

# MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE MONTHS ENDED FEBRUARY 28, 2023

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 three-month period ended February 28, 2023 compared to the three-month period ended February 28, 2022. 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 April 10, 2023, was approved by our Audit Committee on April 11, 2023, and should be read in conjunction with our unaudited interim consolidated financial statements and the notes thereto as at February 28, 2023 ("Interim Financial Statements"), as well as the MD&A and audited annual consolidated financial statements, including the notes thereto, as at November 30, 2022.

Except as otherwise indicated, the financial information contained in this MD&A and in our Interim Financial Statements has been prepared in accordance with International Accounting Standard ("IAS") 34, *Interim Financial Reporting* of 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 Interim Financial Statements are expressed in USD, unless otherwise noted.

In this MD&A, the use of *EGRIFTA*<sup>®</sup> and *EGRIFTA SV*<sup>®</sup> (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and the use of Trogarzo<sup>®</sup> (ibalizumab-uiyk) injection refers to ibalizumab for the treatment of multidrug resistant HIV-1 infected patients. The use of tesamorelin refers to the use of our tesamorelin compound for the potential treatment of 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 forwardlooking statements. Forward-looking statements include, but are not limited to, statements about: our expectations regarding the commercialization of EGRIFTA SV® and Trogarzo®; our ability and capacity to grow the sales of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> successfully in the United States and to meet our financial guidance; our capacity to meet supply and demand for our products; the market acceptance of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> in the United States; the continuation of our collaborations and other significant agreements with our existing commercial partners and third-party suppliers and our ability to establish and maintain additional collaboration agreements; our success in continuing to seek and in maintaining reimbursement for EGRIFTA 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 timelines associated with the filing of an amended protocol with the FDA to resume our Phase 1 clinical trial using TH1902 (as defined below) as well as the timelines associated with the completion of the HFS (as defined below) related to EGRIFTA SV<sup>®</sup> and the filing of a sBLA (as defined below) for an intramuscular method of administration of Trogarzo®; our capacity to meet the undertakings, covenants and obligations contained in the Loan Facility (as defined below) entered into with Marathon's affiliates and not be in default thereunder; 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; our capacity to find a partner to pursue the development of TH1902 once the Phase 1 clinical trial has resumed; our capacity to control expenses to achieve an adjusted EBITDA by the fiscal year end; our expectations regarding our financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and our estimates regarding our capital requirements.

Such statements reflect our current views with respect to future events and are subject to certain risks, uncertainties and assumptions which may cause our actual results. performance or achievements to be materially different from any future results, performance or achievements expressed in or implied by the forward-looking statements. Certain assumptions made in preparing the forward-looking statements include that: sales of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> 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<sup>®</sup> and Trogarzo<sup>®</sup> will occur; no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> in the United States; continuous supply of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> 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; 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 supplement with the FDA for EGRIFTA SV<sup>®</sup> by the end of the 2023 fiscal year; the FDA will approve the supplement; we will not default under the terms and conditions of the Loan Facility, including meeting the minimum liquidity and revenue target covenants therein; we will meet all of the conditions set forth under the Loan Facility to draw down the \$20 million second tranche; the interest rate on the amount borrowed from Marathon's affiliates under the Loan Facility 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 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 information assumptions are subject to a number of risks and uncertainties, many of which are beyond Theratechnologies' control that could cause actual results to differ materially from those that are disclosed in or implied by such forward-looking information. These risks and uncertainties include, but are not limited to, those related to or arising from: the Company's ability and capacity to grow the sales of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> successfully in the United States; the Company's capacity to meet supply and demand for its products; the market acceptance of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> in the United States; the continuation of the Company's collaborations and other significant agreements with its existing commercial partners and third-party suppliers and its ability to establish and maintain additional collaboration agreements; the Company's success in continuing to seek and maintain reimbursements for EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> by third-party payors in the United States; the success and pricing of other competing drugs or therapies that are or may become available in the marketplace; the Company's ability to protect and maintain its intellectual property rights in EGRIFTA SV® and tesamorelin; events that could disrupt the Company's ability to successfully meet the timelines set forth herein; the discovery of a cure for HIV; the Company's failure to meet the terms and conditions set forth in the Loan Facility resulting in an event of default and preventing the Company from accessing the full amount of the term loan; non-approval by the FDA of the amended protocol aimed at resuming the Phase 1 clinical trial studying TH1902; the inability of the Company to enter into a partnership agreement with a third party for its NASH program or for its oncology program; the Company's expectations regarding its financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and the Company's estimates regarding its capital requirements.

