or greater than the price paid by you. In addition, the market price of the Common Shares may be influenced by many factors, some of which are or may be beyond the Corporation's control, including: actual or anticipated variations in the Corporation's operating results and/or research and development activities; announcements by the Corporation or the Corporation's competitors of significant contracts or acquisitions; additions and departures of key personnel; announcement or expectation of additional financing efforts; impairment of assets; changes in accounting principles; changes in the general market and economic conditions; future sales of the Common Shares; the failure of financial analysts to initiate or maintain coverage of the Common Shares, changes in financial estimates by financial analysts, or any failure by the Corporation to meet or exceed any of these estimates, or changes in the recommendations of any financial analysts that elect to follow the Common Shares or the shares of the Corporation's competitors; and investor perceptions of the Corporation and the industry in which the Corporation operates.

In addition, stock markets, in general, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of the Common Shares, regardless of the Corporation's operating performance. Dual listing of the Common Shares on the Nasdaq and the TSX may increase share price volatility on both exchanges because trading is in the two markets, which may result in less liquidity on both exchanges. In addition, different liquidity levels, volumes of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices. In the past, following periods of volatility in the market price of certain companies' securities, securities class action litigation has sometimes been instituted against these companies. This litigation, if instituted against the Corporation, could adversely affect the financial condition or results of operations of the Corporation.

The liquidity of our Common Shares is uneven and oftentimes scarce and shareholders desiring to purchase or sell Common Shares could be unable to, if the liquidity in our Common Shares is low.

The volume of Common Shares traded on the TSX and the Nasdaq has been uneven over time and is often low. Therefore, any investor who desires to purchase or sell Common Shares of the Corporation over the TSX or the

Nasdaq may be unable to rapidly execute its order and, if the liquidity is low, the price at which such investor may purchase or sell Common Shares may be adversely affected by the lack of trading volume.

Our Common Shares may be delisted from the Nasdaq stock market if the minimum bid price of our Common Shares remains below US\$1.00 per share for 30 consecutive trading days. The delisting of our Common Shares could reduce the liquidity in our Common Shares and could trigger a sell-off from U.S. shareholders. Any reduction in the liquidity of our Common Shares or a sell-off our Common Shares would result in a decline in the price of our Common Shares. Being delisted from the Nasdaq stock exchange could also adversely affect analysts coverage of our Common Shares and prevent us from retaining U.S. investment bankers to raise equity in public offerings.

Under Nasdaq minimum bid price requirement, the minimum bid price of our Common Shares may not remain below US\$1.00 per share for 30 consecutive trading days. If such event occurs, the Corporation will receive a deficiency notice providing the Corporation with a 180-calendar day cure period from the date of the notice during which the minimum bid price of the Common Shares will have to be US\$1.00 or more per share for ten consecutive business days in order to avoid delisting. If, at the expiry of the 180-calendar day cure period, the Corporation has not regained compliance with the minimum bid price requirement, the Corporation could be afforded an additional 180-calendar day cure period, provided that it meets certain conditions, one of which could be to undertake a reverse-split of its Common Shares to regain compliance with Nasdaq rules.

If the Common Shares of the Corporation are delisted from the Nasdaq stock market, the liquidity in our Common Shares could decrease and investors may have difficulties in buying or selling our Common Shares. In addition, a delisting of our Common Shares on the Nasdaq stock market could trigger a sell-off from current U.S-based shareholders whose internal policies could prevent them from holding securities of companies that are not traded on a U.S. stock market. Any sell-off by these shareholders could result in a material decline in the price of our Common Shares.

Finally, if the minimum bid price of the Common Shares were to be below US\$1.00 per share for 30-consecutive trading days, there can be no assurance that the cure period provided by Nasdaq rules to regain compliance with the minimum bid price requirement would result in the Corporation regaining compliance with such rules in order to avoid a delisting of the Common Shares. Even if the Corporation was to proceed with a reverse-split of its Common Shares, there can be no assurance that the long term bid price of the Common Shares *post* reverse-split would meet the minimum bid price requirement of the Nasdaq stock market.

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: (a) the level of sales of  $EGRIFTA\ SV^{\circledR}$  in the United States; (b) the level of sales of Trogarzo $^{\circledR}$  in the United States; (c) supply issues with  $EGRIFTA\ SV^{\circledR}$  or Trogarzo $^{\circledR}$ ; (d) default under the terms of the Marathon Credit Facility or our Notes; (e) the inability to adequately manage our liquidity; (f) the outcome of any litigation; (g) payment of fines or penalties for violations of laws; (h) foreign currency and/or interest rate fluctuations; (i) the timing of achievement and the receipt of milestone or royalty payments from future third parties; and (j) 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 **DIRECTORS**

The table below sets forth the following information about our directors as of February 27, 2023: 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: 68 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\$)
15,000	Nil	14,170	Nil	Nil

#### **Committees of the Board of Directors**

Nil



Frank A. Holler Age: 66 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\$)
39,000	5,300	14,170	Nil	Nil

#### **Committees of the Board of Directors**

Member of Audit Committee



**Gérald A. Lacoste** Age: 79 Ste-Adèle, Québec, Canada

# Independent

**Director since:** February 8, 2006

# **Areas of Expertise:**

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

# Other Directorship:

VOLLE

# Principal Occupation

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.

Corporate Director

#### **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: 59 Westmount, Québec, Canada

#### Non-independent

**Director since:** April 6, 2020

#### **Areas of Expertise:**

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

# **Other Directorship:** None

0.1

#### **Principal Occupation**

President and Chief Executive Officer of the Corporation

20,000

Nil

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.

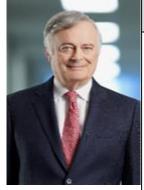
# Securities Held or Controlled Common Shares (#) (#) Options Warrants (US\$) (#) (#) (#) (US\$)

1,134,728

#### **Committees of the Board of Directors**

N.A.

111,200



# **Gary Littlejohn** Age: 67 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

VOILE

#### **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	26,456	46,928	Nil	Nil

#### **Committees of the Board of Directors**

Chair of Compensation Committee Member of Audit Committee



**Dale MacCandlish Weil**Age: 67
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.; and Nuvo Pharmaceuticals 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: 55 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	Warrants	Notes
(#)	(#)	(#)	(#)	(US\$)
30,000	10,123	27,428	Nil	Nil

#### **Committees of the Board of Directors**

Nil



# **Dawn Svoronos** Age: 69 Hudson, Québec, Canada

# Independent

**Director since:** April 8, 2013

#### **Areas of Expertise:**

- -Pharmaceutical Industry
- Commercialization of Drug Products

# Other Directorship:

Xenon Pharmaceuticals Inc.; and 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 two other public companies: Xenon Pharmaceuticals Inc. in British Columbia, Canada, and Adverum Biotechnologies, Inc. in Redwood City, California.

#### **Securities Held or Controlled**

Common Shares	DSU	Options	Warrants	Notes
(#)	(#)	(#)	(#)	(US\$)
323,600	855	84,174	Nil	Nil

#### **Committees of the Board of Directors**

Member of Compensation Committee Member of Nominating and Corporate Governance Committee



Alain Trudeau

Age: 63 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 Loto-Québec, 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	33,737	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, 2022, 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 27, 2023: 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.



Marie-Noël Colussi

**Executive since:** May 9, 2002

Age: 54

Laval, Québec, Canada

# **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**

Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)
11,075	3,182	268,092	Nil	10,000



**Philippe Dubuc** Age: 56

**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



#### **André Dupras** Age: 59

**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: 55

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 Controlled**

Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)
18,000	5,000	414,857	Nil	8,000



John Leasure Age: 58

Executive since: March 29, 2021

Underhill, Vermont, USA

# **Principal Occupation**

Global Commercial Officer

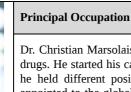
John Leasure was hired as Global Commercial Officer in March 2021. He brings extensive experience in Sales, Marketing, Operations and General Management both in the U.S and internationally. He has expertise managing brands across multiple stages of the product life cycle and has launched numerous products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

Common Shares (#)	DSU (#)	Options (#)	Warrants (#)	Notes (US\$)		
5,000	Nil	154,848	Nil	Nil		



#### 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.

<b>Christian Marsolais</b> Age: 60
Executive since: May 7, 2007
Town of Mount Royal, Québec, Canada

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

# 4.4 <u>CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES OR SANCTIONS</u>

To our knowledge, except with respect to Mr. Frank Holler, no director and executive officer (a) is, as at February 27, 2023, or has been within the ten (10) years before February 27, 2023, 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 27, 2023, 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 SECURITIES HELD BY THE DIRECTORS AND EXECUTIVE OFFICERS

As at February 27, 2023, the total number of common shares (the only securities carrying a voting right) held by our directors and executive officers amounted to 813,372, which represented 0.84% 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, 2022 and 2021:

Fees	Fiscal Year Ended November 30, 2022 (CA\$)	Fiscal Year Ended November 30, 2021 (CA\$)
Audit Fees <sup>(1)</sup>	750,615	639, 382
Audit-Related Fees <sup>(2)</sup>	53,865	48,943
Tax Fees <sup>(3)</sup>	115,293	170,027
All Other Fees		
Total:	919,773	858,352

- (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.
- (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 DIVIDEND POLICY

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

#### 6.3 TRANSFER AGENT AND REGISTRAR

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

# 7.1 PRICE RANGE AND TRADING VOLUME

# **Common Shares**

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

	TSX		NASDAQ			
Period <sup>(1)</sup>	High (CA\$)	Low (CA\$)	Volume	High (US\$)	Low (US\$)	Volume
2021						
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	4.14	3.46	498,623	3.26	2.70	1,575,600
March	3.62	2.90	572,974	2.86	2.30	1,639,500
April	3.40	2.89	378,373	2.70	2.26	1,248,700
May	3.18	2.66	404,673	2.72	2.05	1,369,700
June	3.39	2.76	213,186	2.70	2.13	906,200
July	2.98	2.59	302,783	2.39	1.97	770,200
August	2.96	2.50	131,981	2.29	1.90	1,039,000
September	3.33	2.50	584,549	2.45	1.89	1,801,000
October	3.75	2.45	443,821	2.77	1.78	2,971,300
November	3.05	2.40	305,947	2.30	1.74	10,033,700
December	2.93	1.03	1,527,442	2.20	0.77	12,242,000
2023						
January	1.62	1.22	727,819	1.18	0.88	1,334,200
February (to February 24)	1.42	1.14	489,484	1.05	0.84	1,370,000

<sup>(1)</sup> 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 <sup>(1)</sup>				
Period(2)	High (US\$)	Low (US\$)	Volume		
2021					
December	92.00	88.50	63,000		
2022					
January	88.50	85.10	1,228,000		
February	87.50	85.00	34,000		
March	87.50	83.00	13,000		
April	85.25	84.90	25,000		
May	87.50	83.00	81,000		
June	75.50	75.32	8,000		
July	90.00	75.50	35,000		
August	90.00	88.50	32,000		
September	92.00	85.00	77,000		
October	90.00	85.00	38,000		
November	90.00	87.00	30,000		
December	90.00	87.50	12,000		
2023					
January	94.49	90.00	97,000		
February (to February 24)	94.00	94.00	86,000		

<sup>(1)</sup> 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
December 1, 2021	Options	US\$3.30	269,170
December 1, 2021	Options	CA\$4.21	2,100,219
February 28, 2022	Deferred Share Units (1)	CA\$3.67	8,174
May 2, 2022	Deferred Share Units (1)	CA\$3.11	14,469
May 10, 2022	Options	US\$2.59	101,672
May 10, 2022	Options	CA\$3.38	30,000
uly 19, 2022	Deferred Share Units (1)	CA\$2.78	10,792
July 19, 2022	Options	US\$2.20	5,000

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

Date	Type of Security	Price per Security	Number of Securities
July 19, 2022	Options	CA\$2.83	42,000
October 17, 2022	Deferred Share Units (1)	CA\$2.83	21,200
October 20, 2022	Options	US\$2.01	25,000
October 20, 2022	Options	CA\$2.74	5,000

<sup>(1)</sup> The deferred share 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 27, 2023, we are not subject to any such material proceedings.

#### ITEM 9 MATERIAL CONTRACTS

#### Marathon Credit Facility

On July 13, 2022, we announced that we had entered into a binding commitment with affiliated funds of Marathon Asset Management providing for a non-dilutive term loan of up to \$100 million and, on July 20, 2022, the Company executed the Marathon Credit Facility as amended on February 27, 2023. The Marathon Credit Facility provides for the disbursement of \$100 million in four various tranches. As guarantee for the repayment of the loan, the Company and each of its subsidiaries have granted a first ranking security interest on all of their assets.

The salient features of the Marathon Credit Facility are as follows:

- \$40 million were funded on July 27, 2022 ("Tranche 1 Loan");
- \$20 million ("Tranche 2 Loan") to be made available by no later than June 30, 2023, if the Company has had net revenues of at least \$75 million for the 12-month period immediately preceding the funding of the Tranche 2 Loan and if the Company is not in default of its obligations under the loan facility. If the conditions to obtain the Tranche 2 Loan are not met by June 30, 2023, then it nor any other tranche will be available;
- \$15 million ("Tranche 3 Loan") to be made available by no later than March 31, 2024, if the Tranche 2 Loan has been drawn and the Company has obtained approval from the FDA for its F8 Formulation, has had net revenues of at least \$90 million in the 12-month period preceding the funding of the Tranche 3 Loan and if the Company is not in default of its obligations under the loan facility;
- Up to an additional \$25 million ("Tranche 4 Loan") to be made available if the Tranche 3 Loan has been drawn and the Company has had at least \$110 million in net revenues as well as at least \$20 million in EBITDA in the 12-month period preceding the funding of the Tranche 4 Loan;
- The Marathon Credit Facility has an initial term of five years (July 27, 2027), or six years if the Tranche 3 Loan is drawn, provides for an interest-only period of 24 months (36 months if the Tranche 3 Loan is drawn), and bears interest at SOFR plus 9.5%. The Tranche 1 Loan and the Tranche 2 Loan are repayable in equal monthly installments on an amortization schedule of 36 months starting in July 2024 (July 2025 if the Tranche 3 Loan is funded on or prior to December 31, 2023);
- The Marathon Credit Facility provides quarterly revenue targets and minimum liquidity covenants. Until the F8 Formulation is approved, the Company must maintain at all times cash, cash equivalents and eligible short-term investments in the amount of \$20 million in specified accounts (which amount will be increased to \$30 million if the Company has not obtain approval from the FDA for the F8 Formulation by March 31, 2024);
- The Marathon Credit Facility restricts the ability to incur additional debt, the acquisitions and disposition of assets as well as in-licensing and out-licensing of products, except in very limited circumstances;
- A breach of the terms and conditions of the Marathon Credit Facility will create an event of default resulting in an increase of 300 basis points on the interest rate payable on the outstanding amounts loaned and provide the lender with the ability to demand immediate repayment of the debt, and not advance any additional tranches; and
- The term loan also includes a covenant prohibiting the inclusion of a going concern explanatory paragraph in the annual report of the independent registered public accounting firm, except in connection with the annual report related to the fiscal year ended November 30, 2022.

#### 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.

#### 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  $SV^{\otimes}$  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  $EGRIFTA\ SV^{(0)}$  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 1<sup>st</sup>, 2017, we entered into an amended and restated master services agreement and amended and restated statements of work agreements with RxCrossroads appointing it as our exclusive third-party logistic service provider and exclusive third-party distributor of *EGRIFTA*® and Trogarzo® in the United States. Effective November 1<sup>st</sup>, 2019, we amended the amended and restated statement of work agreements to add *EGRIFTA SV*® 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.

#### **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.

#### Cesar Castillo, Inc.

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

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

# 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 purchase 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.

# Syneos Agreement

On December 4, 2016, we entered into an amended and restated master services agreement with Syneos, as amended on December 1, 2021, providing for the main terms and conditions under which Syneos would provide us with services to commercialize *EGRIFTA SV®* (*EGRIFTA®* at the time) and Trogarzo® in the United States. Each of those services has been described in specific project agreements. To date, we have entered into project agreements relating to the provision of managed market, reimbursement and specialty nurses team. 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, 2024, 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.

#### <u>Transfert Plus License Agreement</u>

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, 2022.

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, 11<sup>th</sup> Floor, Montreal, Québec, Canada H3A 1T8. Except when our securities are in the process of distribution pursuant to a prospectus, we may charge reasonable fees if the request is from a person who does not hold any of our securities.

#### **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. Obligations and Duties

The Committee carries out the duties usually entrusted to an audit committee and any other duty assigned from time to time by the Board. Management has the responsibility to ensure the integrity of the financial information and the effectiveness of the Company's internal controls. The external auditor has the responsibility to verify the fair presentation of the Company's financial statements; at the same time evaluating the internal control process to determine the nature, extent and timing of the auditing procedures used for the financial statement audit. The Committee has the responsibility to supervise the participants involved in the preparation process of the financial information and to report on this to the Board.

Specifically, the Committee is charged with the following obligations and duties:

- A. Integrity of the Company's Financial Statements and Related Information
  - 1. Review annual and quarterly consolidated financial statements and all financial information legally required to be disclosed by the Company, i.e. financial information contained in the "Management Discussion and Analysis" report, the Annual Information Form and the press releases, as the case may be, discuss such with management and the external auditor, as applicable, and suggest recommendations to the Board, as the case may be.
  - 2. Approve the interim Financial Statements, the interim "Management Discussion and Analysis" reports and all supplements to these "Management Discussion and Analysis" reports which have to be filed with regulatory authorities.
  - 3. On a periodic basis, review and discuss with management and the external auditor, as applicable, the following:
    - a. major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles, and major issues as to the adequacy of the

- Company's internal controls and any special audit steps adopted in light of 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;
  - b. all material alternative treatments of financial information within generally accepted accounting principles that have been discussed with management, including the ramifications of the use of such alternate treatments and disclosures and the treatment preferred by the external auditor;
  - c. the external 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. External Advisors

In discharging its duties and responsibilities, the Committee is empowered to retain external legal counsel or other external advisors, as appropriate. The Company shall provide the necessary funds to secure the services of such advisors.

# IV. <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. Term of the Mandate

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

#### VI. <u>Vacancy</u>

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

#### VII. 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. Secretary

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

# IX. Meeting Proceedings

The Committee establishes its own procedures as to how meetings are called and conducted. Unless it is otherwise decided, the Committee shall meet privately and independently from Management at each regularly scheduled meeting. In the absence of the regularly appointed 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. Annual Review

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

# XIII. Effective Date

This charter was adopted by the Directors at its May 3, 2004 Board meeting. It was amended by the Directors during the April 13, 2005, February 8, 2006, February 25, 2015, August 7, 2019 and May 13, 2021 Board meetings.

Consolidated Financial Statements (In thousands of United States dollars)

# THERATECHNOLOGIES INC.

November 30, 2022 and 2021

# THERATECHNOLOGIES INC.

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(In thousands of United States dollars)

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KPMG LLP 600 de Maisonneuve Blvd. West Suite 1500, Tour KPMG Montréal (Québec) H3A 0A3 Canada Telephone (514) 840-2100 Fax (514) 840-2187 Internet www.kpmg.ca

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Theratechnologies Inc.:

### Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated statements of financial position of Theratechnologies Inc. (the "Company") as of November 30, 2022 and 2021, the related consolidated statements of net loss and comprehensive loss, changes in equity, and cash flows for the years then ended, 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, 2022 and 2021, and its financial performance and its cash flows for the years then ended, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

## **Going Concern**

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company's convertible notes mature in June 2023 and its Loan Facility contains various covenants, including minimum liquidity covenants. There is material uncertainty related to events or conditions that cast substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.



Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

(signed) KPMG LLP

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

Montréal, Canada February 27, 2023

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

As at November 30, 2022 and 2021

	Note		November 30, 2022		November 30 2021
Assets					
Current assets					
Cash		\$	23,856	\$	20,399
Bonds and money market funds	6	Ψ	9,214	Ψ	19,955
Trade and other receivables	7		12,045		10,48
Tax credits and grants receivable	8		299		44:
Inventories	9		19,688		29,14
Prepaid expenses and deposits	10		7,665		10,74
Derivative financial assets	21(d)		603		74
Total current assets			73,370		91,90
Non-current assets					
Property and equipment	11		1,494		74
Right-of-use-assets	12		1,595		2,11
Intangible assets	13		15,009		21,38
Deferred financing costs	18 & 21(c)		1,792		62
Other asset	14		-		2,44
Total non-current assets			19,890		27,304
Total assets		\$	93,260	\$	119,212
Liabilities					
Current liabilities					
Accounts payable and accrued liabilities	15	\$	41,065	\$	40,37
Provisions	16	•	7,517		4,12
Convertible unsecured senior notes	19		26,895		-,
Term loan	18		37,894		
Current portion of lease liabilities	20		476		46
Income taxes payable	=0		394		6
Deferred revenue			38		5
Total current liabilities			114,279		45,07
Non-current liabilities			·		
Convertible unsecured senior notes	19		_		54,22
Lease liabilities	20		1,446		2,05
Other liabilities	20		,		
Other liabilities			106		9. 56,37
Total non-current liabilities			1,552		
Total liabilities			115,831		101,45
Equity					
Share capital and warrants	21		338,751		335,75
Equity component of convertible unsecured senior notes			2,132		4,45
Contributed surplus			18,810		12,84
Deficit			(382,649)		(335,248
Accumulated other comprehensive income (loss)	21(i)		385		(44
Total equity			(22,571)		17,76
Commitments	27				
Subsequent events	30				
Total liabilities and equity		\$	93,260	\$	119,212

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

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

Years ended November 30, 2022 and 2021

	Note		2022		2021
Revenue	3	\$	80,057	\$	69,82
Operating expenses					
Cost of sales					
Cost of goods sold			23,838		18,378
Amortization of other asset	14		2,441		4,882
Research and development expenses, net of tax credits of \$316 (2021 – \$277)			36,939		28,27
Selling expenses			39,391		28,909
General and administrative expenses			17,356		14,616
Total operating expenses			119,965		95,059
Loss from operating activities			(39,908)		(25,236)
Finance income	5		673		195
Finance costs	5		(7,559)		(6,621)
			· · · · ·		
			(6,886)		(6,426)
Loss before income taxes			(46,794)		(31,662)
Income tax expense			(443)		(63)
Net loss			(47,237)		(31,725)
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")			(360)		(197)
Exchange differences on translation of foreign operations			789		634
			429		437
Total comprehensive loss		\$	(46,808)	\$	(31,288)
Total Comprehensive 1033		Ψ	(40,000)	Ψ	(31,200
Loss per share					
Basic and diluted	21(h)	\$	(0.50)	\$	(0.34)

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

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

Years ended November 30, 2022 and 2021

	_	Share o		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, 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 Exchange differences on translation of foreign operations		-	-	- -	-	-	(197) 634	(197) 634
Total comprehensive loss		-	-	-	-	(31,725)	437	(31,288)
Transactions with owners, recorded directly in equity								
Public issue of common shares and warrants	21(a)	16,727,900	46,002	-	-	-	-	46,002
Share issue costs	04()	-	-	-	-	(3,394)	-	(3,394)
Exercise of warrants Share issue – Oncology	21(a) 21(b)	233,400 481,928	742 668	-	(668)	-	-	742
Share-based compensation plan:	21(0)	481,928	800	-	(800)	-	-	-
Share-based compensation for stock option plan Exercise of stock options:	21(g)	-	-	-	1,879	-	-	1,879
Monetary consideration	21(g)	665,000	595	-	-	-	-	595
Attributed value	(6)		433	-	(433)		-	-
Total contributions by owners		18,108,228	48,440	_	778	(3,394)	_	45,824
,		-,,	-,			(-,,		
Balance as at November 30, 2021		95,121,639	\$ 335,752	\$ 4,457	\$12,843	\$ (335,248)	\$ (44)	\$ 17,760
Balance as at November 30, 2021  Total comprehensive loss		95,121,639	\$ 335,752	\$ 4,457	\$12,843	\$ (335,248)	\$ (44)	\$ 17,760
Total comprehensive loss Net loss		95,121,639	\$ 335,752	\$ 4,457 -	\$12,843 -	\$ (335,248)	\$ (44)	\$ 17,760 (47,237)
Total comprehensive loss Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of		95,121,639	\$ 335,752	\$ 4,457 -	\$12,843 -	,	-	(47,237)
Total comprehensive loss Net loss Other comprehensive income:		95,121,639	\$ 335,752	\$ 4,457 - -	\$12,843 - -	,	\$ (44) - (360) 789	
Total comprehensive loss  Net loss  Other comprehensive income:  Net change in fair value of FVOCI financial assets, net of tax		-	\$ 335,752	\$ 4,457 - - -	\$12,843 - -	,	(360)	(47,237)
Total comprehensive loss  Net loss  Other comprehensive income:  Net change in fair value of FVOCI financial assets, net of tax		-	\$ 335,752 - - -	\$ 4,457 - - -	\$12,843 - -	,	(360)	(47,237)
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss		-	\$ 335,752	\$ 4,457 - - -	\$12,843	(47,237) - -	(360) 789	(47,237) (360) 789
Total comprehensive loss  Net loss  Other comprehensive income:  Net change in fair value of FVOCI financial assets, net of tax  Exchange differences on translation of foreign operations	21(c)	-	\$ 335,752 - - - 2,960	\$ 4,457 - - -	\$12,843	(47,237) - -	(360) 789	(47,237) (360) 789
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss  Transactions with owners, recorded directly in equity Share issue - ATM program Share issue costs	` ,	-		-	-	(47,237) - -	(360) 789	(47,237) (360) 789 (46,808) 2,960 (164)
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss  Transactions with owners, recorded directly in equity Share issue - ATM program Share issue costs Purchase of convertible unsecured senior notes Share-based compensation plan:	19	1,600,000	2,960	\$ 4,457 - - - - (2,325)	- - - - 2,125	(47,237) - - - (47,237)	(360) 789 429	(47,237) (360) 789 (46,808) 2,960 (164) (200)
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss  Transactions with owners, recorded directly in equity Share issue - ATM program Share issue costs Purchase of convertible unsecured senior notes	19 21(g)	1,600,000	2,960	-	-	(47,237) - - - (47,237)	(360) 789 429	(47,237) (360) 789 (46,808) 2,960 (164) (200) 3,860
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss  Transactions with owners, recorded directly in equity Share issue - ATM program Share issue costs Purchase of convertible unsecured senior notes Share-based compensation plan: Share-based compensation for stock option plan	19	1,600,000	2,960	-	- - - - 2,125	(47,237) - - - (47,237)	(360) 789 429	(47,237) (360) 789 (46,808) 2,960 (164) (200)
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss  Transactions with owners, recorded directly in equity Share issue - ATM program Share issue costs Purchase of convertible unsecured senior notes Share-based compensation plan: Share-based compensation for stock option plan  Exercise of stock options: Monetary consideration	19 21(g)	1,600,000 - - 84,660	2,960 - - - 21 18	- - - (2,325)	- - - 2,125 3,860 - (18)	(47,237) (47,237) (164)	(360) 789 429	(47,237) (360) 789 (46,808) 2,960 (164) (200) 3,860 21
Total comprehensive loss  Net loss Other comprehensive income: Net change in fair value of FVOCI financial assets, net of tax Exchange differences on translation of foreign operations  Total comprehensive loss  Transactions with owners, recorded directly in equity Share issue - ATM program Share issue costs Purchase of convertible unsecured senior notes Share-based compensation plan: Share-based compensation for stock option plan  Exercise of stock options: Monetary consideration Attributed value	19 21(g)	1,600,000	2,960	-	- - - 2,125 3,860	(47,237) - - - (47,237)	(360) 789 429	(47,237) (360) 789 (46,808) 2,960 (164) (200) 3,860

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

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

Years ended November 30, 2022 and 2021

	Note	2022	2022 (recast <sup>1</sup>
Cash flows from (used in)			
sach horro horr (acca in)			
Operating			
Net loss		\$ (47,237)	\$ (31,725
Adjustments for	4.4	000	00
Depreciation of property and equipment	11	390	23
Amortization of intangible assets and other asset	13, 14 12	11,652	8,06
Amortization of right-of-use assets Share-based compensation for stock option plan and stock appreciation rights	12	429 3,872	44 1,93
Change in fair value of derivative financial assets	21(d)	217	(212
Change in fair value of liability related to deferred stock unit plan	21(d)	(221)	20
Interest on convertible unsecured senior notes and term loan	5	4,357	3,30
Interest paid on convertible unsecured senior notes and term loan	•	(4,634)	(3,306
Interest income	5	(316)	(195
Interest received		456	28
Income tax expense		443	6
Income taxes paid		(109)	(19
Foreign exchange		1,209	89
Gain on repurchase of convertible unsecured senior notes	19	(357)	
Accretion expense and amortization of deferred financing costs	5	2,140	2,35
Change in operating assets and liabilities		(27,709)	(17,669
Trade and other receivables		(1,669)	1,85
Tax credits and grants receivable		126	32
Inventories		8,991	(4,217
Prepaid expenses and deposits		3,058	(5,569
Accounts payable and accrued liabilities		(1,100)	5,54
Provisions		3,627	2,22
Deferred revenue		(16)	
		13,017	168
Total cash used in operating activities		(14,692)	(17,501
Financing activities			
Repurchase of convertible unsecured senior notes	19	(28,746)	
Costs related to repurchase of convertible unsecured senior notes	19	(73)	
Costs related to reparentase of convertible unsecured serior notes		(10)	
	18	40 000	
Proceeds from issuance of term loan	18 18	40,000 (2,285)	
Proceeds from issuance of term loan Costs related to issuance of term loan	18	40,000 (2,285)	(5.000
Proceeds from issuance of term loan		,	
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations	18	(2,285)	<b>`</b> 59
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options	18	(2,285)	59 74
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs	18 17	(2,285) - 21 - 2,960 (89)	599 743 46,000 (3,394
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs	18 17 21(c) 21(c)	(2,285) 21 - 2,960 (89) (1,527)	(5,000 59! 74: 46,00: (3,394) (447
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability	18 17 21(c)	(2,285) 21 2,960 (89) (1,527) (605)	59 74 46,00 (3,394 (447 (635
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities	18 17 21(c) 21(c)	(2,285) 21 - 2,960 (89) (1,527)	59 74 46,00 (3,394 (447 (635
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  nvesting activities	18 17 21(c) 21(c)	(2,285) 21 2,960 (89) (1,527) (605)	59 74 46,00 (3,394 (447 (635 37,86
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  nvesting activities Acquisition of intangible assets	18 17 21(c) 21(c) 20	(2,285) 21 - 2,960 (89) (1,527) (605) 9,656	59: 74: 46,00: (3,394 (447 (635 37,86:
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  Nvesting activities Acquisition of intangible assets Acquisition of property and equipment	18 17 21(c) 21(c)	(2,285) 	599 74: 46,000 (3,394 (447 (635 37,86)
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  nvesting activities Acquisition of intangible assets	18 17 21(c) 21(c) 20	(2,285) 21 - 2,960 (89) (1,527) (605) 9,656	59 74 46,00 (3,394 (447 (635 37,86
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  Nvesting activities Acquisition of intangible assets Acquisition of property and equipment Proceeds from sale of bonds and money market funds	18 17 21(c) 21(c) 20	(2,285) - 21 - 2,960 (89) (1,527) (605) 9,656	59 74 44,00 (3,394 (447 (635 37,86 (32 (127 64 (13,210
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  nvesting activities Acquisition of intangible assets Acquisition of property and equipment Proceeds from sale of bonds and money market funds Acquisition of bonds and money market funds	18 17 21(c) 21(c) 20	(2,285) - 21 - 2,960 (89) (1,527) (605) 9,656	59 74 46,00 (3,394 (447 (635 37,86 (127 64 (13,210 (12,736
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Fotal cash from financing activities  **Neesting activities** Acquisition of intangible assets Acquisition of property and equipment Proceeds from sale of bonds and money market funds Acquisition of bonds and money market funds  Fotal cash from (used in) investing activities	18 17 21(c) 21(c) 20	(2,285) - 21 - 2,960 (89) (1,527) (605)  9,656  (985) 9,906 (239)  8,682	59 74 46,00 (3,394 (447 (635 37,86
Proceeds from issuance of term loan Costs related to issuance of term loan Repayment of other obligations Proceeds from exercise of stock options Proceeds from exercise of warrants Proceeds from issue of common shares and warrants Share issue costs Deferred financing costs Payment of lease liability  Total cash from financing activities  nvesting activities Acquisition of intangible assets Acquisition of property and equipment Proceeds from sale of bonds and money market funds Acquisition of bonds and money market funds  Net change in cash	18 17 21(c) 21(c) 20	(2,285) - 21 - 2,960 (89) (1,527) (605)  9,656  - (985) 9,906 (239)  8,682  3,646	59 74 44,00 (3,394 (447 (635 37,86 (127 64 (13,210 (12,736 7,62

<sup>&</sup>lt;sup>1</sup> The company voluntarily changed its accounting policy to classify interest paid and received as part of operating activities, see Note 2.

Refer to Note 23 for supplemental cash flow disclosures.

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

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

Years ended November 30, 2022 and 2021

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").

The Company has two wholly-owned subsidiaries that are material:

- Theratechnologies Europe Limited, a company governed by the Companies Act 2014 (Ireland).
   Theratechnologies Europe Limited provides the services of personnel to Theratechnologies Inc. for its activities in the United States, following the discontinuation of Trogarzo<sup>®</sup> in Europe. (Refer to Note 3)
- 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 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, H3A 1T8, Canada.

#### 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").

These consolidated financial statements were authorized for issue by the Board of Directors on February 27, 2023.

# Going concern uncertainty

As part of the preparation of the financial statements, management is responsible for identifying any event or situation that may cast doubt on the Company's ability to continue as a going concern. Substantial doubt regarding the Company's ability to continue as a going concern exists if events or conditions, considered collectively, indicate that the Company may be unable to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. If the Company concludes that events or conditions cast substantial doubt on its ability to continue as a going concern, it must assess whether the plans developed to mitigate these events or conditions will remove any possible substantial doubt.

For the year ended November 30, 2022, the Company incurred a net loss of \$47,237 (2021-\$31,725) and had negative operating cash flows of \$14,692 (2021-\$17,501). The Company's total current liabilities exceeded total current assets at November 30, 2022. The Company's outstanding \$27,500 convertible unsecured senior notes mature in June 2023 (refer to Note 19) requiring the Company to use its cash balance and draw the Tranche 2 Loan (as defined in Note 18) of its term loan facility available (the "Loan Facility") to repay the principal and the interest thereon. The Loan Facility is available in four tranches and contains various covenants, including minimum liquidity covenants whereby the Company needs to maintain significant cash, cash equivalent and eligible short-term investments balances in specified accounts, which restricts the management of the Company's liquidity (refer to notes 18 and 24). There are also operational milestones and required revenue targets in order for the Company to comply with the conditions of the Loan Facility or to be able to borrow money forming part of the various tranches.

The Company's ability to continue as a going concern for period of at least, but not limited to, 12 months from November 30, 2022 involves significant judgement and is dependent on its ability to increase revenues and manage expenses to generate sufficient positive cash flows from operations and/or find alternative source of funding to respect all the various covenants of its Loan Facility, including obtaining the approval from the FDA for its F8 formulation of tesamorelin on or before March 31, 2024, and/or to obtain the continued support of its lender. On February 27, 2023, the lender removed the condition related to the submission to the FDA of the results from the human factors validation study by no later than June 30, 2023, in order to access the Tranche 2 Loan under the Loan Facility (refer to Note 30). Management believes its plans will comply with all of the other various covenants of the Loan Facility to draw the Tranche 2 Loan, repay all the convertible unsecured senior notes due June 30, 2023 and to comply with the covenants for the foreseeable future. However, there can be no assurance that management's plans will be realized since some elements of these plans are outside of management's control and cannot be predicted at this time. Should management's plans not materialize, the Company may be forced to reduce or delay expenditures and capital additions, seek additional financing through the issuance of equity or obtain from the lender waivers of these covenants, if available. Raising additional equity capital is subject to market conditions. As a result, there is material uncertainty related to events or conditions that cast substantial doubt about the Company's ability to continue as a going concern.

Furthermore, the Loan Facility includes a covenant prohibiting having a going concern explanatory paragraph in the annual report of the independent registered public accounting firm but the lender has agreed to amend the Loan Facility to exclude the fiscal year ended November 30, 2022. There is no assurance that the lender will agree to amend or to waive potential future covenant breaches, if any. As the amendment occurred subsequent to the Company's fiscal year end, the term loan has been classified as a current liability pursuant to IFRS requirements.

These consolidated financial statements have been prepared assuming the Company will continue as a going concern, which assumes the Company will continue its operations in the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. These consolidated financial statements do not include any adjustments to the carrying values and classification of assets and liabilities and reported expenses that might result from the outcome of this uncertainty and that may be necessary if the going concern basis was not appropriate for these consolidated financial statements. If the Company was unable to continue as a going concern, material impairment of the carrying values of the Company's assets, including intangible assets, could be required.

#### **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,

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

Years ended November 30, 2022 and 2021

# 1. Basis of preparation (continued)

### Basis of measurement (continued)

• 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.

# 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.

### Milestones payments

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.

Management uses judgement in determining whether milestone payments are performance-related development milestones which are capitalized as an intangible asset or are milestones related to the activity or usage of an asset which are expensed.

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

Years ended November 30, 2022 and 2021

### 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 authorizations 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. These estimates take into consideration historical experience, current contractual and statutory requirements, specific known market events and trends such as competitive pricing and new product introductions, estimated inventory levels, and the shelf life of products. If actual future results vary, these estimates need to be adjusted, with an effect on sales and earnings in the period of the adjustment. (refer to see Notes 2 "Revenue recognition" and 3 for additional information).

### Recoverability of inventories

The Company regularly reviews inventory to determine whether the inventory cost exceeds its net realizable value. The determination of the net realizable value requires management to make estimates and use judgement in considering shelf life of a product, the effects of technological changes and new product introductions.

### Other

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

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

Years ended November 30, 2022 and 2021

#### 1. Basis of preparation (continued)

### Use of estimates and judgments (continued)

Other (continued)

The Company is subject to risks and uncertainties that may cause actual results to differ from estimated amounts, such as changes in the healthcare environment, competition, litigation, legislation and regulations. Management regularly evaluates estimates and assumptions using historical experience and expectations about the future. Management adjusts estimates and assumptions when facts and circumstances indicate the need for change. Revisions to accounting estimates are recognized in the year in which the estimates are revised and in any future years affected.

### 2. Significant accounting policies

The accounting policies have been applied consistently by the 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 these 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

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

Years ended November 30, 2022 and 2021

### 2. Significant accounting policies (continued)

### Foreign currencies (continued)

translation are recognized in net profit, except for differences arising on the translation of FVOCI financial instruments, which are recognized in other comprehensive income (loss).

## Foreign operations

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

# Revenue recognition

Revenue from contracts with customers - Net sales

The Company derives revenue from the sales of finished goods, which include Trogarzo® and *EGRIFTA SV*®. The Company recognizes revenue at a point in time when it transfers title 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 authorizations 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.

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

Years ended November 30, 2022 and 2021

### 2. Significant accounting policies (continued)

#### 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 as well as write-downs of inventories.

Amortization of the other asset

The amortization of the other asset related to the repurchase of the future royalty rights under the 2013 Termination Agreement (Note 14).

#### **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.

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

Years ended November 30, 2022 and 2021

## 2. Significant accounting policies (continued)

#### Finance income and finance costs

Finance income comprises interest income on financial assets and gains on the disposal of financial assets and financial liabilities. 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 lease liabilities, convertible unsecured senior notes and long-term loans and obligations, impairment losses on financial assets recognized in net loss, changes in fair value of liabilities and derivatives, unrealized foreign currency gain or loss on long-term obligations and other foreign currency gains and losses which are reported on a net basis.

### **Inventories**

Inventories are presented at the lower of cost, determined using the first-in, first-out method, and net realizable value. Inventory costs include the purchase price and other costs directly related to the acquisition of materials and other costs incurred in bringing the inventories to their present location and condition. The Company is responsible for coordinating the production and stability testing and for auditing suppliers at different times during the manufacturing process. Inventory costs also include the costs directly related to the conversion of materials into finished goods. Net realizable value is the estimated selling price in the Company's ordinary course of business less the estimated costs of completion and selling expenses. In determining whether the inventory cost exceeds its net realizable value for prelaunch inventory, the Company considers whether there is a high probability of regulatory approval for the product. In making that determination, the Company considers prior history with approvals of similar products, estimated timing of obtaining regulatory approval, regulatory agencies correspondence regarding safety and efficacy of the product and current market factors.

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.

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.

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

## Property and equipment (continued)

Subsequent costs

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

#### Depreciation

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

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

The method of depreciation is selected based on the most closely expected pattern of consumption of the future economic benefits embodied in the asset.

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.

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

Intangible assets (continued)

Research and development (continued)

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, 2022 and 2021, no development expenditures were capitalized.

Non-refundable advance payments for good and services that will be used in future research and development activities are expenses when the activity has been performed rather than when the payment is made.

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. 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<sup>®</sup> North American Territory are amortized at fixed rates based on their estimated useful life of 142 months on a straight-line basis. Commercialization rights – Trogarzo<sup>®</sup> European Territory were amortized at fixed rates based on their estimated useful life of 148 months on a straight-line basis. They were fully amortized during the year ended November 30, 2022. Refer to Note 13. 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.

# **Asset acquisitions**

Asset acquisitions are acquisitions that do not qualify as business combinations. At the date of acquisition, the Company initially recognizes the individual identifiable assets acquired and liabilities assumed. The cost to the Company at the date of the acquisition is allocated to the individual identifiable assets and liabilities on the basis of their relative fair values at the date of the acquisition. Subsequent consideration for performance-related development milestones is recognized as intangible assets when the specific milestones have been achieved and other recognition criteria are met. Subsequent payments related to activity or usage of an asset, including sales royalties, are expensed as incurred. Asset acquisition transactions do not give rise to goodwill.

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

Years ended November 30, 2022 and 2021

## 2. Significant accounting policies (continued)

#### Other asset

Other asset, which comprised the amount disbursed in connection with the repurchase of the future royalty rights under the 2013 Termination Agreement (Note 14), was amortized over its estimated useful life of 48 months. Other asset was fully amortized during the year ended November 30, 2022.

### Impairment of non-financial assets

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

For the purpose of impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of cash inflows from other assets or groups of assets ("cash-generating unit"). The recoverable amount of an asset or a cash-generating unit is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset or the cash-generating unit.

Impairment losses recognized in prior years are determined by the Company at each reporting date for any indications that the loss has decreased or no longer exists. An asset's carrying amount, increased through the reversal of an impairment loss, must not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized.

#### **Financial instruments**

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

# (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;

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

## Financial instruments (continued)

- (i) Financial assets measured at amortized cost (continued)
  - 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;
- 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 profitor loss.

On initial recognition of an equity investment that is not held for trading, the Company may irrevocably elect to present subsequent changes in the investment's fair value in other comprehensive income (loss).

This election is made on an investment-by-investment basis. These assets are subsequently measured at fair value. Dividends are recognized in profit or loss, unless the dividend clearly represents a repayment of part of the cost of the investment, and other net gains and losses are recognized in other comprehensive income (loss) and are never reclassified in profit or loss.

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.

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

Years ended November 30, 2022 and 2021

## 2. Significant accounting policies (continued)

### Financial instruments (continued)

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

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 loans as financial liabilities measured at amortized cost.

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

### (v) Compound financial instruments

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

The liability component of a compound financial instrument is recognized initially at the fair value of a similar liability that does not have an equity 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. Upon repurchase, the proceeds are allocated based on the same basis that was used for the initial recognition.

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

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

## Financial instruments (continued)

### (vi) Derivative financial instruments

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

### (vii) Offsetting of financial instruments

Financial assets and 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.