We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 27, 2023, available on SEDAR at www.sedar.com and on EDGAR at <u>www.sec.gov</u> as an exhibit to our report on Form 40-F dated February 28, 2023, under Theratechnologies' public filings. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements. Forward-looking statements reflect current expectations regarding future events and speak only as of the date of this MD&A and represent our expectations as of that date.

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

# 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 from one period to another. The Corporation uses this non-IFRS measure to make financial, strategic and operating decisions. Adjusted EBITDA is not a standardized financial measure under the financial reporting framework used to prepare the financial statements of the Corporation to which the measure relates and might not be comparable to similar financial measures disclosed by other issuers. The Corporation has reinstated its use of Adjusted EBITDA starting this guarter and has included Adjusted EBITDA for the comparative period. A quantitative reconciliation of Adjusted EBITDA is presented under the heading "Reconciliation of Adjusted EBITDA" in this MD&A.

# **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*<sup>®</sup> and Trogarzo<sup>®</sup> in the United States. 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.

## **OUR MEDICINES**

The Company commercializes two approved medicines for people living with HIV in the United States, namely *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup>.

*EGRIFTA*  $SV^{\text{®}}$  (tesamorelin for injection) is a new formulation of *EGRIFTA*<sup>®</sup> which was originally approved by the FDA in November 2010 and was launched in the United States in January 2011. *EGRIFTA*  $SV^{\text{®}}$  was approved by the FDA in November 2018, was launched in 2019 and has now replaced *EGRIFTA*<sup>®</sup> in such country. *EGRIFTA*  $SV^{\text{®}}$  can be kept at room temperature, comes in a single vial and has a higher concentration resulting in a smaller volume of administration. *EGRIFTA*  $SV^{\text{®}}$  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 May1<sup>st</sup>, 2014.

Trogarzo<sup>®</sup> was approved by the FDA in March 2018 for the treatment of human immunodeficiency virus type 1 ("HIV-1") infection in heavily treatment-experienced adults with multidrug resistant, or ("MDR"), HIV-1 infection failing their current antiretroviral regimen.

In March 2016, we obtained the rights to commercialize Trogarzo<sup>®</sup> in the United States and Canada pursuant to a distribution and licensing agreement with TaiMed. In March 2017, the agreement was amended to include the commercial rights to Trogarzo<sup>®</sup> in the European Union and in other countries such as Israel, Norway, Russia and Switzerland (the "TaiMed Agreement"). In April 2022, the Company sent a notice of termination to TaiMed in connection with its commercialization and distribution rights of Trogarzo<sup>®</sup> in Europe.

On October 3, 2022, the FDA approved a 30-second Intravenous ("IV") Push method of administration for Trogarzo<sup>®</sup>.

# OUR PIPELINE

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

## Tesamorelin

# EGRIFTA SV<sup>®</sup> Human Factors Study

In HIV-associated lipodystrophy, we are on track to complete the Human Factors Study ("HFS") for *EGRIFTA SV*<sup>®</sup> 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 ("F8 Formulation") 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.

# F8 Formulation

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*<sup>®</sup>, 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*<sup>®</sup> 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.

### 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.

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.