## (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;
- 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.

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

## Leases (continued)

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;
- an estimate of costs to dismantle and remove the underlying asset, restore the site on which it is located or
  restore the underlying asset to the condition required by the terms and conditions of the lease contract.

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

#### Lease liabilities

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

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

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

Years ended November 30, 2022 and 2021

## 2. Significant accounting policies (continued)

### Lease liabilities (continued)

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

#### Classification and presentation of lease-related expenses

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

### **Deferred Financing Costs**

Deferred Financing Costs consists of fees charged by underwriters, attorneys, accountants, and other fees directly attributable to future issuances of shares or debt securities. Provided these costs are determined to be recoverable, these costs are deferred and charged subsequently against the gross proceeds of the related equity or debt issuance 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.

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

Years ended November 30, 2022 and 2021

### 2. Significant accounting policies (continued)

#### Returns

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

### Contingent liability

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

#### Income taxes

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

#### Current tax

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

### Deferred tax

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

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.

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

Deferred tax (continued)

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

## **Share-based compensation**

Share option plan

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

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

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 infinance 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.

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

Cash-settled stock appreciation rights (continued)

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

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

### **Government assistance**

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

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

## Research and development tax credits

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

### 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.

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

Years ended November 30, 2022 and 2021

# 2. Significant accounting policies (continued)

### 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.

### Changes in accounting policies

The Company voluntarily changed its accounting policy to classify interest paid and received as part of operating activities in the consolidated statement of cash flows. Previously, the Company elected to classify interest paid as cash flow from financing activities and interest received as cash flows from investing activities. Accordingly, the Company has recast the fiscal 2021 comparative financial information on the consolidated statement of cash flows resulting in previously reported cash flow from operation decreasing by \$3,024, cash flow used from financing by \$3,306 and cash flow used in investing activities decreased by \$282. In addition to the above, the fiscal 2021 interest received cash inflow was increased and acquisition of bonds and money market funds cash outflow was decreased by \$454, which had no impact on 2021 total cash flows used in investing activities as both amounts were previously classified in investing activities.

Previously reported cash flows for the year ended November 30, 2021 used from operating activities, used from financing activities and used in investing activities were \$14,477, \$34,557 and \$12,454, respectively.

### Standards issued but not yet effective

A number of new standards are effective for annual periods beginning after December 1, 2022 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 the Company's annual reporting periods beginning on December 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.

### Classification of Liabilities as Current or Non-current (Amendments to IAS 1)

For the purposes of non-current classification, the amendments removed the requirement for a right to defer settlement or roll over of a liability for at least twelve months to be unconditional. Instead, such a right must exist at the end of the reporting period and have substance.

The amendments reconfirmed that only covenants with which a company must comply on or before the reporting date affect the classification of a liability as current or non-current. Covenants with which a company must comply after the reporting date do not affect a liability's classification at that date.

The amendments also clarify how a company classifies a liability that includes a counterparty conversion option. The amendments state that: settlement of a liability includes transferring a company's own equity instruments to the counterparty; and when classifying liabilities as current or non-current a company can ignore only those conversion options that are recognized as equity.

The amendments are effective for the Company's annual reporting period beginning on December 1, 2025. The Company is currently evaluating the impact of the amendments on its financial statements.

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

Years ended November 30, 2022 and 2021

#### 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. Refer to Note 29.

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 commercialized *EGRIFTA®* directly in Canada using a distributor until September 2022, after which time the Company withdrew the product from the market in Canada.

### **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.

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

Years ended November 30, 2022 and 2021

# 3. Revenue (continued)

On April 27, 2022, the Company announced that it would focus its commercial operations on the North American territory only and, as a result, would cease its Trogarzo® commercial operations in Europe. At that time, the Company sent a notice of termination to TaiMed Biologics Inc. ("TaiMed"), as per the contractual terms indicating it was returning the European commercialization rights to Trogarzo® to TaiMed within the next 180 days. The discontinuation became effective in December 2022. Refer to Note 13.

Net sales by product were as follows:

	2022	2021
EGRIFTA SV®	\$ 50,454	\$ 43,009
Trogarzo®	29,603	26,814
	\$ 80,057	\$ 69,823
Net sales by geography were as follows:		
	2022	2021
Canada	\$ 52	\$ 269
United States	78,744	68,099
Europe	1,261	1,455
	\$ 80,057	\$ 69,823

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

Years ended November 30, 2022 and 2021

## 4. Personnel expenses

	Note	2022	2021
Salaries and short-term employee benefits		\$ 22,049	\$ 11,480
Post-employment benefits		1,346	644
Share-based compensation	21(e),(g)	3,604	1,651
Termination benefits		566	209

In 2022, \$457 was recorded in (termination benefits as) charges related to severance and other expenses associated with the termination of agreement for Trogarzo $^{\circ}$  commercial operations in Europe.

#### 5. Finance income and finance costs

	Note	2022	2021
Gain on repurchase of convertible unsecured senior notes	19	\$ 357	\$ -
Interest income		316	195
Finance income		673	195
Accretion expense and amortization of deferred financing costs	17, 18, 19, 20	(2,140)	(2,358)
Interest on convertible unsecured senior notes and on long-term loan		(4,357)	(3,306)
Bank charges		(35)	(31)
Net foreign currency loss		(1,027)	(926)
Finance costs		(7,559)	(6,621)
Net finance cost recognized in net profit or loss		\$ (6,886)	\$ (6,426)

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

Years ended November 30, 2022 and 2021

# 6. Bonds and money market funds

	2022	2021
Bonds	\$ 8,990	\$ 12,553
Money market funds	-	7,402
Guaranteed investment certificates	224	-
	\$ 9,214	\$ 19,955

As at November 30, 2022, bonds were interest-bearing financial assets with stated interest rates ranging from 0.65% to 3.90% (2021 - 0.50% to 3.90%) and had an average maturity of 1.78 years (2021 - 2.26 years).

### 7. Trade and other receivables

	2022	2021
Trade receivables	\$ 10,659	\$ 9,261
Sales taxes receivable	538	243
Other receivables	848	983
	\$ 12,045	\$ 10,487

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

Years ended November 30, 2022 and 2021

# 8. Tax credits and grants receivable

Balance as at November 30, 2020	\$ 755
Tax credits and grants recognized in net loss	602
Tax credits and grants received	(922)
Effect of change in exchange rates	6
Balance as at November 30, 2021	\$ 441
Balance as at November 30, 2021  Tax credits and grants recognized in net loss	\$ 441 316
·	\$
Tax credits and grants recognized in net loss	\$ 316

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

Years ended November 30, 2022 and 2021

# 8. Tax credits and grants receivable (continued)

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	\$ 443
2025	1,320
2026	1,620
2027	2,232
2028	2,476
2029	1,669
2030	827
2031	578
2032	303
2033	200
2039	187
2040	318
2041	387
2042	368
	\$ 12,928

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

Years ended November 30, 2022 and 2021

# 9. Inventories

	2022	2021
Raw materials	\$ 2,583	\$ 2,142
Work in progress	5,815	735
Finished goods	11,290	26,264
	\$ 19,688	\$ 29,141

In fiscal 2022, inventories of \$19,587 (2021 - \$18,391) were recognized as an expense and included in cost of goods sold.

Inventories were written down to net realizable value by an amount of \$2,137 in 2022, which was recorded in cost of sales. Included in the 2022 write-down is a provision of \$1,477 on the F8 formulation and \$339 on material for the pen in development to be used in conjunction with the F8 formulation, and \$252 on expired raw material. The 2022 write-down also includes a provision of \$69 on excess stock of  $EGRIFTA^{\otimes}$  as a result of the Company's decision to withdraw the product from the market in Canada.

Inventories were written down to net realizable value by an amount of \$21 in 2021, and a reversal of inventory write down of \$51 in 2021.

# 10. Prepaid expenses and deposits

	2022	2021
Prepaid expenses	\$ 6,320	\$ 7,721
Deposits	1,345	3,024
	\$ 7,665	\$ 10,745

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

Years ended November 30, 2022 and 2021

# 11. Property and equipment

	Computer equipment	Laboratory equipment	Office furniture and equipment	Leasehold improvements	Tota
Cost					
Balance as at November 30, 2020	\$ 272	\$ 107	\$ 334	\$ 642	\$ 1,35
Additions	106	-	1	8	11
Disposals	(5)	-	(3)	-	(8
Balance as at November 30, 2021	\$ 373	\$ 107	\$ 332	\$ 650	\$ 1,46
Additions	180	961	-	_	1,14
Disposals	(263)	-	-	-	(263
Balance as at November 30, 2022	\$ 290	\$ 1,068	\$ 332	\$ 650	\$ 2,34
Accumulated depreciation					
Balance as at November 30, 2020	\$ 162	\$ 50	\$ 114	\$ 164	\$ 49
Depreciation Disposals	72 (5)	19 -	46 (3)	100	23 (8
Balance as at November 30, 2021	\$ 229 157	\$ 69 94	\$ 157 38	\$ 264 101	\$ 71 39
Depreciation Disposals	(263)	94	-	-	(263
Balance as at November 30, 2022	\$ 123	\$ 163	\$ 195	\$ 365	\$84
Net carrying amounts					
November 30, 2022	\$ 167	\$ 905	\$ 137	\$ 285	\$ 1,49
November 30, 2021	\$ 144	\$ 38	\$ 175	\$ 386	\$ 74

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

Years ended November 30, 2022 and 2021

# 12. Right-of-use assets

Balance as at November 30, 2020	\$ 2,618
Amortization	(449)
Effect of change in exchange rates	(58)
Balance as at November 30, 2021	\$ 2,111
Amortization	(429)
Effect of change in exchange rates	(87)
Balance as at November 30, 2022	\$ 1,595

# 13. Intangible assets

	Commercialization rights – Trogarzo® North American Territory	Commercialization rights – Trogarzo® European Territory	Commercialization rights – <i>EGRIFTA SV</i> ®	Oncology platform	Tota
Cost					
Balance as at November 30, 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
Additions	2,832	-	-	-	2,832
Balance as at November 30, 2022	\$ 14,804	\$ 7,612	\$ 14,041	\$ 3,488	\$ 39,94
Accumulated amortization					
Balance as at November 30, 2020	\$ 2,213	\$ 384	\$ 9,948	-	\$ 12,54
Amortization	1,054	615	1,511	-	3,180
Balance as at November 30, 2021	\$ 3,267	\$ 999	\$ 11,459	-	\$ 15,72
Amortization	1,087	6,613	1,511	-	9,21
Balance as at November 30, 2022	\$ 4,354	\$ 7,612	\$ 12,970	-	\$ 24,936
Net carrying amounts					
November 30, 2022	\$ 10,450	\$ -	\$ 1,071	\$ 3,488	\$ 15,009
November 30, 2021	\$ 8,705	\$ 6,613	\$ 2,582	\$ 3,488	\$ 21,388

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

Years ended November 30, 2022 and 2021

### 13. Intangible assets (continued)

The amortization expense of \$9,211 (2021 – \$3,180) is included in selling expenses.

Commercialization rights - Trogarzo®

On March 18, 2016, the Company entered into a distribution and marketing agreement with 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.

<u>Commercialization rights – Trogarzo® in the North American Territory</u>

Under the terms of the TaiMed Agreement, TaiMed was responsible for developing Trogarzo® and for seeking its approval from the US Food and Drug Administration ("FDA"). The Company is responsible, but has no obligation, to seek the approval of Trogarzo® from Health Canada and must use its commercially reasonable efforts to commercialize Trogarzo® in the United States. 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<sup>®</sup> and the right to use TaiMed's trademark in the North American Territory.

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

- (i) \$1,000 was paid in cash at the signature of the TaiMed Agreement entered into in March 2016;
- (ii) \$4,000 through the issuance of the Company's common shares, payable after the first commercial sale of Trogarzo<sup>®</sup> 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.

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

Years ended November 30, 2022 and 2021

### 13. Intangible assets (continued)

#### **Initial payments** (continued)

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.

### Further development milestone payments

Under the terms of the TaiMed Agreement, a further 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 first payment of \$3,500 was made in July 2019, and the second payment was made in June 2020. The Company determined this milestone to be substantially a development milestone and recorded such amount as additions to intangible assets during 2019. The Company also paid TaiMed further development milestones for Trogarzo® in 2022. A \$3,000 milestone (payable in two equal annual installments of \$1,500) became 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. An amount of \$2,832 has been capitalized as an intangible asset in fiscal 2022 related to these milestone payments (refer to Note 15).

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®.

### Further 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	
(i) Upon first achieving annual net sales of \$200,000	\$10,000
(ii) Upon first achieving annual net sales of \$500,000	\$40,000
(iii) Upon first achieving annual net sales of \$1,000,000	\$100,000

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

Years ended November 30, 2022 and 2021

### 13. Intangible assets (continued)

Commercialization rights - Trogarzo® European Territory

On April 17, 2022, the Company announced that it would focus its commercial operations on the North American territory only and, as a result, would cease its Trogarzo® commercial operations in Europe. Refer to Note 3.

Consequently, during the second quarter of 2022, the remaining balance of the intangible amounting to \$6,356 asset was recognized as part of selling expense to accelerate and fully amortize Commercialization rights Trogarzo® European Territory.

### **Oncology platform**

On February 25, 2019, the Company acquired Katana Biopharma Inc. ("Katana") through the purchase of all of its issued and outstanding shares. 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, part of the purchase price was to be settled through the issuance of common shares upon achieving two milestones. 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 22(b)).

The second milestone payment of CA\$2.3 million will occur when the proof of concept will have been 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. During 2019, the Company recorded additions to intangible assets 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.

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

Years ended November 30, 2022 and 2021

### 13. Intangible assets (continued)

#### Oncology platform (continued)

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 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.

The royalties payable under the Licence Agreement vary between 1.0% 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 enrollment of the first patient in the first Phase 1 clinical trial paid in May 2021;
- (ii) Second milestone payment: CA\$100 thousand upon the successful enrollment of the first patient in the first Phase 2 clinical trial;
- (iii) Third milestone payment: CA\$200 thousand upon the successful enrollment of the first patient in the first Phase 3 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.

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

Years ended November 30, 2022 and 2021

#### 14. Other asset

Cost	
Balance as at November 30, 2020, 2021 and 2022	\$ 19,5
A constitution of the second section	
Accumulated amortization	
Balance as at November 30, 2020	\$ 12,2
Amortization	4,8
Balance as at November 30, 2021	\$ 17,0
Amortization	2,4
Balance as at November 30, 2022	\$ 19,5
Net carrying amounts	
November 30, 2022	\$
November 30, 2021	\$ 2,4

On May 29, 2018, the Company entered into an 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 "Other asset" on the consolidated statement of financial position and was amortized through "Cost of sales" on the consolidated statement of net loss.

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

Years ended November 30, 2022 and 2021

### 15. Accounts payable and accrued liabilities

	Note		2022		2021
Frada navablas		Φ.	10.000	Φ.	45 500
Trade payables		\$	12,886	\$	15,526
Accrued liabilities and other payables			18,951		19,932
Salaries and benefits due to key management personnel	29		3,387		880
Employee salaries and benefits payable			1,298		1,942
iability related to deferred stock unit plan	21(d)		589		710
Accrued interest payable on convertible unsecured senior notes and					
long-term loan	18 and 19		1,108		1,386
TaiMed milestone (a)	13		2,846		-
		\$	41.065	\$	40.376

<sup>(</sup>a) On October 3, 2022, the Company announced that the United States Food and Drug Administration approved Trogarzo® (ibalizumab-uiyk) for administration by intravenous (IV) push, a method by which the undiluted medication is "pushed" by syringe for faster administration into the body's circulation. Under the TaiMed agreement, the Company has additional contingent cash-based milestones based on the attainment of the above milestones. Accordingly a \$3,000 cash payment, payable in two equal annual installments of \$1,500 has been accrued. The second payment has been discounted to reflect the effective interest rate of the liability due in one year.

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

Years ended November 30, 2022 and 2021

## 16. Provisions

	Chargebacks and rebates	Returns	Other	Total
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
Provisions made	12,910	2,004	-	14,914
Provisions used	(10,358)	(929)	-	(11,287)
Effect of change in exchange rate	(233)	-	-	(233)
Balance as at November 30, 2022	\$ 6,032	\$ 1,485	\$ -	\$ 7,517

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

Years ended November 30, 2022 and 2021

#### 17. Other obligations

The movement in the other obligations is as follows:

	Commercialization rights – Trogarzo® European Territory		Total	
Balance 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	\$	-	\$	-

#### 18. Term Loan

On July 20, 2022, the Company entered into a credit agreement providing for up to \$100,000 (the "Loan Facility") in loan. The disbursement of the loan is available in four various tranches.

The salient features of the Loan Facility are as follows:

- Senior secured term loan of up to \$100,000 across four tranches;
- \$40,000 funded on July 27, 2022 ("Tranche 1 Loan");
- \$20,000 ("Tranche 2 Loan") to be made available no later than June 30, 2023 if the Company has had net revenues of at least \$75,000 for the 12-month period immediately preceding the funding of the Tranche 2 Loan, conditional upon the submission to the FDA of the results from a human factors validation study the Company is currently conducting (the "HFS Study") and subject to the Company not being in default of its obligations under the Loan Facility. Subsequent to year-end, the lender removed the condition to submit to the FDA the results from the HFS Study the Company is currently conducting. If the other conditions to obtain Tranche 2 Loan are not met by June 30, 2023, then it nor any other tranche will be available;

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

Years ended November 30, 2022 and 2021

### 18. Term Loan (continued)

- \$15,000 ("Tranche 3 Loan") to be made available no later than March 2024 if the Tranche 2 Loan has been drawn and the Company has obtained approval from the FDA for its F8 formulation of tesamorelin, has had net revenues of at least \$90,000 in the 12-month period preceding the funding of the Tranche 3 Loan and if the Company is not in default of its obligations under the Loan Facility;
- Up to an additional \$25,000 ("Tranche 4 Loan") to be made available if the Tranche 3 Loan has been drawn and the Company has had at least \$110,000 in net revenues in the 12-month period preceding the funding of the Tranche 4 Loan and at least \$20,000 in EBITDA for the same period (as defined in the Loan Facility document until December 31, 2024);
- The Loan Facility has an initial term of five years (six years if Tranche 3 Loan is drawn), provides for an interestonly period of 24 months (36 months if Tranche 3 Loan is drawn), and bears interest at the Secured Overnight Financing Rate ("SOFR") plus 9.5%. The Tranche 1 Loan and Tranche 2 Loan are repayable in equal monthly installments on an amortization schedule of 36 months starting in July 2024 (July 2025 if the Tranche 3 Loan is funded on or prior to December 31, 2023);
- The Loan Facility provides quarterly revenue targets and minimum liquidity covenants. Until the F8 formulation is approved, the Company must maintain at all times cash, cash equivalents and eligible short-term investments in the amount of \$20,000 in specified accounts which amount will be increased to \$30,000 if the Company has not obtained approval from the FDA for its F8 formulation by March 31, 2024;
- The Loan Facility restricts the ability to incur additional debt, acquisitions, dispositions, in-licensing and out-licensing of products or assets, except in very limited circumstances. A breach of the terms and conditions of the Loan Facility will create an event of default resulting in an increase of 300 basis points on the outstanding loan and provide the lender with the ability to demand immediate repayment of the debt, and not advance any additional tranches:
- The term loan also includes a covenant prohibiting the inclusion of a going concern explanatory paragraph in the annual report of the independent registered public accounting firm, except for the fiscal year ended November 30, 2022.
- Subsequent to year end and before the issuance of the annual report of the independent registered accounting
  firm, the lender has agreed to amend the Loan Facility to remove the HFS Study condition to access the Tranche 2
  Loan and to amend the condition prohibiting the inclusion of a going concern explanatory paragraph in the annual
  report of the independent registered public accounting firm for the fiscal ended November 30, 2022 in
  consideration of the issuance of common share purchase warrants of the Company (refer to Note 30).

The lender has a first ranking security interest on all of our assets, subject to certain credit card arrangements restrictions (refer to Note 25). In connection with the entering into of the Loan Facility, the Company incurred transaction costs totalling \$3,612 of which \$2,285 was allocated to the first tranche and \$1,327 is deferred and amortized until subsequent tranches will be drawn down.

The movement in the carrying value of the term loan is as follows:

Proceeds from Loan Facility on July 27, 2022	\$ 40,000
Transaction costs	(2,285)
Accretion expense	179
Term loan as at November 30, 2022	\$ 37,894

#### 19. 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.

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

Years ended November 30, 2022 and 2021

### 19. Convertible unsecured senior notes (continued)

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

	Са	rrying Value
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
Changes from financing cash flows:		
Cash paid on repurchase		(28,546)
Transaction costs incurred		(73)
Other changes:		
Gain on repurchase		(357)
Accretion expense		1,644
Convertible unsecured senior notes as at November 30, 2022	\$	26,895

The Company announced on July 13, 2022 the signing of purchase agreements with a number of convertible US noteholders aggregating a \$30,000 principal amount of Convertible Notes for a cash consideration of \$28,746. Total transaction costs incurred in relation with the repurchase are \$73.

At the date of repurchase, the cash consideration paid, including transaction costs, was allocated between the liability and equity components. Based on the estimated fair value of the liability component, \$28,546 of the repurchase price has been allocated to the financial liability and \$200 to the equity components.

As at November 30, 2022, the aggregate principal amount outstanding of the convertible unsecured senior notes was \$27,500, maturing on June 30, 2023.

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

Years ended November 30, 2022 and 2021

## 20. Leases liabilities

	Car	rying value
Balance as at December 1, 2020	\$	2,980
Balance as at December 1, 2020	Ψ	2,900
Accretion expense		200
Lease payments		(635)
Effect of change in exchange rates		(27)
Balance as at November 30, 2021	\$	2,518
		·
Accretion expense		157
Lease payments		(605)
Effect of change in exchange rates		(148)
Balance as at November 30, 2022	\$	1,922
Current portion		(476)
Non-current portion	\$	1,446

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

Years ended November 30, 2022 and 2021

#### 21. Share capital and warrants

Authorized in unlimited number and without par value

Common shares;

Preferred shares, issuable in one or more series.

All issued shares were fully paid on November 30, 2022 and 2021.

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. During the year ended November 30, 2022, no Warrants were exercised. In 2021, 233,400 Warrants were exercised for proceeds of \$742. On November 30, 2022 and 2021, 8,130,550 Warrants were 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).

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

Years ended November 30, 2022 and 2021

### 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 for a period ending in December 2023. 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. In the fourth quarter of 2022, 1,600,000 common shares (2021 - no common shares) were sold for a proceed of \$2,960 under the ATM program. Commission, legal and other costs related to this equity raise were charged directly to equity in the amount of \$126 (2021 - nil). Costs related to setting up the program are deferred on the statement of financial position and amounted to \$26 in 2022 (2021 - \$621). The shares were sold at the prevailing market prices, which resulted in a price of \$1.85 per share. Accordingly, proportional costs of \$38 related to the common shares sold have been reclassified from deferred financing costs to share issue costs.

#### (d) DSU plan

On December 10, 2010, the Board of Directors adopted a deferred stock unit ("DSU") 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.

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

Years ended November 30, 2022 and 2021

### 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, 2022, \$126 (2021 – \$78) 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, 2022, a gain of \$221 (2021 – loss of \$209) was recognized within finance costs (Note 5). As at November 30, 2022, the Company had a total 270,143 DSUs outstanding (2021 – 215,508 DSUs) and a liability related to the DSUs of \$589(2021 – liability of \$710).

#### 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, 2022, the cash-settled forward stock contracts outstanding correspond to a total of 270,143 (2021 - 220,171) common shares at a price of \$4.92 per share (2021 - \$5.84 per share) expiring on December 19, 2023 (2021 - 2023). As at November 30, 2022, the fair value of cash-settled forward stock contracts was \$603 (2021 - \$740) and is recorded in derivative financial assets. During the year ended November 30, 2022, a loss of \$217 (2021 - 923) 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 a 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, 2022, \$12 (2021 – \$53) 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. The liability is recorded in other liabilities on the statement of financial position.

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

Years ended November 30, 2022 and 2021

### 21. Share capital and warrants (continued)

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

Granted in 2019	Measurement date as at November 30, 2022	Measurement date as at November 30, 2021
Risk-free interest rate	3.31%	1.57%
Expected volatility	58.4%	59.01%
Average option life in years	4.2 years	5.2 years
Share price	\$ 2.18 (CA\$2.93)	\$ 3.29 (CA\$4.21)
Option exercise price	\$ 5.98 (CA\$8.05)	\$ 6.30 (CA\$8.05)

Granted in 2021	Measurement date as at November 30, 2022	Measurement date as at November 30, 2021
Risk-free interest rate	3.61%	1.57%
Expected volatility	58.4%	65.5%
Average option life in years	7.2 years	8.2 years
Share price	\$ 2.18 (CA\$2.93)	\$ 3.29 (CA\$4.21)
Option exercise price	\$ 3.21 (CA\$4.32)	\$ 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 years ended November 30, 2022 and 2021.

	Number of SARs	Weighted average grant date fair value
2022 2021	- 75,000	\$ 2.13 (CA\$2.73)

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

Years ended November 30, 2022 and 2021

### 21. Share capital and warrants (continued)

#### (f) Shareholder rights plan

On March 3, 2022, the Company's Board of Directors approved the amendment and renewal of the shareholder rights plan and, on April 6, 2022, 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 10, 2022. 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 2025 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 (the "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. On March 3, 2022, the Company's Board of Directors amended the Plan to convert it from a "fixed plan" to a "rolling plan", whereby the maximum number of Common Shares which may be issued under the Plan (and under any other security-based compensation arrangements of the Company) was changed from a fixed number of Common Shares to a number of Common Shares equal to 10% of all Common Shares issued and outstanding from time to time, on a non-diluted basis, and including a "reloading" or "evergreen" feature, so that when options are exercised, the number of Common Shares issuable will be replenished and exercised options will be available to be regranted in the future. Shareholders ratified this amendment on May 10, 2022. Generally, the options vest at the grant date or over a period of up to three years.

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

Years ended November 30, 2022 and 2021

## 21. Share capital and warrants (continued)

(g) Stock option plan (continued)

As at November 30, 2022, 4,365,432 options could still be granted by the Company (2021 - 4,251,404) under the Plan.

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

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

Changes in the number of options outstanding during the p	,				verage se price option
	Number of options		CA\$		US\$
Options outstanding in US\$	•				
Options outstanding as at November 30, 2020	3,203,693	\$	3.59	\$	2.76
options satisfactioning as at the remiser co, 2020	3,233,033	Ψ	0.00	Ψ	2.70
Granted – CA\$	1,057,831		3.94		3.10
Forfeited and expired – CA\$	(406,240)		6.61		5.26
Exercised (share price: CA\$4.18 (US\$3.36))	(665,000)		1.11		0.89
Options outstanding as at November 30, 2021	3,190,284	\$	3.83	\$	3.00
Granted – CA\$	2,191,389		4.17		3.25
Forfeited and expired – CA\$	(576,853)		4.45		3.38
Exercised (share price: CA\$2.78) (US\$2.06))	(84,660)		0.31		0.23
Options outstanding as at November 30, 2022 – CA\$	4,720,160	\$	3.98	\$	2.96
Options exercisable as at November 30, 2022 – CA\$	2,217,415	\$	4.08	\$	3.03
Options exercisable as at November 30, 2021 – CA\$	1,630,476	\$	3.96	\$	3.10
Options outstanding in US\$					
Options as at November 30, 2020 – US\$	12,500				2.35
Granted – US\$	102,608		-		3.18
Forfeited – US\$	(34,375)		-		3.06
Options outstanding as at November 30, 2021 – US\$	80,733	\$	-	\$	3.09
Granted – US\$	386,672		_		3.02
Forfeited – US\$	(40,834)		-		3.13
Options outstanding as at November 30, 2022 – US\$	426,571	\$	_	\$	2.50
Options exercisable as at November 30, 2022 – US\$	31,076	\$	-	\$	2.99
Options exercisable as at November 30, 2021 – US\$	4,166	\$	-	\$	2.35

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

Years ended November 30, 2022 and 2021

## 21. Share capital and warrants (continued)

(g) Stock option plan (continued)

The following table provides stock option information as at November 30, 2022 (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 – 0.89	230,000	0.05	0.38	0.28
2.01 – 3.75	1.50 – 2.79	1,298,449	6.49	2.79	2.08
3.76 – 6.00	2.80 – 4.46	2,799,382	8.59	4.20	3.13
6.01 - 9.00	4.47 - 6.70	273,633	6.00	7.91	5.89
9.01 – 10.00	6.70 – 7.44	118,696	5.35	9.56	7.11
		4,720,160	7.36	3.98	2.96

The following table provides stock option information as at November 30, 2022 (options outstanding in US\$).

Weighted average exercise price	Weighted average remaining life	Number of options outstanding	Price range
US\$	(years)		US\$
2.49	9.05	426,571	2.01 – 3.75

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

Years ended November 30, 2022 and 2021

## 21. Share capital and warrants (continued)

## (g) Stock option plan (continued)

For the year ended November 30, 2022, \$3,860 (2021 – \$1,879) was recorded as share-based compensation expense for the stock option plan. The fair value of options granted in 2022 and 2021 was estimated at the grant date using the Black-Scholes model and the following weighted average assumptions.

Options granted in CA\$	2022	2021
Risk-free interest rate	1.62%	1.35%
Expected volatility	65.5%	70%
Average option life in years	9 years	8.5 years
Grant-date share price	\$ 3.25 (CA\$4.17)	\$ 3.10 (CA\$3.94)
Option exercise price	\$ 3.25 (CA\$4.17)	\$ 3.10 (CA\$3.94)

Options granted in US\$	2022	2021
Risk-free interest rate	1.95%	1.37%
Expected volatility	64%	72%
Average option life in years	9 years	8.5 years
Grant-date share price	\$ 2.09	\$ 3.18
Option exercise price	\$ 2.09	\$ 3.18

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

Years ended November 30, 2022 and 2021

### 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, 2022 and 2021.

Options granted in CA\$	Number of stock options granted	Weighted average grant date fair value
2022	2,191,389	\$ 2.16 (CA\$2.91)
2021	1,057,831	\$ 2.13 (CA\$2.72)

Options granted in US\$	Number of stock options granted	Weighted average grant date fair value
2022	386,672	\$ 2.09
2021	102,608	\$ 2.22

The Black-Scholes model used by the Company to calculate option values was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differs from the Company's stock option awards. This model also requires four highly subjective assumptions, including future stock price volatility and average option life, which greatly affect the calculated values.

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

Years ended November 30, 2022 and 2021

### 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 \$47,237 (2021 - \$31,725) and a weighted average number of common shares outstanding of 95,253,348 (2021 - 92,350,198), calculated as follows.

	2022	2021
Issued common shares as at December 1	0E 121 620	77 012 411
Effect of share options exercised	95,121,639 13,353	77,013,411 374,247
Effect of public issue common shares	10,000	14,816,285
Effect of share issue - ATM program	118,356	-
Effect of broker warrants exercised	-	146,255
Weighted average number of common shares, basic and diluted	95,253,348	92,350,198

For the year ended November 30, 2022, 5,146,731 (2021 – 3,271,017) share options, 8,130,550 (2021 – 8,130,550) Warrants and 1,851,852 (2021- 3,872,053) common shares potentially issuable from the conversion of the \$27,500 aggregate principal amount of convertible unsecured senior notes (Note 19), 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)

	2022	2021
Unrealized losses on FVOCI financial assets, net of tax	\$ (555)	\$ (195)
Cumulative exchange difference on translation of foreign operations	940	151
	\$ 385	\$ (44)

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

Years ended November 30, 2022 and 2021

### 22. Income taxes

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

		2022	2021
Current tax expense	\$	443	\$ 63
Deferred tax expense (recovery)			
Origination and reversal of temporary differences	\$ (	[11,705)	\$ (7,796)
Change in unrecognized deductible temporary differences		11,705	7,796
Total deferred tax expense (recovery)	\$	0	\$ -
Total current and deferred tax expense	\$	443	\$ 63
Reconciliation between effective and applicable tax amounts.			
		2022	2021
Income taxes at domestic tax statutory rate	\$ (	(12,400)	\$ (8,390)
Change in unrecognized deductible temporary differences		11,705	7,796
Impact of differences in statutory tax rates		102	64
Non-deductible expenses and other		1,036	593
Total income tax expense	\$	443	\$ 63

The applicable statutory tax rate was 26.5% in 2022 and 2021. The Company's applicable tax rate is the Canadian combined rates applicable in the jurisdictions in which the Company operates.

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

Years ended November 30, 2022 and 2021

### 22. Income taxes (continued)

Unrecognized deferred tax assets

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

		2022		2021
Research and development expenses	\$	25,110	\$	26,046
Non-capital losses	Ť	45,228	•	38,615
Property and equipment		138		225
Intellectual property and patent fees		2,854		3,054
Available deductions and other		10,298		7,535
	\$	83,628	\$	75,475

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.

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

Years ended November 30, 2022 and 2021

### 22. Income taxes (continued)

Unrecognized deferred tax assets (continued)

As at November 30, 2022 and 2021, the amounts and expiry dates of Canadian tax attributes for which no deferred tax asset was recognized were as follows:

		2022		2021
	Federal	Provincial	Federal	Provincial
Research and development expenses, without time limitation	\$ 86,768	\$ 105,174	\$ 89,740	\$ 109,034
Losses carried forward				
2027	5,569	5,561	5,960	5,952
2028	34,110	16,426	36,877	17,949
2029	14,494	12,250	15,513	13,111
2030	8,510	8,507	9,109	9,105
2031	17,525	15,556	18,758	16,651
2032	11,874	10,902	12,709	11,669
2033	8,532	8,451	9,132	9,046
2034	7,813	7,744	8,362	8,289
2037	6,972	6,889	7,462	7,373
2038	2,034	1,958	2,177	2,095
2039	1,340	1,302	1,434	1,394
2040	7,317	7,292	7,832	7,805
2041	19,350	19,276	21,220	21,153
2042	31,181	31,190	-	-
Other temporary differences, without time limitation				
Excess of tax value of property and equipment over carrying value	1,000	454	868	838
Excess of tax value of intellectual property and patent fees over carrying value	10,765	10,765	11,522	11,518
Available deductions and other	69,448	28,034	60,940	16,607

In addition to the above attributes, as at November 30, 2022, the Company has available \$8,883 of losses carried forward in Ireland without expiry dates for which no deferred tax assets are recognized. As at November 30, 2022, deferred tax liabilities have not been recognized for taxable temporary differences arising from investments in a subsidiary 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.

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

Years ended November 30, 2022 and 2021

### 23. Supplemental cash flow disclosures

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

	2022	2021
Deferred financing costs included in accounts payable and accrued liabilities	\$ <u>-</u>	\$ 174
Additions to property and equipment included in accounts payable and accrued liabilities	156	-
Acquisition of derivative financial assets included in accounts payable and accrued liabilities	104	-
Additions to intangible assets included in accounts payable and accrued liabilities	2,832	-
Reclassification of other Deferred financing costs to deficit	38	-
Share issue cost included in accounts payable and accrued liabilities	37	-

### 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. In addition to currency risk, the Company has exposure to risks from disputed accounts receivables.

### Credit risk

Credit risk refers to 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 (refer to 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 \$10,659 (2021 – \$9,261), all of which were aged under 60 days or received after year end. There was no amount recorded as bad debt expense for the years ended November 30, 2022 and 2021. Financial instruments other than cash and trade and other receivables that potentially subject the Company to significant credit risk consists principally of bonds and money market funds. The Company invests its available cash in highly liquid fixed

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

Years ended November 30, 2022 and 2021

### 24. Financial instruments (continued)

#### Credit risk (continued)

income instruments from governmental, paragovernmental, municipal and high-grade corporate bodies and money market funds (2022 – \$9,214; 2021 – \$19,955). As at November 30, 2022, 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 refers to 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 regards to the expected timing of expenditures and prevailing interest rates.

The Company is required to maintain cash, cash equivalents and eligible short-term investments for an aggregate value of at least \$20,000 currently (which amount will be increased to \$30,000 if the Company has not obtained approval from the FDA for its F8 formulation by March 31, 2024) relating to the Loan Facility, which restricts the management of the Company's liquidity. Refer to notes 1 and 18.

The following are amounts due on the contractual maturities of financial liabilities as at November 30, 2022 and 2021.

·	·			·	2022
	Carrying amount	Total contractual amount	Less than 1 year	From 1 to 2 years	More than 3 years
Accounts payable and accrued liabilities	\$ 41,065	\$ 41,065	\$ 41,065	\$ -	\$ -
erm loan, including interest (1)	37,894	57,667	5,649	28,421	23,597
Convertible unsecured senior notes, including interest	26,895	29,081	29,081	-	-
Lease liabilities	1,922	2,196	595	1,145	456
	\$ 107,776	\$ 130,009	\$ 76,390	\$ 29,566	\$ 24,053

<sup>(1)</sup> Based on SOFR forward rates. The maturities above reflect the fact that the Loan Facility has been amended in the subsequent event period and, as such, the contractual maturities are used.

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

Years ended November 30, 2022 and 2021

### 24. Financial instruments (continued)

Liquidity risk (continued)

	Carrying amount	Total contractual amount	Less than 1 year	From 1 to 2 years	2021 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

### **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 euros.

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, 2022 and 2021.

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

Years ended November 30, 2022 and 2021

## 24. Financial instruments (continued)

Currency risk (continued)

		2022		2021
	CA\$	EURO	CA\$	EURO
Cash	1,547	236	589	61
Bonds and money market funds	12,387	-	16,298	-
Trade and other receivables	733	2,141	331	1,553
Tax credits and grants receivable	66	239	385	123
Accounts payables and accrued liabilities	(10,784)	(5,849)	(6,819)	(7,256)
Lease liabilities	(1,362)	(873)	(1,755)	(1,010)
Provisions	-	(3,486)	-	(1,970)
Total exposure	2,587	(7,592)	9,029	(8,499)

The following exchange rates are those applicable as at November 30, 2022 and 2021.

		2022		2021
	Average rate	Reporting date rate	Average rate	Reporting date rate
CA\$ – US\$	0,7722	0,7439	0,7979	0,7822
Euro – US\$	1,0600	1,0406	1,1906	1,1338

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

Years ended November 30, 2022 and 2021

### 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.

		2022		2021
	CA\$	Euro	CA\$	Euro
Positive (negative) impact	129	(380)	451	(425)

An assumed 5% weakening of the CA\$ or of the euro 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 refers to 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 fair value through OCI, 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, 2022, 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 \$79 (2021 - \$141); 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, 2022 of 23,505 (2021 – 41,491), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately 118 (2021 – 207); an assumed decrease of 0.5% would have had an equal but opposite effect.

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

Years ended November 30, 2022 and 2021

### 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.

Based on the value of the Company's long-term loan as at November 30, 2022, an assumed 0.5% increase in SOFR rate during such year would have decreased future cash flows and net profit by approximately \$70 and an assumed increase of 0.5% would have had an equal but opposite effect.

### 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 (refer to Note 21(c)) under which it may sell, from time to time, up to \$47,000 of its common shares.

The capital management objectives remain the same as for the previous year, except that the Company's cash deposit and brokerage accounts are subject to control agreements relating to the Loan Facility and certain credit card arrangements allowing creditors to collateralized outstanding loaned values. Furthermore, the Company is required to maintain cash, cash equivalents and eligible short-term investments for an aggregate value of at least \$20,000 currently (which amount can increase in certain circumstances) relating to the Loan Facility and up to 105% of the credit available under the credit card arrangements.

As at November 30, 2022, cash, bonds and money market funds amounted to \$33,070 (2021-\$40,354).

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.

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

Years ended November 30, 2022 and 2021

### 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, 2022 was approximately \$24,200 (2021–\$52,756) (Level 1) based on market quotes.

The Company has determined that the carrying value of its term loan approximates its fair value because it was issued near the 2022 year-end.

### **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.

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

Years ended November 30, 2022 and 2021

#### 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  $EGRIFTA~SV^{\otimes}$  and  $Trogarzo^{\otimes}$ . As at November 30, 2022, the Company had outstanding purchase orders and minimum payments required under these agreements amounting to \$1,644 (2021 – \$6,598) for the manufacture of  $Trogarzo^{\otimes}$ ,  $EGRIFTA~SV^{\otimes}$  and for various services.

As at November 30, 2022, the Company also has research commitments and outstanding clinical material purchase orders amounting to \$1,310 (2021 – \$1,253) in connection with the oncology platform and \$868 (2021 – \$724) in connection with a new formulation of tesamorelin and of a multi-dose pen injector developed for this new formulation.

#### (b) 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, the Company 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.

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

Years ended November 30, 2022 and 2021

### 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.

	2022	2021
RxCrossroads	\$ 78,744	\$ 68,917
Others	1,313	906
	\$ 80,057	\$ 69,823

All of the Company's non-current assets are located in Canada, the United States and Ireland. Of the Company's non-current assets of \$19,890 (2021 - \$27,304), \$18,980 (2021 - \$26,206) are located in Canada, \$69 (2021 - \$5) are located in the United States and \$841 (2021 - \$1,093) are located in Ireland.

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

Years ended November 30, 2022 and 2021

#### 29. Related parties

The key management personnel of the Company are the directors, the President and Chief Executive Officer, the Senior Vice President and Chief Financial Officer, the Global Commercial Officer and the Senior Vice President and Chief Medical Officer.

Key management personnel compensation comprises:

	2022	2021
Short-term employee benefits	\$ 3,191	\$ 2,690
Post-employment benefits	86	72
Share-based compensation	2,078	1,243
	\$ 5,355	\$ 4,005

As at November 30, 2022, the key management personnel controlled 0.8% (2021 - 0.7%) of the voting shares of the Company and held 0.3% (2021 - 0.2%) of the convertible unsecured senior notes.

### 30. Subsequent events

On February 27, 2023, the Company issued to affiliates of Marathon Asset Management (collectively, "Marathon"), prorata to their participation under the Loan Facility, an aggregate of 5,000,000 common share purchase warrants (the "Warrants"). Each Warrant entitles the holder thereof to subscribe for one common share of the Company at a price of \$1.45 for a period of seven years. The Warrants will not be traded on any stock exchange. They are transferable only to affiliates of Marathon or to other potential lenders under the terms of the Loan Facility and their affiliates.

The Warrants were issued as consideration for various amendments made to the Loan Facility, including:

- An amendment to remove the second tranche condition requiring the Company to have filed with the FDA the
  results of its HFS Study before June 30, 2023; and
- An amendment to allow for to the inclusion of a going concern explanatory paragraph in the annual report of the independent registered public accounting firm for the fiscal year ended November 30, 2022.



#### MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE YEAR ENDED NOVEMBER 30, 2022

The following Management's Discussion and Analysis ("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, 2022 ("Fiscal 2022"), compared to the year ended November 30, 2021 ("Fiscal 2021"). 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 27, 2023, was approved by our Board of Directors on February 27, 2023 and should be read in conjunction with our audited annual consolidated financial statements and the notes thereto as at November 30, 2022 ("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  $EGRIFTA^{\circledR}$  and EGRIFTA  $SV^{\circledR}$  (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and the use of Trogarzo $^{\circledR}$  (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:

Theratechnologies Inc. 2015 Peel Street, 11<sup>th</sup> Floor Montreal, Québec H3A 1T8

- our expectations regarding the commercialization of *EGRIFTA SV®* and Trogarzo®, despite new market entrants;
- 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;
- the filing of a supplemental biologic application ("sBLA") for an intramuscular method of administration of Trogarzo®;
- the approval of an intramuscular method of administration of Trogarzo® by the United States Food and Drug Administration ("FDA");
- the filing of a sBLA with the FDA for a new formulation of tesamorelin ("F8 Formulation");
- the approval of the F8 Formulation by the FDA;
- our ability to successfully complete the human factors validation study ("HFS") and to resubmit a CBE supplement with the FDA for *EGRIFA SV*® in the 2023 fiscal year;
- our capacity to meet the undertakings, covenants and obligations contained in the credit agreement entered into with Marathon's affiliates and not be in default thereof;
- our capacity to find a partner to conduct a Phase 2b/3 clinical trial using tesamorelin for the treatment of NASH in the general population;
- the filing of an amendment to our protocol to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our capacity to find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;

- our capacity to pursue the development of other PDCs in the field of oncology;
- our capacity to acquire, in-license, or copromote new products;
- 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:

- sales of EGRIFTA SV® and Trogarzo® in the United States will increase over time;
- our expenses will remain under control;
- our commercial practices in the United States 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 the United States;
- continuous supply of EGRIFTA SV® and Trogarzo® will be available to meet market demand on a timely basis;
- our relations with third-party suppliers of EGRIFTA SV® and Trogarzo® will be conflict-free;
- the level of product returns and the value of chargebacks and rebates will not exceed our estimates in relation thereto;
- 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;

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- we will file a sBLA for the F8 Formulation in the 2023 fiscal year;
- the FDA will approve the F8 Formulation;
- no vaccine or cure will be found for the prevention or eradication of HIV;
- the HFS will be successfully completed and we will resubmit a CBE supplement with the FDA for *EGRIFTA SV*® by the end of the 2023 fiscal year;
- the FDA will approve the CBE supplement;
- we will not default under the terms and conditions of the credit agreement entered into with Marathon's affiliates, including meeting the minimum liquidity and revenue target covenants therein;
- we will meet all of the conditions set forth under the credit agreement entered into with Marathon's affiliates to draw down the \$20 million second tranche;
- the interest rate on the amount borrowed from Marathon's affiliates under the credit agreement will not materially vary upwards;
- the Corporation will continue as a going concern;
- we will find a partner to conduct a Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population;
- the FDA will approve the amendments to our protocol allowing us to resume the conduct of our Phase 1 clinical trial using TH1902 in various types of cancer;
- our Phase 1 clinical trial studying TH1902 in various types of cancer will demonstrate positive efficacy and safety results;
- we will find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed;
- our research and development activities will yield positive results;
- the data obtained from our market research on the potential market for *EGRIFTA SV*® and on the potential market for Trogarzo® in the United States are accurate;
- 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;
- our business plan will not be substantially modified; and
- no international event, such as a pandemic or worldwide war, will occur and adversely affect global trade.

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 Risks and Uncertainties (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.

### **NON-IFRS AND NON-US GAAP MEASURE**

The information presented in this MD&A includes a measure that is not determined in accordance with International Financial Reporting Standards ("IFRS") or U.S. generally accepted accounting principles ("U.S. GAAP"), being the term "Adjusted EBITDA". "Adjusted EBITDA" is used by the Corporation as an indicator of financial performance and is obtained by adding to net profit or loss, finance income and costs, depreciation and amortization, income taxes, share-based compensation from stock options, and certain write-downs (or related reversals) of inventories. "Adjusted EBITDA" excludes the effects of items that primarily reflect the impact of long-term investment and financing decisions rather than the results of day-to-day operations. The Corporation believes that this measure can be a useful indicator of its operational performance and financial condition from one period to another. The Corporation uses this non-IFRS measure to make financial, strategic and operating decisions.

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### **BUSINESS 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 and to achieve a positive Adjusted EBITDA from the sale of our existing and potential future assets in North America 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*® and Trogarzo® in the United States.

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 the first HIV treatment approved with a new mechanism of action in more than 10 years. The treatment is administered every two weeks. It is a long-acting antiretroviral ("ARV") therapy that can lead to an undetectable viral load in combination with other ARVs.

Trogarzo® was also approved by the EMA in September 2019 and is no longer under licence to us in Europe further to our decision to terminate and return to TaiMed our commercialization rights to this product in April 2022. The EMA has since withdrawn the marketing approval of Trogarzo® in Europe.

In addition to the sale of our products, we are conducting research and development activities. We have a pipeline of investigational medicines in the areas of NASH and oncology. Tesamorelin, the active ingredient in  $EGRIFTA\ SV^{\otimes}$ , 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+ Technology<sup>TM</sup> that attaches to docetaxel, is designed to specifically target Sortilin ("SORT1") receptors expressed in cancer cells of various types of cancer. TH1902 was studied in a Phase 1 clinical trial until we decided to voluntarily pause the recruitment of patients in December 2022. We are also working on the development of other PDCs.

Our plan to initiate a Phase 2b/3 clinical trial to study tesamorelin for the treatment of NASH in the general population has been postponed until we can find a partner.

To date, we have completed the in-house bioequivalence study of the F8 Formulation and have begun assessing the development of a device, such as a pen (the "Pen"), intended to be used eventually with the F8 Formulation. As a result of issues in sourcing bacteriostatic water for injection in the past fiscal year, we have delayed the filing of a sBLA with the FDA seeking the approval of the F8 Formulation until later in fiscal 2023.

We have also completed the enrollment of patients for the development of an intramuscular method of administration of Trogarzo® and plan on filing a sBLA with the FDA seeking its approval in the current fiscal year.

### 2022 Year in Review

- 2023 Fiscal Year Guidance and Key Objectives. On January 4, 2023, we announced, among other things, revenue guidance between \$90 million and \$95 million for the fiscal year 2023, our key objectives for the fiscal year 2023 consisting of achieving positive Adjusted EBITDA and the creation of an advisory scientific committee whose mandate is to optimize the protocol amendments for the development of TH1902.
- Voluntary Pause of Phase 1 Clinical Trial Studying TH1902. On December 1, 2022, we announced our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 and to revisit the study design of this clinical trial.
- FDA Approval of 30-Second Intravenous Push Method of Administration of Trogarzo<sup>®</sup>. On October 3, 2022, we announced that the FDA approved the 30-Second Intravenous Push Method of Administration of Trogarzo<sup>®</sup>.
- Closing of Funding of \$40 million Under Credit Agreement. On July 27, 2022, we announced that we received \$40 million under the terms of a credit agreement with affiliated funds of Marathon Asset Management.
- Conclusion of Non-Dilutive Term Loan of Up to \$100 million. On July 13, 2022, we announced that we had entered into a binding commitment with affiliated funds of Marathon Asset Management providing for a non-dilutive term loan of up to \$100 million (the "Marathon Credit Facility"). On February [27], 2023, we entered into a first amendment to the Marathon Credit Facility (the "First Amendment to the Marathon Credit Facility"). The First Amendment to the Marathon Credit Facility and the Marathon Credit Facility are collectively referred to as the "Marathon Credit Facility". See "Item 9 Material Contracts Marathon Credit Facility" below for a description of the Marathon Credit Facility.
- Strategic Hire Supporting Investor Relations. On May 31, 2022, we announced the hiring of a new Head of Investor Relations.
- Initiation of Basket Trial in Phase 1 Clinical Trial Studying TH1902. On May 10, 2022, we announced the initiation of the recruitment of patients in the basket

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portion of the first-in-human study of TH1902. The dose of TH1902 was then established at 300 mg/m<sup>2</sup>.

- Return of European Commercialization Rights of Trogarzo® to TaiMed. On April 27, 2022, we announced that we notified TaiMed of our decision to return the European commercialization rights to Trogarzo® to TaiMed within the next 180 days pursuant to the terms of the TaiMed Agreement.
- Launch of an Internal Sales Force. On February 15, 2022, we announced the launch of our own field force through the hiring of key account managers joining from our long-term contract sales organization. We also announced the hiring of medical science liaison and community liaison personnel as part of the internalization of commercial and medical dedicated personnel.

### **OUR 2023 BUSINESS OBJECTIVES**

Our business objectives in 2023 is focused on: increasing sales of *EGRIFTA SV®* and Trogarzo® in the United States and on managing our expenses to achieve a positive Adjusted EBITDA by year-end; continuing pursuing potential product acquisition, in-licensing transactions, copromotion, or other similar opportunities to grow our revenues; filing sBLAs in the United States for both the intramuscular method of administration of Trogarzo® and the F8 Formulation; resubmitting a CBE supplement with the FDA in relation to the HFS for *EGRIFTA SV®*; filing an amended protocol with the FDA to resume our Phase 1 clinical trial studying TH1902 in various types of cancer; seeking potential partners for our Phase 2b/3 in NASH using tesamorelin and, once our Phase 1 clinical trial has resumed, for TH1902; and, managing our financial position to ensure we can successfully execute on our 2023 business objectives.

### **Program Updates in Review**

### **EGRIFTA SV®**

In HIV-associated lipodystrophy, we are on track to complete the Human Factors Study (HFS) for *EGRIFTA SV*® in the first half of 2023, and we are diligently completing the work associated to the supplemental biologic license application (sBLA) filing for the F8 formulation of Tesamorelin with the United States Food and Drug Administration ("FDA").

We are also confident in successfully addressing the shortage of bacteriostatic water for injection ("BWFI") by placing the sourcing of this drug component under our own control via the services of a third-party manufacturer, thereby securing a secondary source of supply for this important component to the F8 formulation. The further development of Tesamorelin allows Theratechnologies to maintain its positioning as one of the few options for drug developers to immediately partner with a company in order to launch a Phase 2b/3 NASH clinical trial.

# **Trogarzo® Lifecycle Management**

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During 2022, we made progress towards improving Trogarzo®'s method of administration and now have FDA approval for Trogarzo®'s 30-Second Intravenous ("IV") Push administration, simplifying the method of administration for heavily treatment-experienced populations. We are also working closely with our partner, TaiMed Biologics, in completing the development of an intra-muscular method of administration for Trogarzo®, and subsequent filing of a new supplemental sBLA with the FDA. These projects will serve to ensure lifecycle management of Trogarzo® for years to come.

# **TH1902 Development Pathway**

Subsequent to the end of the quarter and FY2022, the Company announced on December 1, 2022 that it had decided to pause the enrollment of patients in its Phase 1 clinical trial of TH1902, the Company's lead investigational peptide drug conjugate (PDC) for the treatment of sortilin-expressing cancers.

Theratechnologies voluntarily made the decision to pause enrollment and revisit the study design after consulting with its investigators. Efficacy results observed thus far were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. As previously reported, these adverse events consist mainly of neuropathy and eye toxicity.

Following the voluntary pause, the Company formed a Scientific Advisory Committee (SAC) to help determine the best developmental path forward for TH1902. In addition to the study's principal investigator, the SAC includes several medical oncologists from across the U.S., who are leading experts in the end-to-end lifecycle of oncology drug development:

- Erika Hamilton, MD, director of Breast Cancer and Gynecologic Cancer Research for Sarah Cannon Research Institute at Tennessee Oncology;
- Daniel Petrylak, MD, professor of medicine in Medical Oncology and Urology and chief, Genitourinary Oncology at Yale School of Medicine; and
- Anthony Tolcher, MD, medical oncologist at Texas Oncology-San Antonio Medical Center.

The Company will continue to seek advice and input from Mace Rothenberg, MD, who is currently a scientific advisor to Theratechnologies.

Since announcing our decision to pause enrollment in the basket trial, we have had discussions with the FDA, and the agency has indicated that it agreed with our voluntary pause. Further to our discussions with the FDA, we received a letter indicating that our Phase 1 clinical trial was placed on a partial clinical hold subject to our responses to a list of questions.

Theratechnologies is currently analyzing data and preparing responses to questions received from the FDA. This work is well underway and will be considered by the SAC as part of their meeting, which is scheduled for the latter

half of March when the analyses are expected to be ready. Once expert advice is considered, the Company intends to promptly amend the protocol and re-submit to the FDA.

The FDA had earlier indicated that their review of the protocol amendment would be completed within thirty days of submission.

Consistent with the Company's 2023 objective of generating positive Adjusted EBITDA by fiscal year end, any new investments in TH1902 will be stage gated. Once the Phase 1 clinical trial has resumed, Theratechnologies will also evaluate potential partnerships for TH1902.

### **NASH**

Our NASH program is still on pause pending availability of BWFI for the F8 formulation and finding a partner with resources and capabilities. We continue to have discussions with potential NASH partners and are encouraged to see renewed NASH interest with recent industry announcements.

### **RESEARCH AND DEVELOPMENT ACTIVITIES**

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

### Tesamorelin

EGRIFTA SV® Human Factors Study

Following complaints received by patients relating to the reconstitution of *EGRIFTA SV*® after its launch in 2019, we have submitted in March 2021 to the FDA a Changes Being Effected ("CBE") supplement to the Instructions For Use ("IFU") included in the *EGRIFTA SV*® product labeling and, per the timelines set forth in the regulation, we implemented these changes, which included an amended IFU. We also provided patients with detailed training through our call center, *THERA Patient Support*®, related to the changes and the number of complaints has since been significantly reduced. The FDA responded to our CBE supplement with a complete response letter asking us to carry out a HFS to ensure that patients reconstitute the product in the proper manner. We had one year to complete and resubmit the supplemental application including the HFS to the FDA and the FDA has recently granted until September 15, 2023, a six-month extension period, to submit the response to the FDA complete response letter. The first part of the HFS, the formative study, has now been completed and the Company filed its proposed HFS protocol with the FDA for its review prior to initiate the summative study. The Company has yet to receive a response from the FDA on its proposed protocol.

### 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  $EGRIFTA\ SV^{®}$  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. To date, all process validation batches have been manufactured.

The F8 Formulation requires the use of bacteriostatic water for injection ("BWFI") since the reconstituted product will be used for seven daily injections. In the spring of 2022, we were informed by the sole global supplier of BWFI that its manufacturing plant had been the subject of an FDA inspection that resulted in this supplier having to make modifications to its facilities before being able to resume manufacturing and shipment of its BWFI. As a result, our plan to file a sBLA by the end of the first quarter of 2022 had to be delayed until this supplier could resume the manufacture of BWFI and the shipment thereof or until we could find an alternate supplier to source BWFI. We have entered into a development agreement with a third party supplier for the manufacture of our own supply of BWFI and, to date, the engineering and validation batches of BWFI have been manufactured. We have initiated discussions with this third party supplier with the aim of entering into a long term supply agreement for BWFI. In addition, with the requirement of the FDA to conduct a HFS for *EGRIFTA SV*®, we have proactively decided to conduct one for the F8 Formulation as well prior to submitting a sBLA seeking the approval of the F8 Formulation. This study is expected to be completed after the *EGRIFTA SV*® HFS. We now plan on filing an sBLA with the FDA seeking the approval of the F8 Formulation in the fourth quarter of 2023 for the treatment of lipodystrophy in people living with HIV.

The F8 Formulation is also intended to be used in our Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population. See "Tesamorelin for NASH in the General Population" below.

### Multi-Dose Pen Injector

In the fiscal year 2021, 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 assessing the feasibility. As a result, no timeline has been set for the development of 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 ("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.

In July 2021, we 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. To date, we are still continuing to seek a partner and discussions are still ongoing.

In order to de-risk the Phase 3 trial, in February 2022, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address these with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes 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. The amended protocol would allow us to generate hard endpoint data on NAS score and fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

NAFLD includes nonalcoholic fatty liver ("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.

#### **Ibalizumab**

Intramuscular Method of Administration of Trogarzo®

The Corporation has now completed the enrollment of all patients for this study and the study is completed. We are presently completing the analysis of the data related thereto. The study consisted of assessing the safety and pharmacokinetic levels of Trogarzo® when administered intramuscularly using a syringe. We expect to file a sBLA with the FDA seeking the approval of the intramuscular method of administration in the course of the 2023 fiscal year.

### TH1902

#### Phase 1 Clinical Trial

In December 2020, we filed an IND application with the FDA for the initiation of a 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, we initiated our Phase 1 clinical trial evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design included a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose (the "MTD") and preliminary anti-tumor activity of TH1902

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administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Part B of the Phase 1 clinical trial, also known as the "basket trial" consisted in recruiting a total of approximately 70 patients to study the safety and tolerability of TH1902 in the following various solid tumor types, including HR+ breast cancer, triple negative breast cancer, ovarian cancer, endometrial cancer, melanoma, thyroid cancer, small cell lung cancer, and prostate cancer.

As per the study protocol, the MTD is established once a significant adverse event is observed in two or more patients.

Part A of the Phase 1 clinical trial was completed in the summer of 2022. We then reported that a total of 18 heavily pre-treated patients, who received an average of eight prior cancer treatments, were enrolled in the dose escalation portion of the study. Following the safety observations at 420 mg/m2 including grade 3 neuropathy, grade 4 neutropenia, grade 3 ocular changes (visual acuity, keratitis and ocular surface dryness) and grade 2 skin toxicities (rash, pruritis and inflammation), the dose of TH1902 was decreased to 300 mg/m2 for the next dose level and was expanded to a total of six patients. No dose limiting toxicities ("DLTs") were observed during the first cycle, therefore, the dose of 300 mg/m2 was selected for continuation of the basket trial.

In addition, we reported that the levels of free docetaxel were low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m2. 300 mg/m2 appeared to be a well-tolerated dose level.

We further reported the observation of signs of efficacy in three heavily pretreated patients and the recorded results included:

- confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m2, although the prostate specific antigen ("PSA") continued to progress;
- stabilized disease in a prostate cancer patient with measurable reduction in target lesion sizes (single digit percentages), including one PSA response (the patient was treated with mixed cycles of TH1902 from 420 mg/m2 to 300 mg/m2); and
- stabilized disease in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages) after receiving a total of 11 cycles (the patient's dose was escalated from 60 mg/m2 to 360 mg/m2).

Following the determination of the MTD, we began enrolling patients in the basket trial and, in December 2022, we decided to voluntarily pause the enrollment of patients and revisit the study design of our clinical trial studying TH1902 in various types of cancer. The decision was made after consulting with our investigators. The efficacy results observed were not convincing enough to pursue the enrollment of patients and did not outweigh the adverse events seen in some patients.

The Corporation is currently studying the data from its Phase 1 clinical trial and has formed a scientific advisory committee ("SAC") comprised of the study's principal investigator, and several medical oncologists from across the United States who are leading experts in the end-to-end lifecycle of oncology drug development to help determine the best developmental path forward for TH1902. The meeting of the SAC is scheduled to take place in the latter half of March 2023.

Further to our decision to voluntarily pause the enrollment of patients, we have had discussions with the FDA. Following such discussions, we received a letter from the FDA indicating that our Phase 1 clinical trial was placed on a partial clinical hold subject to our responses to a list of questions. We intend to respond to the FDA's questions along with the filing of the amended protocol. Questions raised by the FDA were already being addressed by our team as part of our analysis of the data accumulated so far in the Phase 1 clinical trial and we are confident that we will be able to address all of the FDA's questions. The FDA indicated that their review of the protocol amendment would be completed within thirty days of submission.

Consistent with our 2023 objectives of achieving a positive Adjusted EBITDA, any new investment in the development of TH1902 will be stage-gated. Once the Phase 1 clinical trial has resumed, we plan on evaluating potential partnerships for TH1902.

### **SORT1+ Technology™ Platform**

#### Description

SORT1+ Technology™ is the name we gave our platform that provides for the development of new proprietary peptides for cancer drug development targeting SORT1 receptors. 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 the SORT1+ Technology<sup>TM</sup> 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, SN38 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+ Technology<sup>TM</sup>, 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.

We are no longer conducting research and development work on TH1904, one of our other investigational PDCs. However, we continue the conduct of research and development activities on other PDCs, primarily to advance a PDC using SN38.

Since announcing our decision to voluntarily pause the enrollment of patients in our Phase 1 clinical trial studying TH1902 in various types of cancer, partnership discussions in Greater China regarding the development and commercialization of TH1902 have been paused as well.

### Acquisition of SORT1+ Technology™ Platform

We acquired the SORT1+ Technology™ platform following the acquisition of all of the issued and outstanding shares of Katana BioPharma Inc. ("Katana") on February 25, 2019 (the "Katana Agreement"). Katana had the exclusive worldwide rights, through a royalty-bearing licence agreement entered into with Transfert Plus, LP ("Transfert Plus"), to a technology platform using peptides as a vehicle to specifically deliver cytotoxic agents to sortilin receptors, which are overexpressed on cancer cells (the "Transfert Plus License Agreement"). Katana has since been wound up into Theratechnologies and we became a party to the Transfer Plus License Agreement.

In consideration of the acquisition of all of the issued and outstanding shares of Katana, the Corporation agreed to pay a purchase price aggregating CAD 6.9 million in various tranches. To date, there remains a balance of CAD 2,880,000 payable through the issuance of common shares upon our decision to pursue the development of TH1902, or any other PDCs studied in a Phase 1 clinical trial, that warrant the pursuit of its development beyond the completion of such Phase 1 clinical trial.

### **NOTABLE TRANSACTIONS 2022**

### \$100 million Credit Agreement with Marathon Asset Management

On July 13, the Company announced it received a binding commitment letter with respect to a non-dilutive term loan with Marathon Asset Management for up to \$100,000 (the "Loan Facility"). Highlights of the agreement are as follows:

- Senior secured term loan of up to \$100,000 across four tranches;
- \$40,000 is expected to be funded before July 29, 2022 ("Tranche 1 Loan");
- \$20,000 to be made available by no later than June 30, 2023, if the Company has filed with the FDA its sBLA for the EGRIFTA SV® human factor study and has had net revenues of at least \$75,000 for the 12-month period immediately preceding the funding of the tranche ("Tranche 2 Loan");
- \$15,000 to be made available by no later than March 2024 if the Company has obtained approval from the FDA for its F8 formulation of tesamorelin and has had net revenues of at least \$90,000 for the 12-month period immediately preceding the funding of the tranche ("Tranche 3 Loan");
- Up to an additional \$25,000 to be made available no later than December 31, 2024, if the Company has had at least \$110,000 in net revenues for the 12-month period immediately preceding the funding of the tranche and at least \$20,000 in EBITDA (as defined in the Credit Agreement) ("Tranche 4 Loan");

- The facility will have an initial term of five years (six years if Tranche 3 is drawn), provide for an interest-only period of 24 months (36 months if Tranche 3 is drawn), and bear interest at the Secured Overnight Financing Rate (SOFR) plus 9.5%;
- The proceeds from the Tranche 1 Loan shall be used to purchase \$30,000 principal amount of issued and outstanding convertible unsecured senior notes and the proceeds of the Tranche 2 Loan shall be used to reimburse the remaining issued and outstanding Convertible Notes at maturity; and,
- The proceeds of both the Tranche 3 Loan and Tranche 4 Loan can be used for general corporate purposes.