We continue to see interest and momentum build in the NASH discussion space based on promising new industry data. Now that the BWFI supply issue has been resolved, we can confidently ensure potential partners that further development and the potential launch of a Phase 2b/3 NASH clinical trial would not be impeded by further supply issues. As of current, we continue to pursue potential NASH partners in the marketplace. We continue to maintain that the further development of Tesamorelin allows Theratechnologies to keep 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.

## 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<sup>®</sup> 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.

# Sudocetaxel Zendusortide ("TH1902") Phase 1 Clinical Trial

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.

Following the determination of the MTD, we began enrolling patients in the basket trial. 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.

In 2023, the Company commenced the use of sudocetaxel zendusortide in reference to TH1902. Sudocetaxel zendusortide is the generic name assigned by the International Non-Proprietary Names for TH1902.

## **Recent Highlights:**

### Sudocetaxel Zendusortide (TH1902) Development Pathway

On December 1, 2022, Theratechnologies announced the decision to voluntarily 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.

Following the voluntary pause, the Company formed a Scientific Advisory Committee ("SAC") to help determine the best developmental path forward for TH1902. A meeting was held on March 22, with several medical oncologists from across the United States, who are leading experts in the end-to-end lifecycle of oncology drug development.

Theratechnologies presented the pre-clinical and clinical data gathered thus far to the SAC, which made recommendations to modify the frequency of administration, selection of tumor types and criteria for patient selection to further improve our chances of a successful outcome. The Company is finalizing adjustments to the protocol and aims to submit to the FDA before end of April.

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.

#### Amendment to Term Loan Facility with Affiliates of Marathon Asset Management

On February 28<sup>th</sup>, the Company announced that it entered into a first amendment to its credit agreement dated July 20, 2022 (the "Loan Facility") with certain funds and accounts for which Marathon Asset Management, L.P. acts as investment manager (collectively, "Marathon").

The Company and Marathon agreed to amend the terms of the Loan Facility by removing the condition related to the submission to the FDA of its human factors study ("HFS") related to *EGRIFTA SV*<sup>®</sup> in order to access a US\$20 million second tranche of the Loan Facility, and by allowing the inclusion of a going concern explanatory paragraph in the auditor's report to shareholders for the fiscal year ended November 30, 2022, without triggering an event of default.

The amendments were entered into in consideration of the issuance of an aggregate of 5,000,000 common share purchase warrants (the "Marathon Warrants") to Marathon.

Each Marathon Warrant entitles the holder thereof to purchase one common share of the Company at a price of \$1.45 per share until February 27, 2030.

# Conference on Retroviruses and Opportunistic Infections ("CROI")

On February 22, Theratechnologies announced a presentation at the 30<sup>th</sup> Conference on Retroviruses and Opportunistic Infections (CROI), highlighting new Tesamorelin data demonstrating improvement of metabolic syndrome in people with HIV. The presentation demonstrated association between excess visceral abdominal fat reduction and decreased prevalence of metabolic syndrome with tesamorelin treatment. These data provided further evidence of potential utility of tesamorelin in addressing metabolic syndrome and complements research in fatty liver diseases.

# American Association for Cancer Research ("AACR")

On March 14, subsequent to the end of the first quarter, Theratechnologies announced that it will have three presentations at the annual meeting of the American Association for Cancer Research (AACR) on April 18, 2023. These new data, to be presented in three poster sessions highlight a synergistic effect of TH1902 in combination with programmed death-ligand 1 (PD-L1), checkpoint inhibitor therapy in a melanoma mouse model; high expression of the sortilin (SORT1) receptor in multiple tumor types compared to healthy tissues; and the rationale for using TH1902 as a potential therapeutic approach in SORT1-positive triple-negative breast cancer (TNBC) and HER2-positive breast cancers.

# JANUARY 2021 OFFERING - USE OF PROCEEDS

The following table shows the estimated use of proceeds of the unit offering completed in January 2021, compared with the actual use of proceeds as at February 28, 2023:

In millions	Estimated Proceeds	Use of	Actual Use of Proceeds	Variance
Nash Phase 3 clinical trial		\$30.5	\$2.8	\$(27.7)
Oncology R&D		\$7.0	\$ 9.2	\$2.2
Commercial and marketing activities		\$3.5		\$(3.5)
Other		\$1.5	\$1.3	\$(0.2)
Net Proceeds		\$42.5	\$13.3	\$(29.2)

As at February 28, 2023, approximately \$2,828,000 had been used in connection with the NASH Phase 3 clinical trial.

As at February 28, 2023, approximately \$9,234,000 had been used in connection with oncology research and development activities and the variance between the amount reserved and the amount used as at February 28, 2023 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.

### 2023 Revenue Guidance

Our anticipated FY2023 revenue guidance range is confirmed between \$90 million and \$95 million, or growth of the commercial portfolio in the range of 13% and 19%, as compared to the 2022 fiscal year results.

#### First-Quarter 2023 Revenues

(in thousands of U.S. dollars)

	Three Mont Februa	Change	
	2023	2022	
EGRIFTA <sup>®</sup> , EGRIFTA SV <sup>®</sup> net sales	12,711	11,704	8.6%
Trogarzo <sup>®</sup> net sales	7,197	6,853	5.0%
Revenue	19,908	18,557	7.3%

### First Quarter Fiscal 2023 Financial Results

#### Revenue

Consolidated revenue for the three months ended February 28, 2023, amounted to \$19,908,000 compared to \$18,557,000 for the same period last year, representing an increase of 7.3%.

For the first quarter of Fiscal 2023, sales of *EGRIFTA SV*<sup>®</sup> reached \$12,711,000 compared to \$11,704,000 in the first quarter of the prior year, representing an increase of 8.6%. Growth in sales of *EGRIFTA SV*<sup>®</sup> was mostly the result of increased unit sales and a higher net selling price but were offset by greater rebates to government payers.

In the first quarter of Fiscal 2023, Trogarzo<sup>®</sup> sales amounted to \$7,197,000 compared to \$6,853,000 for the same quarter of 2022, representing an increase of 5.0%. Trogarzo<sup>®</sup> unit sales in the first quarter of 2023 were up marginally and were positively impacted by a higher net selling price and more favorable government rebates and chargebacks.

## Cost of Sales

For the three-month period ended February 28, 2023, cost of sales was \$4,693,000 compared to \$6,099,000 in the comparable period of Fiscal 2022. In the first quarter of 2022, cost of sales included an amortization charge of \$1,221,000 in connection with the settlement of the future 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 first quarter of Fiscal 2023.

Cost of goods sold decreased to \$4,693,000 compared to \$4,878,000 for the same period last year. Cost of goods sold for the first quarter of last year was higher because of an

adjustment to the cost of goods sold for Trogarzo in Europe related to the provision for rebates to the French government.

### R&D Expenses

R&D expenses in the three-month period ended February 28, 2023 amounted to \$9,356,000 compared to \$8,003,000 in the comparable period of Fiscal 2022. The increase during the first quarter of Fiscal 2023 was largely due to expenses related to the production of the validation batches of BWFI (\$536,000) and \$838,000 in expenses related to the production of clinical batches of TH1902. Other project spending included the *EGRIFTA SV*<sup>®</sup> Human Factors Study and spending on the TH1902 Phase 1 trial.

### Selling Expenses

Selling expenses in the three-month period ended February 28, 2023, amounted to \$6,814,000 compared to \$7,807,000 in the comparable period of Fiscal 2022 or a 12.7% decrease.

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

### General and Administrative Expenses

General and administrative expenses in the first quarter of Fiscal 2023 amounted to \$4,452,000, compared to \$4,368,000 reported in the same period of Fiscal 2022. The slight increase 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 and is offset by lower spending in Europe.