The Company also announced the signing of purchase agreements with a number of convertible noteholders aggregating \$30,000 principal amount of Convertible Notes. The purchase price of these Convertible Notes will be made promptly after the funding of the Tranche 1 Loan.

On July 27, 2022, the Company announced that it received funding of \$40 million under the terms of this Credit Agreement. A portion of the net proceeds from this amount was used to buy back and cancel \$30 million principal amount of convertible notes due June 30, 2023, through private agreements with certain 7 Theratechnologies Inc. 2015 Peel Street, 11th Floor Montreal, Québec H3A 1T8 noteholders, while the remainder was allocated to working capital. All amounts drawn under the Credit Agreement bear interest at SOFR plus 9.5%.

### **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, 2022:

In millions	Estimated Use of Proceeds	Actual Use of Proceeds	Variance
Nash Phase 3 clinical trial	\$30.5	\$2.8	\$(27.7)
Oncology R&D	7.0	8.1	1.1
Commercial and marketing activities	3.5		(3.5)
Other	1.5	2.0	0.5
Net Proceeds	\$42.5	\$12.9	\$(29.6)

As at November 30, 2022, approximately \$2,828,000 had been used in connection with the NASH Phase 3 clinical trial.

As at November 30, 2022, approximately \$8,114,000 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, 2022 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.

# Fourth-Quarter and Fiscal 2022 Revenue Highlights (in 000s of US\$)

	periods	Three-month periods ended November 30,		% Years ended change November 30,		% change
	<u>2022</u>	<u>2021</u>		<u>2022</u>	<u>2021</u>	
EGRIFTA®, EGRIFTA SV® net sales Trogarzo® net sales	14,458 6,963	12,753 6,001	13.4% 16.0%	50,454 29,603	43,009 26,814	17.3% 10.4%
Revenue	\$21,421	\$18,754	14.2%	\$80,057	\$69,823	14.7%

### Fourth-Quarter Fiscal 2022 Financial Results

#### Revenue

Consolidated revenue for the three months ended November 30, 2022 amounted to \$21,421,000 compared to \$18,754,000 for the same period last year, representing an increase of 14.2%.

For the fourth quarter of Fiscal 2022, sales of *EGRIFTA SV*® reached \$14,458,000 compared to \$12,753,000 in the fourth quarter of the prior year, representing an increase of 13.4%. Strong sales of *EGRIFTA SV*® were mostly the result increased unit sales and a higher net selling price.

In the fourth quarter of Fiscal 2022, Trogarzo® sales amounted to \$6,963,000 compared to \$6,001,000 for the same quarter of 2021, representing an increase of 16.0%. 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"). Trogarzo sales in the fourth quarter of 2022 were up marginally in the United States and were affected by lower inventory levels at our distributor at the close of the quarter and slightly higher rebates to government payers.

#### Cost of Sales

For the three-month period ended November 30, 2022, cost of sales was \$5,909,000 compared to \$6,411,000 in the comparable period of Fiscal 2021. Cost of goods sold increased to \$5,909,000 compared to \$5,191,000 for the same period last year. Cost of goods sold for the fourth quarter of 2022 includes a provision of \$1,477,000 related to the write down of F8 formulation of tesamorelin for pre-commercial material which could expire prior to the launch of the F8, if approved.

In the fourth quarter of 2021, cost of sales included an amortization charge of \$1,220,000 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. The Other asset was fully amortized during the first half of Fiscal 2022, and thus this charge was Nil in the fourth quarter of Fiscal 2022.

### **R&D Expenses**

R&D expenses in the three-month period ended November 30, 2022 amounted to \$9,455,000 compared to \$8,678,000 in the comparable period of Fiscal 2021. The increase during the fourth quarter of Fiscal 2022 was largely due to the development of our oncology platform, including the Phase 1 trial for TH1902, the Human Factor Study for *EGRIFTA SV*®, as well as the development of the Intramuscular method of administration of Trogarzo®.

### **Selling Expenses**

Selling expenses in the three-month period ended November 30, 2022 amounted to \$7,809,000 compared to \$8,193,000 in the comparable period of Fiscal 2021.

The decrease in selling expenses is largely associated to the decision to exit the European market in 2022, and is offset by higher spending in the United States.

### **General and Administrative Expenses**

General and administrative expenses in the fourth quarter of Fiscal 2022 amounted to \$3,956,000, compared to \$3,537,000 reported in the same period of Fiscal 2021. The increased is due to an overall increase in activity to reflect the growth of our business in North America related to the on boarding of our field force during 2022.

#### **Net Finance Costs**

Net finance costs for the three-month period ended November 30, 2022 were \$2,078,000 compared to \$1,817,000 in the same period last year. The increase in net finance cost is due to the higher interest on the company's outstanding long-term debt due to the new Loan Facility in Q3 of fiscal 2022. The increase was offset by higher interest income and a lower net foreign currency loss.

#### **Net loss**

Taking into account the revenue and expense variations described above, we recorded a net loss of \$7,929,000, or \$0.09 per share, in the fourth quarter of Fiscal 2022 compared to a net loss of \$9,901,000, or \$0.10 per share, in the fourth quarter of Fiscal 2021.

# **Quarterly Financial Information**

The following table is a summary of our unaudited consolidated operating results for the last 8 quarters of Fiscal 2022 and Fiscal 2021.

### (in thousands of dollars, except per share amounts)

	2022			2021				
	Q4	Q3	Q2	Q1	Q4	Q3	Q2	Q1
Revenue	21,421	20,811	19,268	18,557	18,754	17,852	17,787	15,430
Operating expenses								
Cost of sales								
Cost of goods sold	5,909	5,292	7,759	4,878	5,191	4,283	4,714	4,190
Amortization of other asset	-	-	1,220	1,221	1,220	1,221	1,220	1,221
R&D	9,455	8,425	11,056	8,003	8,678	8,296	6,417	4,883
Selling	7,809	8,404	15,371	7,807	8,193	7,657	6,901	6,158
General and administrative	3,956	4,209	4,823	4,368	3,537	3,633	3,884	3,562
Total operating expenses	27,129	26,330	40,229	26,277	26,819	25,090	23,136	20,014
Net finance costs	(2,078)	(1,879)	(1,644)	(1,285)	(1,817)	(2,254)	(1,023)	(1,332)
Income taxes	(143)	(151)	(122)	(27)	(19)	(18)	(20)	(6)
Net loss	(7,929)	(7,549)	(22,727)	(9,032)	(9,901)	(9,510)	(6,392)	(5,922)
Basic and diluted loss per share	(0.09)	(0.08)	(0.24)	(0.09)	(0.10)	(0.10)	(0.07)	(0.07)

### **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 expenses in 2022 were associated with the development of our product pipeline and our decision to stop commercialisation activities for Trogarzo in the European territory.

### Fiscal Year 2022 Financial Results

#### Revenue

Consolidated revenue for Fiscal 2022 was \$80,057,000 compared to \$69,823,000 for the same period last year, representing an increase of 14.7%.

For Fiscal 2022, sales of *EGRIFTA SV*<sup>®</sup> reached \$50,454,000 compared to \$43,009,000 for the same period last year representing growth of 17.3%. Strong sales of *EGRIFTA SV*<sup>®</sup> were mostly the result a higher number of units sold compared to the previous year, as well as higher net selling price. In addition, COVID-19 had a lesser impact on new prescriptions in Fiscal 2022 compared to Fiscal 2021.

In Fiscal 2022, Trogarzo® sales were \$29,603,000 compared to \$26,814,000 last year, an increase of 10.4%. Higher sales were a result of higher unit sales and a higher net selling price in the United States but were offset by slightly lower revenue in Europe. During Fiscal 2021, Trogarzo® net sales in Europe 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").

### **Cost of Sales**

For Fiscal 2022, cost of sales was \$26,279,000 compared to \$23,260,000 in the comparable period of Fiscal 2021. Cost of sales included cost of goods sold that amounted to \$23,838,000 in Fiscal 2022 compared to \$18,378,000 in Fiscal 2021. The increase in cost of goods sold was mainly due to (1) higher product sales, (2), to a charge arising from the non-production of scheduled batches of *EGRIFTA SV*® that were cancelled due to the planned transition to the F8 formulation of tesamorelin in the amount of \$1,788,000, and (3) a provision of \$1,477,000 related to the write down of F8 formulation of tesamorelin for pre-commercial material which could expire prior to the launch of the F8, if approved. Cost of goods sold for 2022 also includes other write downs totalling \$660,000 (See Note 9 of the Audited Financial Statements).

In Fiscal 2021, cost of sales included an amortization charge of \$4,882,000 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. The Other asset was fully amortized during the first half of Fiscal 2022, and thus this charge was lower in Fiscal 2022, in the amount of \$2,441,000.

### **R&D Expenses**

R&D expenses were \$36,939,000 for Fiscal 2022 compared to \$28,274,000 for Fiscal 2021. The increase in R&D expenses was largely due to the development of our oncology platform, including the Phase 1 study, the Intramuscular method of administration clinical trial clinical trial, spending on the development of the multi-dose pen injector for the F8 formulation, spending on the Human factors study for *EGRIFTA SV®*. Fiscal 2022 spending also includes costs associated to the VAMOS and Promise studies in the United States, as well as increased salaries related to the higher level of activity. These costs were offset by lower spending on the preparation of the NASH clinical trial and a decrease level of activity in Europe.

### Selling Expenses

Selling expenses for Fiscal 2022 were \$39,391,000 compared to \$28,909,000 for the same period in Fiscal 2021. The increase is mainly due to the addition of personnel and an increase in promotional activities related to our commercial products in the United States and was offset by lower levels of activity in Europe. The increase is also related to the accelerated amortization of the Trogarzo® commercialization rights for the European territory in the amount of \$6,356,000 following our decision to cease commercialization activities in that territory in Q2 2022.

### **General and Administrative Expenses**

General and administrative expenses for Fiscal 2022 were \$17,356,000 compared to \$14,616,000 for the same period in Fiscal 2021. The increase in general and administrative expenses was mainly associated with an overall increase in business activities following the on boarding of our field force in the United States, as well as higher share-based compensation expense.

#### **Net Finance Costs**

Net finance costs for Fiscal 2022 were \$6,886,000 compared to \$6,426,000 in Fiscal 2021. The increase in net finance costs in 2022 versus the comparable period in 2021 was mostly due to higher interest expense on the Company's Loan Facility in Q3 of Fiscal 2022 and convertible notes and were offset by higher interest income and a gain on the repurchase of convertible notes in July 2022.

#### **Net loss**

Taking into account the revenue and expense variations described above, we recorded a net loss of \$47,237,000, or \$0.50 per share, in Fiscal 2022 compared to \$31,725,000, or \$0.34 per share, in Fiscal 2021.

### **Selected Annual Information**

(in thousands of dollars, except per share amounts)

Theratechnologies Inc. 2015 Peel Street, 11<sup>th</sup> Floor Montreal, Québec H3A 1T8

Years ended November 30	2022	2021	2020
Revenue	80,057	69,823	66,053
Selling expenses	39,391	28,909	26,859
Research and development expenses	36,939	28,274	18,019
General and administrative expenses	17,356	14,616	12,230
Net loss	(47,237)	(31,725)	(22,667)
Loss per share:			
Basic and diluted	(0.50)	(0.34)	(0.29)
Cash, bonds and money market funds	33,070	40,354	20,768
Total assets	93,260	119,212	100,142
Term loan and other obligations	37,894		4,666
Lease liabilities (including current portion)	1,922	2,518	2,980
Convertible unsecured senior notes	26,895	54,227	52,403

# **Financial Position, Liquidity and Capital Resources**

# Going Concern Uncertainty

As part of the preparation of the financial statements, management is responsible for identifying any event or situation that may cast doubt on the Company's ability to continue as a going concern. Substantial doubt regarding the Company's ability to continue as a going concern exists if events or conditions, considered collectively, indicate that the Company may be unable to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. If the Company concludes that events or conditions cast substantial doubt on its ability to continue as a going

concern, it must assess whether the plans developed to mitigate these events or conditions will remove any possible substantial doubt.

For the year ended November 30, 2022, the Company incurred a net loss of \$47,237,000 (2021 – \$31,725,000) and had negative operating cash flows of \$14,692,000 (2021 – \$17,955,000). The Company's total current liabilities exceeded total current assets at November 30, 2022. The Company's outstanding \$27,500,000 convertible unsecured senior notes mature in June 2023 (refer to Note 19 to the Audited Financial Statements) requiring the Company to use its cash balance and draw the Tranche 2 Loan (as defined in Note 18 to the Audited Financial Statements) of its term loan facility available (the "Loan Facility") to repay the principal and the interest thereon. The Loan Facility is available in four tranches and contains various covenants, including minimum liquidity covenants whereby the Company needs to maintain significant cash, cash equivalent and eligible short-term investments balances in specified accounts, which restricts the management of the Company's liquidity (refer to notes 18 and 24 to the Audited Financial Statements). There are also operational milestones and required revenue targets in order for the Company to comply with the conditions of the Loan Facility or to be able to borrow money forming part of the various tranches.

The Company's ability to continue as a going concern for period of at least, but not limited to, 12 months from November 30, 2022 involves significant judgement and is dependent on its ability to increase revenues and manage expenses to generate sufficient positive cash flows from operations and/or find alternative source of funding to respect all the various covenants of its Loan Facility, including obtaining the approval from the FDA for its F8 formulation of tesamorelin on or before March 31, 2024, and/or to obtain the continued support of its lender. On February 27, 2023, the lender removed the condition related to the submission to the FDA of the results from the human factors validation study by no later than June 30, 2023, in order to access the Tranche 2 Loan under the Loan Facility (refer to Note 30 to the Audited Financial Statements). Management believes its plans will comply with all of the other various covenants of the Loan Facility to draw the Tranche 2 Loan, repay all the convertible unsecured senior notes due June 30, 2023 and to comply with the covenants for the foreseeable future. However, there can be no assurance that management's plans will be realized since some elements of these plans are outside of management's control and cannot be predicted at this time. Should management's plans not materialize, the Company may be forced to reduce or delay expenditures and capital additions, seek additional financing through the issuance of equity or obtain from the lender waivers of these covenants, if available. Raising additional equity capital is subject to market conditions. As a result, there is material uncertainty related to events or conditions that cast substantial doubt about the Company's ability to continue as a going concern.

Furthermore, the Loan Facility includes a covenant prohibiting having a going concern explanatory paragraph in the annual report of the independent registered public accounting firm but the lender has agreed to amend the Loan Facility to exclude the fiscal year ended November 30, 2022. There is no assurance that the lender will agree to amend or to waive potential future covenant breaches, if any. As the amendment occurred subsequent to the Company's fiscal year end, the term loan has been classified as a current liability pursuant to IFRS requirements.

These consolidated financial statements have been prepared assuming the Company will continue as a going concern, which assumes the Company will continue its operations in the foreseeable future and will be able to realize its assets and discharge its liabilities and

commitments in the normal course of business. These consolidated financial statements do not include any adjustments to the carrying values and classification of assets and liabilities and reported expenses that might result from the outcome of this uncertainty and that may be necessary if the going concern basis was not appropriate for these consolidated financial statements. If the Company was unable to continue as a going concern, material impairment of the carrying values of the Company's assets, including intangible assets, could be required.

### Analysis of cash flows

As at November 30, 2022, cash, bonds and money market funds amounted to \$33,070,000 compared to \$40,354,000 at November 30, 2021. Available cash is invested in highly liquid fixed income instruments including governmental, municipal and paragovernmental organizations, high-grade corporate bonds and money market funds.

The Company voluntarily changed its accounting policy in Fiscal 2022 to classify interest paid and received as part of operating activities, which were previously classified as cash flow from financing activities and interest received as cash flows from investing activities. The Fiscal 2021 amounts presented herein have been recasted to reflect the change in policy.

For Fiscal 2022, cash flow used in operating activities was \$14,692,000 compared to \$17,501,000 in Fiscal 2021. Changes in operating assets and liabilities for Fiscal 2022 had a positive impact on cash flow of \$13,017,000. These changes included a decrease of \$8,991,000 in inventories, a decrease in prepaid expenses and deposits of \$3,058,000, and an increase in provisions of \$3,627,000 and these were offset by an increase in trade and other receivables of \$1,669,000, and a decrease in accounts payable and accrued liabilities of \$1,131,000. The decrease in inventories is mainly due to a planned reduction of Trogarzo inventory levels.

During Fiscal 2022, the Company realized net proceeds from the issuance of a long-term loan of \$37,715,000. We also received net proceeds for the issuance of common stock to an institutional investor in the amount of \$2,871,000 under its ATM program. Significant uses of cash for financing activities included the purchase of convertible notes for \$28,819,000 (including costs related to the purchase), and \$1,527,000 in deferred financing costs related to the establishment of the Loan Facility.

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.

During Fiscal 2022, cash used in investing activities included \$985,000 for the acquisition of research equipment.

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#### Commitments

# Off Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

### Subsequent events

On February 27, 2023, the Company issued to affiliates of Marathon Asset Management, prorata to their participation under the Loan Facility, an aggregate of 5,000,000 common share purchase warrants (the "Marathon Warrants"). Each Warrant entitles the holder thereof to subscribe for one common share of the Company at a price of \$1.45 for a period of seven years. The Marathon Warrants will not be traded on any stock exchange and are non-transferable.

The Marathon Warrants were issued as consideration for various amendments made to the Loan Facility, including:

- An amendment to one of the second tranche hurdles requiring the Company to have filed with the FDA the
  results of its HFS Study before June 30, 2023; and
- An amendment related to the inclusion of a going concern explanatory paragraph in the annual report of the independent registered public accounting firm for the fiscal year ended November 30, 2022.

The Warrants' estimated fair value at the date of issuance using Black-Scholes model is approximately \$2,000,000. This non-cash financial charge will be expensed in the first quarter of 2023.

### **Contractual obligations**

The following table lists as of November 30, 2022 information with respect to the Company's contractual obligations.

Contractual Obligations	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Convertible unsecured senior notes, including					
interest	29,081,000	29,081,000	_	_	_
Lease Liabilities	2,196,000	595,000	1,145,000	405,000	51,000
Term loan, including interest (1)	57,667,000	5,649,000	28,421,000	23,597,000	
Purchase Obligations (2)	3,822,000	3,822,000			_
Total	\$ 92,766,000	\$ 39,147,000	\$ 29,566,000	\$ 24,002,000	\$ 51,000

(1) Based on SOFR forward rates. The maturities above reflect the fact that the Loan

Facility has been amended in the subsequent event period and as such, the contractual maturities are used.

(2) The Corporation has long-term procurement agreements with third party suppliers in connection with the commercialization of *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup>. As at November 30, 2022, the Corporation had outstanding purchase orders and minimum payments under these agreements amounting to \$1,644,000 for the manufacture of Trogarzo<sup>®</sup>, *EGRIFTA SV*<sup>®</sup> and for various services. The Corporation also had research commitments and outstanding clinical material purchase orders amounting to \$1,310,000 in connection with its oncology platform and \$868,000 in connection with a new formulation of tesamorelin and a multi-dose pen injector developed for this new formulation.

### 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.

#### Milestones

Reference should be made to Note 13 (Intangible Assets) to the Audited Financial Statements for a description of potential commercial milestones payable by the Company.

### **Financial Risk Management**

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

#### Credit Risk

Credit risk is the risk of a loss if a customer or counterparty to a financial instrument fails to meet its contractual obligations. The Company regularly monitors credit risk exposure and takes steps to mitigate the likelihood of this exposure resulting in losses.

The Company's exposure to credit risk currently relates to accounts receivable with one major customer (see Note 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 \$10,659,000 (2021 – \$9,261,000), all of which were aged under 60 days, or received after year-end. There was no amount recorded as bad debt expense for the years ended November 30, 2022 and 2021. 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 (2022 – \$9,214,000; 2021 – \$19,955,000). As at November 30, 2022, 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 25 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.

The Company is required to maintain cash, cash equivalents and eligible short-term investments for an aggregate value of at least \$20 million currently (which amount can increase in certain circumstances) relating to the Loan Facility, which restricts the management of the Company's liquidity. Refer to notes 1 and 18 to the Audited Financial Statements.

### 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, 2022 and 2021.

# (in thousands)

		2022		2021
	CA\$	EURO	CA\$	EURO
Cash	1,547	236	589	61
Bonds and money market funds	12,387	_	16,298	_
Trade and other receivables	733	2,141	331	1,553
Tax credits and grants receivable	66	239	385	123
Accounts payables and accrued liabilities	(10,784)	(5,849)	(6,819)	(7,256)
Lease liabilities	(1,362)	(873)	(1,755)	(1,010)
Provisions	_	(3,486)	_	(1,970)
Total exposure	2,587	(7,592)	9,029	(8,499)

The following exchange rates are those applicable as at November 30, 2022 and 2021.

		2022		2021
	Average rate	Reporting date rate	Average rate	Reporting date rate
CA\$ – US\$	0,7722	0,7439	0,7979	0,7822
Euro – US\$	1,0600	1,0406	1,1906	1,1338

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)

		2022		2021
	CA\$	EURO	CA\$	EURO
Positive (negative) impact	129	(380)	451	(425)

An assumed 5% weakening of the CA\$ or the EURO 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, 2022, 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 \$79,000 (2021 – \$141,000); an assumed increase in market interest rates of 0.5% would have an equal but opposite effect, assuming that all other variables remained constant.

Cash and money market funds bear interest at a variable rate. Trade and other receivables, accounts payable and accrued liabilities and provisions bear no interest.

Based on the average value of variable interest-bearing cash and money market funds during the year ended November 30, 2022 of \$23,505,000 (2021 - \$41,491,000), an assumed 0.5% increase in interest rates during such year would have increased future cash flows and net profit by approximately \$118,000 (2021 - \$207,000); 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.

Based on the value of the Company's long-term loan as at November 30, 2022, an assumed 0.5% increase in SOFR rate during such year would have decreased future cash flows and net profit by approximately \$70,000; and assumed an increase of 0.5% would have had an equal but opposite effect.