#### Net Finance Costs

Net finance costs for the three-month period ended February 28, 2023, were \$4,940,000 compared to \$1,285,000 in the same period last year. The increase in net finance cost is mostly due to the loss on debt modification of \$2,650,000 related to the issuance of the Marathon Warrants issued in connection to the amendments to the Credit Agreement as well as the higher interest expense on the company's outstanding long-term debt due to the new Loan Facility entered into in Q3 of Fiscal 2022.

#### Adjusted EBITDA

Adjusted EBITDA was \$(3,892,000) for the first quarter of fiscal 2023 compared to \$(4,094,000) for the same period of 2022. Adjusted EBITDA in the first quarter of 2023 was negatively affected by certain production costs, namely an expense related to the production of the validation batches of BWFI of \$536,000, and \$838,000 in expenses related to production batches of TH1902. See "Non-IFRS and Non-US-GAAP Measure" above and see "Reconciliation of Adjusted EBITDA" below for a reconciliation to Net Loss for the relevant periods.

#### Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$10,443,000, or \$0.11 per share, in the first quarter of Fiscal 2023 compared to a net loss of \$9,032,000, or \$0.09 per share, in the first quarter of Fiscal 2022.

## Financial Position, Liquidity and Capital Resources

#### Going Concern Uncertainty

As part of the preparation of the interim 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 February 28, 2023. 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 three-month period ended February 28, 2023, the Company incurred a net loss of \$10,443,000 (2022 – \$9,032,000) and had positive operating cash flows of \$2,361,000 (2022 - \$42,000). The Company's total current liabilities exceeded total current assets at February 28, 2023. The Company's outstanding \$27,467,000 convertible unsecured senior notes mature in June 2023 (refer to Note 7 of the Interim Financial Statements) requiring the Company to use its cash balance and draw the Tranche 2 Loan (as defined in Note 18 of the annual consolidated financial statements as at November 30, 2022) 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 of the annual consolidated financial statements as at November 30, 2022). 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 February 28, 2023 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 of the annual consolidated financial statements as at November 30, 2022). 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 amended the Loan Facility on February 27, 2023 to exclude the fiscal year ended November 30, 2022. The term loan has been reclassified from current at November 30, 2022 to long-term at February 28, 2023 as a result of the waiver received within the first quarter. There is no assurance that the lender will agree to amend or to waive potential future covenant breaches, if any.

The interim 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. The interim 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 interim 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

We ended the first quarter of fiscal 2023 with \$29,156,000 in cash, bonds and money market funds. Available cash is invested in highly liquid fixed income instruments including governmental and municipal bonds, and money market funds.

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

For the three-month period ended February 28, 2023, cash used in operating activities was relatively stable at \$3,339,000, compared to \$5,690,000 in the comparable period of Fiscal 2022.

In the first quarter of fiscal 2023, changes in operating assets and liabilities had a positive impact on cash flow of \$2,361,000 (2022-positive impact of \$42,000). These changes included a positive impact from lower accounts receivable (\$2,085,000), a decrease in inventories (\$4,578,000), lower prepaid expenses (\$1,644,000) and deposits and also include a negative impact from lower accounts payable (\$6,545,000). The decrease in inventories is mainly due to a planned reduction of Trogarzo<sup>®</sup> 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 during Fiscal 2022 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 "Public Offering Warrant"). Each Public Offering Warrant entitles the holder to purchase one common share of the Company at an exercise price of \$3.18 until January 19, 2024.

During the first quarter of 2023, cash used in investing activities included \$222,000 for the acquisition of research equipment, and financing activities used \$162,000 in cash.

# **Quarterly Financial Information**

The following table is a summary of our unaudited consolidated operating results for the Company's last 8 fiscal quarters.

	2023	2022			2021			
	Q1	Q4	Q3	Q2	Q1	Q4	Q3	Q2
Revenue	19,908	21,421	20,811	19,268	18,557	18,754	17,852	17,787
Operating expenses								
Cost of sales								
Cost of goods sold	4,693	5,909	5,292	7,759	4,878	5,191	4,283	4,714
Amortization of other asset	-	-	-	1,220	1,221	1,220	1,221	1,220
R&D	9,356	9,455	8,425	11,056	8,003	8,678	8,296	6,417
Selling	6,814	7,809	8,404	15,371	7,807	8,193	7,657	6,901
General and administrative	4,452	3,956	4,209	4,823	4,368	3,537	3,633	3,884
Total operating expenses	25,315	27,129	26,330	40,229	26,277	26,819	25,090	23,136
Net finance costs	(4,940)	(2,078)	(1,879)	(1,644)	(1,285)	(1,817)	(2,254)	(1,023)
Income taxes	(96)	(143)	(151)	(122)	(27)	(19)	(18)	(20)
Net loss	(10,443)	(7,929)	(7,549)	(22,727)	(9,032)	(9,901)	(9,510)	(6,392)
Basic and diluted loss per share	(0.11)	(0.09)	(0.08)	(0.24)	(0.09)	(0.10)	(0.10)	(0.07)

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

# 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.

# **Recent Changes in Accounting Standards**

## Standards issued but not yet effective

Refer to Note 2 of the Interim Financial Statements for changes in accounting policy, new standard adopted and standard issued but not yet effective.

## **Outstanding Securities Data**

As at February 28, 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 9,131,243. 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.

## **Contractual Obligations**

On February 28<sup>th</sup>, the Company announced that it entered into a first amendment to its Loan Facility.

The Company and Marathon agreed to amend the terms of the Loan Facility by removing the condition related to the submission to the FDA of its HFS related to *EGRIFTA SV*<sup>®</sup> in order to access a US\$20 million second tranche of the Loan Facility, and by allowing the inclusion of a going concern note in the auditor's report to shareholders for the fiscal year ended November 30, 2022 without triggering an event of default.

The amendment was entered into in consideration of the issuance of the Marathon Warrants.

## Internal Control

The Company identified a material weakness as at November 30, 2022 in the Company's process level controls 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. Refer to our annual MD&A for additional details.

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 of the Company's internal control over financial reporting, as defined under National Instrument 52-109 – Certification of Disclosure as at February 28, 2023. Based upon that evaluation, our President and Chief Executive Officer

and our Senior Vice President and Chief Financial Officer, have concluded that our internal control over financial reporting were not effective as of February 28, 2023 as the controls related to the above-described material weakness have not yet been adequately remediated.

The Company's management team has begun remediating the ineffective controls related to the above-described material weakness. The material weaknesses 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. During the first quarter of 2023, the Company worked on a remediation plan and began implementing new internal controls to remediate to this material weakness. We expect to complete the implementation of these new controls by the end of the second quarter of 2023 and test their effectiveness in the third and fourth quarters of 2023.

Other than the remediation efforts disclosed above, there were no changes in our internal controls over financial reporting that occurred during the period from December 1<sup>st</sup>, 2022 to February 28, 2023 that materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

# **Reconciliation of Adjusted EBITDA**

(In thousands of U.S. dollars)

	Three-month periods ended February 28,		
	2023	2022	
Net loss	(10,443)	(9,032)	
Add :			
Depreciation and amortization <sup>1</sup>	939	2,184	
Net Finance costs <sup>2</sup>	4,940	1,285	
Income taxes	96	27	
Share-based compensation	576	1,442	
Adjusted EBITDA	(3,892)	(4,094)	

<sup>&</sup>lt;sup>1</sup> Includes depreciation of property and equipment, amortization of intangible, other assets and right-of-use assets.

<sup>&</sup>lt;sup>2</sup> Includes all finance income and finance costs consisting of: Foreign exchange, interest income, accretion expense and amortization of deferred financing costs, interest expense, bank charges, gain or loss on financial instruments carried at fair value and loss on debt modification.