### **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, accounts payable and

accrued liabilities and 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, 2022 was approximately \$24,200,000 (\$52,756,000 at November 30, 2021) based on market quotes.

The Company has determined that the carrying value of its term loan approximates its fair value because it was issued near the 2022 year-end.

### **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.

### Milestones payments

The purchase consideration for the oncology platform (see 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.

Management uses judgement in determining whether milestone payments are performance-related development milestones which are capitalized as an intangible asset or are milestones related to the activity or usage of an asset which are expensed.

### 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. These estimates take into consideration historical experience, current contractual and statutory requirements, specific known market events and trends such as competitive pricing and new product introductions, estimated inventory levels, and the shelf life of products. If actual future results vary, these estimates need to be adjusted, with an effect on sales and earnings in the period of the adjustment. (see Notes 2 (Revenue recognition) and 3 to the Audited Financial Statements for additional information).

### Recoverability of inventories

The Company regularly reviews inventory to determine whether the inventory cost exceeds its net realizable value. The determination of the net realizable value requires management to make estimates and use judgement in considering shelf life of a product, the effects of technological changes and new product introductions.

#### Other

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

The Company is subject to risks and uncertainties that may cause actual results to differ from estimated amounts, such as changes in the healthcare environment, competition, litigation, legislation and regulations. Management regularly evaluates estimates and assumptions using historical experience and expectations about the future. Management adjusts estimates and assumptions when facts and circumstances indicate the need for change. 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, 2022 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 the Company's annual reporting periods beginning on December 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.

### Classification of Liabilities as Current or Non-current (Amendments to IAS 1)

For the purposes of non-current classification, the amendments removed the requirement for a right to defer settlement or roll over of a liability for at least twelve months to be unconditional. Instead, such a right must exist at the end of the reporting period and have substance.

The amendments reconfirmed that only covenants with which a company must comply on or before the reporting date affect the classification of a liability as current or non-current. Covenants with which a company must comply after the reporting date do not affect a liability's classification at that date.

The amendments also clarify how a company classifies a liability that includes a counterparty conversion option. The amendments state that: settlement of a liability includes transferring a company's own equity instruments to the counterparty; and when classifying liabilities as current or non-current a company can ignore only those conversion options that are recognized as equity.

The amendments are effective for the Company's annual reporting period beginning on December 1, 2025. The Company is currently evaluating the impact of the amendments on its financial statements.

#### **Outstanding Securities Data**

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As at February 27, 2023, the number of common shares issued and outstanding was 96,806,299, we also had 8,130,550 Warrants and 5,000,000 Marathon Warrants issued and outstanding, while outstanding options granted under our stock option plan amounted to 5,137,137. We also had \$27,500,000 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 1,851,852 common shares.

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

#### Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in the annual filings, interim filings or other reports filed under securities legislation is recorded, processed, summarized and reported within the time periods specified in the securities legislation and include controls and procedures designed to ensure that information required to be disclosed is accumulated and communicated to management, including our President and Chief Executive Officer, and our Senior Vice President and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Our management, including our President and Chief Executive Officer and our Senior Vice President and Chief Financial Officer, have evaluated, or caused the evaluation of, under their direct supervision, the design and operating effectiveness of the Company's disclosure controls and procedures, as defined under National Instrument 52-109 – Certification of Disclosure and Rule 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934 within the U.S. in Issuer's Annual and Interim Filings as at November 30, 2022. 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, 2022, our disclosure controls and procedures were designed and operating effectively.

### Management's Report on 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 and Rule 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934 within the U.S. 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, 2022 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 a material weakness exists as described below, and due to this material weakness, the Company's internal control over financial reporting is not effective as of November 30, 2022.

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 the Company's annual or interim financial statements will not be prevented on a timely basis.

In connection with the Company's evaluation of internal controls over financial reporting, the follow control deficiency was considered to be a material weakness;

• The process level controls were ineffective relating to the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in a financing arrangement. This control failure caused ineffective controls over the assessment of going concern uncertainty, including the underlying financial data and assumptions supporting the forecasted financial information utilized to prepare projected cash flows and liquidity requirements to comply with some of the covenants in such financing arrangement.

Notwithstanding this material weakness, management has concluded that the Company's Audited Financial Statement as at and for the year ended November 30, 2022 present fairly, in all material respects, the Company's financial position, financial performance, changes in equity and cash flows in accordance with IFRS as issued by the IASB. The material weakness did not have an impact on the Company's financial reporting and as a result, there were no material adjustments to the Company's audited annual financial statements for the year ended November 30, 2022 and there were no changes to previously released financial results. However, because the material weakness creates a

reasonable possibility that a material misstatement to our financial statements would not be prevented or detected on a timely basis, we concluded that as of November 30, 2022 the internal control over financial reporting was not effective.

Management has initiated and continues to implement remediation measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented and operating efficiently. The remediation actions include;

- Documentation enhancement of the analysis and the monitoring of certain conditions and covenants of the Company's financing agreements;
- Review with the CEO and CFO, among others, of the analysis and monitoring, on a monthly and quarterly basis, of all relevant conditions and covenants included in the Company's financing arrangements; and,
- Relevant documentation and review of financial data and assumptions used in financial forecasts to ensure the Company meets and expects to continue to meet all conditions and covenants included in the financing arrangements; and,
- Quarterly reporting on the remediation measures to the Audit Committee of the Board of Directors.

While remediation measures related to the Company's financing arrangement are expected to be completed in the 2023 fiscal year, the Company cannot be certain when the remediation will be completed. The material weakness will not be considered fully remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

# Changes in Internal Control over Financial Reporting

Other than the material weakness described above, there were no changes in our internal controls over financial reporting that occurred during the period from September 1<sup>st</sup>, 2022 to November 30, 2022 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

### **RISK 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 CORPORATION'S CASH POSITION**

The Corporation's report of independent registered public accounting firm (the "Auditors Report") to shareholders and the Board of Directors of the Corporation, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022 contains a going concern note about

the Corporation's ability to continue as a going concern and its capacity to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from November 30, 2022. The going concern note casts substantial doubt about the capacity of the Corporation to meet its monetary obligations. The inclusion of a going concern note in the Corporation's Auditors Report triggers an event of default under the Marathon Credit Facility. However, in connection with the issuance of the Auditors Report for the fiscal year ended November 30, 2022, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that additional amendments or waivers of such event of default will be obtained from Marathon in future years if the yearly Auditors Report of the Corporation contains a going concern note. In the event there occurs an event of default under the Marathon Credit facility, the interest rate payable on the loaned amount increases by 300 basis points and Marathon has the right to declare all amounts outstanding under the loan immediately due and payable and not fund any additional tranches under the Marathon Credit Facility. If Marathon was to declare all loaned amounts due and payable under the Marathon Credit Facility, the Corporation would not currently be able to repay such amount unless it secures additional financings. Therefore, the Corporation would have to issue additional equity or secure access to alternative funding enabling it to repay wholly the loaned amounts under the Marathon Credit Facility. The issuance of additional equity would dilute current shareholders and such dilution could be substantial depending on the amount of money the Corporation would have to raise and the price at which such equity offering would be made. In the event the Corporation is unable to implement measures allowing it to secure the repayment of its debt, the Corporation could also have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

The Corporation's Auditors Report to the shareholders and Board of Directors, as well as note 1 to the audited consolidated financial statements of the Corporation for the fiscal year ended November 30, 2022 contains a going concern note about the Corporation's ability to continue as a going concern and the capacity of the Corporation to realize its assets and discharge its liabilities and commitments in the normal course of business. The going concern note casts doubt about the capacity of the Corporation to meet its monetary obligations. For the year ended November 30, 2022, the Company incurred a net loss of \$47.2 million and had negative operating cash flows of \$10.5 million. The Corporation's total current liabilities exceeded total current assets at November 30, 2022. The Corporation's outstanding \$27.5 million convertible unsecured senior notes mature on June 30, 2023 (the "Notes") requiring the Corporation to use its cash balance to repay the principal of the Notes.

The Marathon Credit Facility contains various covenants, including a prohibition on the inclusion of a going concern note in the Corporation's Auditors' Report related to the Corporation's audited consolidated financial statements would trigger an event of default under the Marathon Credit Facility resulting in the interest rate payable on any outstanding loaned

amount to be increased by 300 basis points and would allow Marathon to declare such principal amount and interest thereon immediately due and payable. Marathon would also no longer have the obligation to fund any additional tranches under the Marathon Credit Facility and would have the option to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation.

Subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to exclude the inclusion of a going concern note in the Auditors Report of the Corporation for the fiscal year ended November 30, 2022, the effect of which has been to waive any default under the Marathon Credit Facility. There can be no assurance that Marathon will agree to amend the Marathon Credit Facility or grant a waiver in future years if the Corporation's future Auditors Report include a going concern note. The failure to amend the Marathon Credit Facility or to obtain a waiver from Marathon in future years in the event additional going concern notes are included in the Corporation's Auditors Reports could have a material adverse effect on the Corporation and its business prospects in the event Marathon declares all principal amounts and interest thereon immediately due and payable and the Corporation is unable to repay the loaned amounts.

An event of default under the Marathon Credit Agreement resulting in Marathon declaring all principal amount and interest thereon immediately due and payable would require the Corporation to seek and find alternative sources of financing. Such alternative sources of financing could be the issuance of equity, subject to then prevailing market conditions. The issuance of equity security would dilute shareholders and such dilution could be substantial depending on the price at which the equity offering would be made and the amount to be raised. If the Corporation was unable to secure additional financing to repay any of its outstanding loaned amount, the Corporation could have to sell or liquidate its assets or resort to insolvency laws. A recourse to any of these alternatives would have a material adverse effect on the Corporation and its shareholders.

We did not generate a profit from our operations in the fiscal year ended November 30, 2022. In addition, despite announcing our goal to achieve a positive Adjusted EBITDA by the end of the 2023 fiscal year, there can be no guarantee that we will achieve these milestones, nor that we will achieve profitability.

We have a history of net losses, including a net loss of \$47.2 million for the fiscal year ended November 30, 2022. In the future, our profitability will mainly depend on our capacity to maintain the commercialization of *EGRIFTA SV*® and Trogarzo® successfully in the United States through a low-cost and effective distribution network, the recruitment and retention of talented personnel, 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. Our profitability will also depend on our ability and capacity to control our operating expenses.

There is no guarantee that we will continue succeeding in growing sales of *EGRIFTA SV*® and Trogarzo® in the United States. 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 obtain or sustain profitability.

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

Our ability to repay the \$27.5 million outstanding Notes due on June 30, 2023 requires that we access the \$20 million second tranche of the loan under the Marathon Credit Facility or obtain alternative equity financing in the near term and also depends on our future financial and operating performance to avoid, among other things, being in default under the Marathon Credit Facility. Future financial and operating performance remain subject to prevailing economic and competitive conditions and to certain financial, business and other factors beyond our control. We may be unable to achieve a level of positive cash flows from operating activities sufficient to pay the principal and interest on the loan provided by Marathon or our Notes. Furthermore, 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) and, therefore, we need to ensure we have adequate cash resources available by June 30, 2023, to repay the Notes and to continue our operations.

To mitigate the aforementioned risk, subsequent to the fiscal year end of the Corporation, the Marathon Credit Facility was amended to remove as a condition to accessing the \$20 million second tranche of the loan, being the filing to the FDA of the results of the HFS the Corporation is currently conducting. Notwithstanding the removal of this condition, access to the \$20 million second tranche remains subject to compliance by June 30, 2023 with a twelve-month revenue target of \$75 million and other covenants. As a result, there remain risks under the Marathon Credit Facility that the Corporation will not be able to access the second tranche for the repayment of the Notes on June 30, 2023 since a default under the Marathon Credit Facility, unless waived by Marathon, prevents the Corporation from borrowing additional money.

For the year ended November 30, 2022, the Corporation had negative operating cash flows of \$10.5 million. In addition, the Corporation had a working capital deficiency (total current liabilities exceed total current assets) at November 30, 2022 of \$40.9 million due in part to the amount borrowed under the Marathon Credit Facility being classified as a current liability as a result of the amendment to the Marathon Credit Facility having been entered into after the fiscal year end of the Corporation. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay expenditures and capital additions, 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 or in the absence of accessing the \$20 million second tranche, we could face substantial liquidity problems and we could have to resort to insolvency laws to seek protection from our creditors.

Interest rate fluctuations may have a material adverse effect on our capacity to reimburse the loaned amounts under the Marathon Credit Facility and on our capacity to execute on our business plan.

The interest rate we have to pay Marathon under the Marathon Credit Facility is based on the Secured Overnight Financing Rate ("SOFR"), plus 9.5%.

SOFR is a broad measure of the cost of borrowing cash overnight collateralized by U.S. Treasury securities. SOFR has a limited history, and the future performance of SOFR cannot be predicted based on its limited historical performance. The level of SOFR may bear little or no relation to historical actual or indicative data. Prior observed patterns, if any, in the behavior of market variables and their relation to SOFR, such as correlations, may change in the future. While some pre-publication historical data have been released by the Federal Reserve Bank of New York, such analysis inherently involves assumptions, estimates and approximations, and hypothetical or historical performance data are not indicative of, and have no bearing on, the potential performance of SOFR. The future performance of SOFR is therefore impossible to predict, and no future performance of SOFR may be inferred from any of the historical actual or indicative data. Changes in the levels of SOFR will affect the interest rate we have to pay to Marathon under the Marathon Credit Facility during the term of the loan and may adversely affect the amount of cash we will have to allocate to the repayment of the loan.

Interest rates are highly sensitive to many factors, including governmental monetary policies, domestic and international economic and political conditions, and other factors beyond our control. If SOFR increases as a result of events over which we have no control, this could have a material adverse effect on our financial condition and results of operations. If SOFR increases, our debt service obligations would increase even if the amount borrowed remained the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease.

The Marathon Credit Facility includes significant operating and financial restrictions on the Corporation, any of which could prevent us from capitalizing on business opportunities. In addition, our failure to comply with such restrictions could trigger an event of default which would increase by 300 basis points the interest payable on any loaned amounts under the Marathon Credit Facility and would allow Marathon to declare the outstanding loaned amounts immediately due and payable in addition to providing Marathon with the right to foreclose on all of the assets of the Corporation pursuant to the liens registered against all of the assets of the Corporation. If we are unable to cure an event of default or obtain a waiver from Marathon in relation to such event of default, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws.

The Marathon Credit Facility governing our outstanding \$40 million loan and potential additional tranches which may be drawn thereunder impose significant operating and financial restrictions on the Corporation. These restrictions limit our ability and the ability of certain of our subsidiaries to, among other things: (i) incur or guarantee additional debt or issue disqualified stock or preferred stock; (ii) pay dividends and make other distributions on, or redeem or repurchase, capital stock; (iii) make certain investments; (iv) incur additional liens; (v) enter into transactions related to the acquisition, disposition, in-licensing or out-licensing of assets; and (vi) merge or consolidate.

In addition, the Marathon Credit Facility imposes that we maintain a minimum of \$20 million in cash and cash equivalent at all times. This minimum liquidity amount goes up to \$30 million if we do not obtain the approval of the F8 Formulation by March 31, 2024. The minimum liquidity covenant restricts the management of the Corporation's liquidity and could increase the likelihood that the Corporation may not be able to meet its

obligations as they become due. The Marathon Credit facility also imposes revenue targets on a quarterly basis. The Marathon Credit Facility further imposes reporting requirements on our business activities on a quarterly basis. These reporting requirements extend beyond those that we have to comply with under securities regulations and add a layer of complexity to our reporting obligations. The minimum liquidity covenant restricts the management of the Corporation's liquidity and increases the likelihood that the Corporation may not be able to meet its obligations as they become due. As a result of the restrictions and obligations described above, we will be limited as to how we conduct our business and we may be unable to enter into transactions that may be accretive to our business to compete effectively or to take advantage of new business opportunities. Debt financing opportunities will also be limited in the event that we are unable to raise capital through the issuance of equity. There can be no assurances that we will be able to maintain compliance with these requirements and covenants in the future and, if we fail to do so, that we will be able to obtain waivers from Marathon and/or amend the covenants contained in the Marathon Credit Facility to remove those obligations.

Our failure to comply with the covenants described above as well as other terms of our indebtedness will result in an event of default under the Marathon Credit Facility which, if not cured or waived, will result in an increase of 300 basis point on the interest payable on the outstanding loaned amount. An event of default under the Marathon Credit Facility would also allow Marathon to declare all loaned amounts immediately due and payable and entitle Marathon to execute on its first ranking security interest on all of our assets and foreclose on our assets. If we were to default under the Marathon Credit Facility and Marathon were to declare all amounts outstanding under the loan immediately due and payable, this would also trigger a default under the terms of the Notes. In the event there occurs an event of default under the Marathon Credit Facility and we are unable to cure such event of default or obtain a waiver from Marathon in relation thereto, and if we do not have the financial capacity to repay any amount loaned becoming due and payable, we may have to cease our operations and to resort to insolvency laws. Any of those circumstances will have a material adverse effect on shareholders as they will lose the entire value of their investment in the capital of the Corporation.

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

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

Our ability to generate revenue and sustain growth is currently concentrated solely on the commercialization of EGRIFTA SV® and Trogarzo® in the United States. Our success in generating sales revenue from *EGRIFTA SV®* and Trogarzo® in the United States will depend on our capacity: (a) to pursue the deployment of a commercialization strategy that will be accepted by patients, healthcare professionals and third-party payors; (b) to maintain reimbursement coverage for *EGRIFTA SV®* and Trogarzo® by third-party payors; (c) to maintain the registration of *EGRIFTA SV®* and Trogarzo® on U.S. governmental forms as drugs available for purchase in the United States; (d) to ensure that adequate supplies of *EGRIFTA SV®* and Trogarzo® are available; (e) to maintain conflict-free relationships with our principal third-party suppliers of services, namely our manufacturers (TaiMed and Jubilant HollisterStier, General Partnership ("Jubilant")), our distributor in the

United States (RxC Acquisition Company, LLC ("RxCrossroads")), as well as other specialized third parties; and (f) to defend our intellectual property rights regarding tesamorelin against third parties.

Our success in commercializing our products in the United States will also depend on our capacity 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 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 solely 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 some of our core business activities pertaining to the commercialization of our products, namely their manufacturing and distribution. 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 Americas, Inc. ("Bachem") and Jubilant to manufacture and supply all of our required raw materials, drug substance and drug product for sales of EGRIFTA SV®. We will also rely on a single third-party supplier, Lyophilization Services of New England, Inc. ("LSNE") for the manufacture of the F8 Formulation. 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 thirdparty 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®, for the F8 Formulation and for our potential Phase 2b/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<sup>®</sup>. TaiMed does not currently own or operate any manufacturing facilities for the production of Trogarzo<sup>®</sup> and must rely on its suppliers, WuXi and Samsung. We are not in a contractual relationship with WuXi and Samsung for Trogarzo<sup>®</sup> and, therefore, we may not be able to interact with any of them in the event they encounter issues which could adversely affect the supply of Trogarzo<sup>®</sup>. 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<sup>®</sup> and, accordingly, materially adversely affect our revenues.

We do not have state licensure in the United States to distribute  $EGRIFTA\ SV^{\otimes}$ , Trogarzo $^{\otimes}$  or any other product we may acquire or in-license and we have not made any application 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  $EGRIFTA\ SV^{\otimes}$  and Trogarzo $^{\otimes}$  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  $EGRIFTA\ SV^{\otimes}$  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.

Syneos Health, Inc. ("Syneos") continues to provide us with support for the commercialization of  $EGRIFTA\ SV^{\$}$  and Trogarzo $^{\$}$  in the United States through the provision of personnel as part of the managed market and reimbursement teams. Although we are aware that there exist 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 may retain contract research organizations ("CROs") to support us with the conduct of 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 a sBLA or NDA seeking the approval of our products.

Our reliance on single third-party service providers for some 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  $EGRIFTA\ SV^{\circledast}$ , the F8 Formulation and Trogarzo® if a third-party manufacturer: (a) becomes unavailable to us, or to TaiMed, for any reason, including as a result of the failure to comply with GMP regulations; (b) 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 (c) fails to perform its contractual obligations under our agreement, such as failing to deliver the quantities requested on a timely basis or not meeting product specifications.

We may also be subject to distribution disruption and interrupted sales of *EGRIFTA SV*® and Trogarzo® in the United States if: (a) RxCrossroads becomes unavailable to us for any reason, including as a result of its failure to meet applicable laws; (b) RxCrossroads 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 (c) RxCrossroads 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 we may face reimbursement challenges if Syneos (a) 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®; (b) experiences compliance issues with the FDA; or (c) 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  $EGRIFTA\ SV^{\circledcirc}$  and Trogarzo $^{\circledcirc}$  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. 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  $EGRIFTA\ SV^{\circledcirc}$  and  $Trogarzo^{\circledcirc}$ .

Sales of *EGRIFTA SV®* and Trogarzo® to patients benefitting from U.S. Government funded reimbursement programs represent a significant part of our sales. Denial of coverage for any of those products under any of the current programs would materially adversely affect our revenues.

Even though EGRIFTA SV® and Trogarzo® are approved for sale in the United States, revenue that we generate from their sales may be limited.

Sales of *EGRIFTA SV*® and Trogarzo® will continue to depend upon the acceptance of such products by the medical community, including physicians, patients and third-party payors. The degree of market acceptance of these products will depend on a number of factors, including: (a) demonstrated product safety, including the prevalence and severity of side effects, and effectiveness as a treatment that addresses a significant unmet medical need; (b) storage requirements, dosing regimen and ease of administration; (c) the availability of competitive alternatives; (d) 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; (e) the willingness and ability of patients to pay out-of-pocket for medications; (f) the product price; and (g) the effectiveness of sales and marketing efforts.

If our products are not accepted by the marketplace, the revenue generated therefrom will be limited and our capacity to grow our revenue and become profitable will be hampered. Our failure to grow our revenue and to become profitable will adversely impact the value of the Corporation, including the market price of our shares. If we fail to 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 and Lenacapavir in the United States. In addition, we are aware of other agents, including dolutegravir and darunavir, that are either indicated or commonly used in combination in regimens to treat heavily-treatment experienced patients with MDR HIV-1. 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

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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.

The development of new therapies is 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 method or route of administration or provide a new treatment, such as the development of the F8 Formulation and the Pen, the development of tesamorelin for the potential treatment of NASH in the general population and the development of our peptide-drug conjugates resulting from our SORT1+ Technology<sup>TM</sup> 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, a new method or route of administration or a drug product could hamper the future growth of our business and have long-term adverse effects on our potential revenues and operating results.

The development of TH1902 for the potential treatment of various types of sortilin-expressing cancers is still uncertain given that, after consultation with investigators, we have voluntarily paused the enrollment of patients in the Phase 1 clinical trial since efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the Phase 1 clinical trial of TH1902 on partial clinical hold and asked a series of questions to the Corporation requiring satisfactory responses thereto prior to resuming the Phase 1 clinical trial. If the Corporation is unable to answer the questions raised by the FDA to the FDA's satisfaction and if the Corporation is unable to resume its Phase 1 clinical trial with TH1902, the Corporation will have to discontinue its Phase 1 clinical trial. Any halt in the Corporation's Phase 1 clinical trial could materially adversely affect the development of its SORT1+ Technology™ platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects.

The enrollment of patients in the Corporation's Phase 1 clinical trial evaluating TH1902 was voluntarily paused by the Corporation after consulting with its investigators. The efficacy results observed were not convincing enough to pursue enrolling patients and did not outweigh the adverse events seen in some patients. The FDA has since placed the clinical trial on partial clinical hold and has issued a series of questions to the Corporation that will need to be answered to the satisfaction of the FDA prior to resuming the Phase 1 clinical trial. The Corporation has also formed a SAC to help determine the best developmental path forward for TH1902. The decision made by the Corporation illustrates that, to date, we have not been able to replicate results obtained from our preclinical *in vivo* work and that the conduct of clinical trials is risky as results may adversely vary from those that are expected.

If the Corporation is unable to resume its Phase 1 clinical trial with TH1902 because (i) it is unable to adequately answer to all of the questions raised by the FDA, (ii) the SAC is

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unable to agree on the best developmental path forward for TH1902, or (iii) the FDA does not accept the terms of an amended protocol, the development program of TH1902 will need to be halted. Any halt in the Corporation's Phase 1 clinical trial would materially adversely affect the development of its SORT1+ Technology<sup>TM</sup> platform and reduce its pipeline of drug candidates, all of which would materially adversely affect its long-term growth and prospects. Even if the Corporation is allowed to resume its Phase 1 clinical trial with TH1902, the Corporation may have difficulty enrolling new patients in the resumed trial. The difficulty in enrolling patients would cause additional delays in advancing the development of TH1902. In addition, there can be no guarantee that the results obtained from the resumed Phase 1 clinical trial would yield positive results. In the event that the resumed clinical trial did not yield positive results, the value associated to the SORT1+ Technology<sup>TM</sup> platform asset would be depreciated, thereby adversely impacting the market value of the Corporation, including the price of its Common Shares.

The conduct of research and development activities is very costly and capital intensive. We have already indicated that the development of tesamorelin for the treatment of NASH in the general population was on pause until we find a partner and that the development of TH1902 would be stage-gated in order to meet our goal of achieving a positive Adjusted EBITDA in the 2023 fiscal year. We have also indicated that we would assess a partnership for the development of TH1902 once the Phase 1 clinical trial has resumed. If we are unable to find a partner for the development of tesamorelin for the treatment of NASH or for the pursuit of the development of TH1902 once the Phase 1 clinical trial has resumed, we may have to cease the development of those assets, any of which could have a material adverse effect on our long-term potential revenue growth and business prospects.

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

As a result of our assessment of the costs associated with our proposed Phase 2b/3 clinical trial studying tesamorelin for the treatment of NASH in the general population, we have decided to seek a partner prior to launching such trial. The contemplated development of tesamorelin for the treatment of NASH will require the enrollment of over 2,000 patients and the study will be conducted over many years. Therefore, we expect the development of tesamorelin for the treatment of NASH in the general population to cost multiple millions of dollars.

Consistent with our objective of achieving a positive Adjusted EBITDA by the end of the current fiscal year and beyond, we also announced that the development of TH1902 would be stage-gated and that further to resuming the Phase 1 clinical trial, we would assess partnering the development of TH1902.

There can be no assurance that we will be able to find a partner for either the development of tesamorelin for the potential treatment of NASH or for the further development of TH1902. Finding a partner for those development programs will depend on a variety of factors, including the preclinical and clinical data that we have generated for those drug candidates, the current advancement of the programs and the risk related thereto, the regulatory path to seek approval of those drug candidates, the market environment related to NASH and oncology, competition from other products and general market conditions. In addition, even we were to find a partner for any of those programs, there can be no assurance that the terms and conditions contained in any partnership agreement would

be suitable to us. The failure to find a partner for the development of tesamorelin for the potential treatment of NASH and the further development of TH1902 could lead to a halt in the development of those programs.

A complete halt in the conduct of those programs could adversely impact our long-term growth and business prospect since the Corporation would have a reduced pipeline of product candidates.

The Corporation has not filed a sBLA seeking the approval of the F8 Formulation and, consequently, the FDA has not approved the F8 Formulation as being bioequivalent to the Corporation's original formulation of EGRIFTA®. If the FDA does not approve the F8 Formulation, 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 a sBLA with the FDA seeking the approval of the F8 Formulation for commercial use although this is planned for 2023.

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 and inventory write-downs, 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 pursuing the assessment of the development of the Pen, or any other device to be used with the F8 Formulation. Finally, the non-approval of the F8 Formulation would expose the Corporation to the entry of biosimilar versions of tesamorelin for the treatment of lipodystrophy given that the patent protection for this product will expire in August 2023. Since the F8 Formulation is patent protected until 2033 in the United States, the commercialization of tesamorelin for the treatment of lipodystrophy using the F8 Formulation could protect the entry of biosimilar versions until the expiry of this patent in 2033.

The Corporation has decided to seek a partner to conduct a Phase 2b/3 clinical trial evaluating tesamorelin for the treatment of NASH in the general population. Although the Corporation has begun the search for a potential partner and preliminary discussions are ongoing, 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 may have to cancel this program unless it has access to substantial financial resources to pursue such development program and there can be no guarantee that the Corporation will secure such substantial resources in an amount sufficient to initiate or complete the Phase 2b/3 clinical trial. Moreover, the FDA has issued comments and asked questions on the revised protocol filed by the Corporation in February 2022 and the Corporation has voluntarily decided not to reply to those comments and questions until it can find a partner. In addition, the Corporation's decision to design its Phase

2b/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 find a partner to develop tesamorelin for the treatment of NASH in the general population or to secure substantial financial resources to do it on its own, the Corporation may cancel this program and the development of tesamorelin for the treatment of NASH may never occur. Even if the Corporation finds a partner, the conduct of the Phase 2b/3 clinical trial may be delayed or never begun if the Corporation is unable to properly address the comments and questions raised by the FDA based on the Corporation's amended protocol. Finally, if the Corporation is unable to meet the endpoints of its Phase 2b/3 clinical trial, it will not receive approval for tesamorelin for the treatment of NASH in the general population. Even if the Corporation meets the endpoints of the clinical trial, the FDA could issue a conditional approval letter such that if the Corporation is unable to meet the conditions contained in such letter, the Corporation could lose such approval. 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.

In July 2021, we 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. There are currently ongoing preliminary discussions with potential partners.

In February 2022, in order to de-risk the Phase 3 trial, the Corporation submitted an amended protocol to the FDA resulting in the FDA providing us with a list of questions and comments on this amended protocol. We have voluntarily decided not to respond to those questions and comments in order to address them with any potential partner we may find to optimize the design, if deemed relevant. The amended protocol includes 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. The amended protocol would allow us to generate hard endpoint data on NAS score and fibrosis. A decision would then be made whether to continue the study until the full number of patients (1,094) have completed 18 months of treatment. These amendments would not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH, but it would inform the continuation of enrollment while providing an indication of benefit to patients.

There can be no guarantee that tesamorelin will be studied for the treatment of NASH in the general population if the Corporation is unable to find a partner to conduct the development program on its own. 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 satisfactory to the Corporation or may be unfavorable. Under such circumstances, the Corporation may decide to forego the development of tesamorelin for the treatment of NASH in the general population or turn to alternative sources of financing. 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 business prospects.

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Even if the Corporation finds a partner to initiate a Phase 2b/3 clinical trial, there can be no guarantee that the FDA will be satisfied with the responses to the questions and comments asked in connection with the amendments to the protocol filed in February 2022 and allow the initiation of such trial. Even if the FDA or any other regulatory agency approves the study of tesamorelin for the treatment of NASH in the general population, there can be no guarantee that the results will meet the endpoints of the study and that tesamorelin will be approved for such treatment. Even if the Corporation meets the FDA's primary endpoints and approval is received from the FDA, such approval may be conditioned on conducting additional studies which, if not conducted or if the results therefrom are not positive on certain clinical outcomes, could result in the FDA withdrawing its approval for the use of tesamorelin for the treatment of NASH in the general population.

The Corporation has decided to design its Phase 2b/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 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: (a) negative results from the Corporation's clinical trial resulting in a failure to meet the endpoints of its clinical trial; (b) 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; (c) 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; (d) inadequate quantity or quality of the active pharmaceutical ingredient or other materials necessary to conduct clinical trials; (e) 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; (f) severe or unexpected adverse drug effects experienced by patients; (g) 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 trials, or may change the requirements for approval even after they

have approved the sponsor's Phase 3 clinical trial design; and (i) 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.

### RISKS RELATED TO OUR INTELLECTUAL PROPERTY

Our patent protection related to the use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is scheduled to expire in August 2023. Until we can commercialize tesamorelin using the F8 Formulation, the FDA-approved use of tesamorelin for the treatment of lipodystrophy will no longer be patent protected and we may face direct competition from biosimilar versions of EGRIFTA SV®. If we face competition from biosimilar products, our revenues are likely to be reduced thus adversely affecting our revenue growth and results of operations.

The use of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy is patent protected in the United States until August 2023. Tesamorelin, the composition of matter, is no longer patent protected and the formulation of EGRIFTA  $SV^{(0)}$  is not patent protected. If, and when approved, the Corporation will rely on the use of the F8 Formulation to benefit from patent protection until 2033 in the United States in connection with the sale of tesamorelin for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.

Although we are not aware that a company has filed any biosimilar version of tesamorelin with the FDA, nothing prevents a company from filing with the FDA a biosimilar version of tesamorelin using the same formulation as that of *EGRIFTA SV* $^{\otimes}$  and to seek the same indication as that of *EGRIFTA SV* $^{\otimes}$ .

If such a filing was made and the FDA were to approve a biosimilar version of  $EGRIFTA\ SV^{\otimes}$ , we would expect the price of that biosimilar to be lower than that of  $EGRIFTA\ SV^{\otimes}$  and we could have to lower our price in order to be able to compete with such biosimilar. A lower price of  $EGRIFTA\ SV^{\otimes}$  would reduce our revenue and could have an adverse effect on our goal of achieving a positive Adjusted EBITDA by the end of the 2023 fiscal

year. Even if were to introduce the F8 Formulation, such biosimilar version could still be a direct competitor to us, albeit with an older formulation of tesamorelin.

# 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

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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  $EGRIFTA\ SV^{\circledcirc}$  and Trogarzo $^{\circledcirc}$  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 the United States and in other jurisdictions does not guarantee that we are not infringing one or more third-party patents in such country or in other 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 ("FFDCA"), as well as with 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 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  $EGRIFTA\ SV^{(8)}$  and  $Trogarzo^{(8)}$  in Canada and in Europe since none of those products have been approved in

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this territory. Promotional activities may begin once a drug is approved by the heath authority of a country.

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: (a) 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; (b) 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; (c) 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; (d) the FFDCA and similar laws regulating advertisement and labeling; and (e) 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 ("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 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 such 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. Additionally, if such third-party service providers do not meet their obligations under agreements and we decide to litigate any breach or dispute any amount owed under our agreements, this might materially adversely affect our relationship with such third-party services providers which, in turn, could adversely affect our capacity and ability to deliver on 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: (a) disruptions of important government services; (b) differing regulatory requirements for drug approvals in foreign countries; (c) potentially reduced protection for intellectual property rights, including unexpected changes in the rules governing patents and their enforcement; (d) potential third-party patent rights in foreign countries; (e) 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; (f) unexpected changes in tariffs, trade barriers and regulatory requirements; (g) economic weakness, including inflation, or political instability, particularly in foreign economies and markets; (h) compliance with tax, employment, immigration and labor laws for employees traveling abroad; (i) foreign taxes; (j) 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; (k) workforce uncertainty in countries where labor unrest is more common than in the United States and Canada; (l) production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and (m) 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 our presence in Canada and Europe, we must comply with privacy laws and regulations of Québec and Europe. Both of those laws and regulations introduced data protection requirements 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. These laws have increased the responsibility of all parties collecting personal data. We are currently reviewing and complementing our in-house policies and related procedures to ensure compliance with those laws. In the United States, there exists no federal laws regarding the protection of personal information and all such laws are State-regulated. With the addition of a sales and medical team in-house, we are in the process of assessing compliance with the privacy laws in each of the States where the bulk of our activities is conducted. However, there can be no guarantee that the Corporation will not be found to violate some of those laws as a result of the combination of our business activities in various jurisdictions and the complexity of those laws and their interpretations.

The secure and uninterrupted operation of third-party information technology systems and of ours is material to our business operations and strategy. More and more businesses are subject to information technology system intrusion for which cyberterrorists often use ransomware to demand payment of a ransom to allow those businesses to regain access to its data. Despite the measures that we have implemented against unwanted intrusion by third parties, there can be no guarantee that our systems could resist to a cyber-attack. 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 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 in-license or acquire approved products, to meet our compliance obligations with various rules and regulations to which we are subject, and to conduct research and development activities related to our 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, with the consent of Marathon, 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, medical, regulatory 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. We have recently hired a team comprised of key account managers and medical science liaison personnel and the loss of any of those individuals and our inability to attract and retain them could have a material adverse effect on our commercial and medical activities related to EGRIFTA SV® and Trogarzo®, and, accordingly, on 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 growth 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 financial, milestones or our commercial objectives on time.

In January 2023, we announced revenue guidance for the fiscal year ended November 30, 2023, in the range of \$90 million to \$95 million. 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 achievement of such guidance or 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.

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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 sales allowances and chargebacks, recoverability of inventories, estimation of accruals for clinical trial expenses, measurement and recoverability of intangible assets, the measurement of derivative financial assets, and the measurement of share-based arrangements. 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.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022 in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. A material weakness may hamper our ability to meet our reporting obligations and could result in a material misstatement in the Corporation's financial statements. As a result, 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 we are unable to comply with our reporting obligations and/or that the financial information we report contains material errors. Any of those events could materially adversely affect the trading price of our Common Shares. A failure to comply with our reporting requirements could also subject us to sanctions and/or investigations by securities regulatory authorities.

We have identified a material weakness in our internal controls over financial reporting for the fiscal year ended November 30, 2022, in connection with the documentation of the analysis and relating to the monitoring of certain conditions and covenants included in the Marathon Credit Facility. This control failure caused ineffective controls over the assessment of going concern uncertainty, including the underlying financial data and assumptions supporting the forecasted financial information utilized to prepare projected cash flows and liquidity requirements to comply with some of the covenants in the Marathon Credit Facility. The Corporation's management team has initiated and continues to implement remediation measures designed to ensure that control deficiencies contributing to the material weakness are remediated, such that these controls are designed, implemented and operating efficiently. While the Corporation expects these remediation measures to be completed in the fiscal year 2023, it cannot be certain when the remediation will be completed. If the Corporation fails to fully remediate this material weakness or fails to maintain effective internal controls in the future, it could result in a material misstatement of the Corporation's financial statements, which could cause investors to lose confidence in the Corporation's financial statements and cause the trading price of its Common Shares to decline.

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. We are not currently required, and do not, obtain an audit of our internal controls 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.

#### **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.

The Corporation's Common Shares are listed on the TSX and on the Nasdaq. The market price of the Common Shares on the Nasdaq and the TSX has fluctuated significantly in the past and the Corporation expects the market prices to continue to fluctuate in the future, and such prices may decline. For example, since the Corporation's listing of its Common Shares on Nasdaq to December 31, 2022, the Corporation's closing share price on Nasdaq has ranged from a low of \$0.8262 to a high of \$11.23. Consequently, you may not be able to sell your Common Shares at prices equal to or greater than the price paid by you. In addition, the market price of the Common Shares may be influenced by many factors, some of which are or may be beyond the Corporation's control, including: actual or anticipated variations in the Corporation's operating results and/or research and development activities; announcements by the Corporation or the Corporation's competitors of significant contracts or acquisitions; additions and departures of key personnel; announcement or expectation of additional financing efforts; impairment of assets; changes in accounting principles; changes in the general market and economic conditions; future sales of the Common Shares; the failure of financial analysts to initiate or maintain coverage of the Common Shares, the failure of financial analysts to initiate or maintain coverage of the Common Shares or the shares of the Corporation's competitors; and investor perceptions of the Corporation and the industry in which the Corporation operates.

In addition, stock markets, in general, have experienced substantial price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of particular companies affected. These broad market and industry factors may materially harm the market price of the Common Shares, regardless of the Corporation's operating performance. Dual listing of the Common Shares on the Nasdaq and the TSX may increase share price volatility on both exchanges because trading is in the two markets, which may result in less liquidity on both exchanges. In addition, different liquidity levels, volumes of trading, currencies and market conditions on the two exchanges may result in different prevailing trading prices. In the past, following periods of volatility in the market price of certain companies' securities, securities class action litigation has sometimes been instituted against these companies. This litigation, if instituted against the Corporation, could adversely affect the financial condition or results of operations of the Corporation.

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The liquidity of our Common Shares is uneven and oftentimes scarce and shareholders desiring to purchase or sell Common Shares could be unable to, if the liquidity in our Common Shares is low.

The volume of Common Shares traded on the TSX and the Nasdaq has been uneven over time and is often low. Therefore, any investor who desires to purchase or sell Common Shares of the Corporation over the TSX or the Nasdaq may be unable to rapidly execute its order and, if the liquidity is low, the price at which such investor may purchase or sell Common Shares may be adversely affected by the lack of trading volume.

Our Common Shares may be delisted from the Nasdaq stock market if the minimum bid price of our Common Shares remains below US\$1.00 per share for 30 consecutive trading days. The delisting of our Common Shares could reduce the liquidity in our Common Shares and could trigger a sell-off from U.S. shareholders. Any reduction in the liquidity of our Common Shares or a sell-off our Common Shares would result in a decline in the price of our Common Shares. Being delisted from the Nasdaq stock exchange could also adversely affect analysts coverage of our Common Shares and prevent us from retaining U.S. investment bankers to raise equity in public offerings.

Under Nasdaq minimum bid price requirement, the minimum bid price of our Common Shares may not remain below US\$1.00 per share for 30 consecutive trading days. If such event occurs, the Corporation will receive a deficiency notice providing the Corporation with a 180-calendar day cure period from the date of the notice during which the minimum bid price of the Common Shares will have to be US\$1.00 or more per share for ten consecutive business days in order to avoid delisting. If, at the expiry of the 180-calendar day cure period, the Corporation has not regained compliance with the minimum bid price requirement, the Corporation could be afforded an additional 180-calendar day cure period, provided that it meets certain conditions, one of which could be to undertake a reverse-split of its Common Shares to regain compliance with Nasdaq rules.

If the Common Shares of the Corporation are delisted from the Nasdaq stock market, the liquidity in our Common Shares could decrease and investors may have difficulties in buying or selling our Common Shares. In addition, a delisting of our Common Shares on the Nasdaq stock market could trigger a sell-off from current U.S-based shareholders whose internal policies could prevent them from holding securities of companies that are not traded on a U.S. stock market. Any sell-off by these shareholders could result in a material decline in the price of our Common Shares.

Finally, if the minimum bid price of the Common Shares were to be below US\$1.00 per share for 30-consecutive trading days, there can be no assurance that the cure period provided by Nasdaq rules to regain compliance with the minimum bid price requirement would result in the Corporation regaining compliance with such rules in order to avoid a delisting of the Common Shares. Even if the Corporation was to proceed with a reverse-split of its Common Shares, there can be no assurance that the long term bid price of the Common Shares *post* reverse-split would meet the minimum bid price requirement of the Nasdaq stock market.

Our revenues and expenses may fluctuate significantly and any failure to meet financial expectations and/or our own financial guidance, if any, may disappoint

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#### 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: (a) the level of sales of  $EGRIFTA\ SV^{\otimes}$  in the United States; (b) the level of sales of  $EGRIFTA\ SV^{\otimes}$  or  $EGRIFTA\ SV^{\otimes}$  or EGRI

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.

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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.

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#### 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 28, 2023

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 28, 2023

By: /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 "Corporation") for the fiscal year ended November 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Paul Lévesque, President and Chief Executive Officer of the Corporation 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 Corporation.

Date: February 28, 2023

/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 "Corporation") for the fiscal year ended November 30, 2022, 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 Corporation 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 Corporation.

Date: February 28, 2023

/s/ Philippe Dubuc

Name: Philippe Dubuc

Title: Senior Vice President and Chief Financial Officer



KPMG LLP 600 de Maisonneuve Blvd West Suite 1500, Tour KPMG Montréal (Québec) H3A 0A3 Tel. 514-840-2100 Fax. 514-840-2187 www.kpmg.ca

#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors Theratechnologies Inc.

We 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 27, 2023 on the consolidated financial statements of Theratechnologies Inc. which comprise the consolidated statements of financial position as of November 30, 2022 and 2021, the related consolidated statements of net loss and comprehensive loss, changes in equity and cash flows for the years ended November 30, 2022 and 2021, 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, 2022, and further consent to the use of such report in such annual report on Form 40-F.

February 28, 2023 Montreal, Canada

KPMG LLP

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