

#### MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE- AND NINE-MONTH PERIODS ENDED AUGUST 31, 2021

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- and nine-month periods ended August 31, 2021 compared to the three- and nine-month periods ended August 31, 2020. Unless otherwise indicated or unless the context requires otherwise, all references in this MD&A to "Theratechnologies", the "Company", the "Corporation", "we", "our", "us" or similar terms refer to Theratechnologies Inc. and its subsidiaries on a consolidated basis. This MD&A is dated October 11, 2021, was approved by our Audit Committee on October 12, 2021 and should be read in conjunction with our unaudited interim consolidated financial statements and the notes thereto as at August 31, 2021 (Interim Financial Statements), as well as the MD&A and audited annual consolidated financial statements, including the notes thereto, as at November 30, 2020.

Except as otherwise indicated, the financial information contained in this MD&A and in our Interim Financial Statements has been prepared using accounting policies consistent with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB), and in accordance with International Accounting Standard (IAS) 34, *Interim Financial Reporting*.

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®* and *EGRIFTA SV®* (tesamorelin for injection) refers to tesamorelin for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy and the use of Trogarzo® (ibalizumab-uiyk) injection refers to ibalizumab for the treatment of multidrug resistant HIV-1 infected patients. The use of tesamorelin refers to the use of our tesamorelin compound for the potential treatment of nonalcoholic steatohepatitis (NASH) in the general population and in people living with HIV.

#### **Forward-Looking Information**

This MD&A contains forward-looking statements and forward-looking information (collectively, Forward-Looking Statements), within the meaning of applicable securities laws, that are based on our management's beliefs and assumptions and on information currently available to our management. You can identify Forward-Looking Statements by terms such as "may", "will", "should", "could", "promising", "would", "outlook", "believe", "plan", "envisage", "anticipate", "expect" and "estimate", or the negatives of these terms, or variations of them. The Forward-Looking Statements contained in this MD&A include, but are not limited to, statements regarding the conduct of our clinical trials with TH1902 and tesamorelin, the results expected to be obtained from the conduct of these clinical trials, the timelines associated with the filing of a supplemental Biologic License Application (sBLA) with the U.S. Food and Drug Administration (FDA) and with the beginning of the screening of patients for the intramuscular (IM) study using Trogarzo®, the potential approval by regulatory agencies of tesamorelin for the treatment of NASH, the development of a multi-dose pen injector using the F8 formulation, the potential benefits to be derived from the addition of a partner for our Phase 3 clinical trial evaluating

tesamorelin for the treatment of NASH, and the growth of our revenues from sales of  $EGRIFTA\ SV^{@}$  and Trogarzo<sup>®</sup>.

Although the Forward-Looking Statements contained in this MD&A are based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on these statements since actual results may vary from the Forward-Looking Statements. Certain assumptions made in preparing the Forward-Looking Statements include that; the current COVID-19 pandemic will have limited adverse effect on the Company's operations and its business plan; sales of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> in the United States will increase over time; the Company's commercial practices in the U.S. and the countries of the European Union (EU) will not be found to be in violation of applicable laws; the long-term use of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> will not change their respective current safety profile; no recall or market withdrawal of EGRIFTA SV® and Trogarzo® will occur; no laws, regulation, order, decree or judgment will be passed or issued by a governmental body negatively affecting the marketing, promotion or sale of EGRIFTA SV® and Trogarzo® in countries where such products are commercialized; continuous supply of EGRIFTA SV® and Trogarzo® will be Company's relations with third-party EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply EGRIFTA SV® and Trogarzo® to meet market demand on a timely basis; no biosimilar version of EGRIFTA SV® will be approved by the FDA; the Company's intellectual property will prevent companies from commercializing biosimilar versions of EGRIFTA SV<sup>®</sup> in the U.S.; Trogarzo<sup>®</sup> will be reimbursed in key European countries; the FDA will approve the F8 formulation and the multi-dose pen injector; the Company will succeed in pursuing the conduct of its Phase 1 clinical trial using TH1902; the Company will be able to secure additional resources to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH; research and development activities using peptides derived from its oncology platform will yield positive results allowing for the development of new drugs for the treatment of cancer; the Company's European infrastructure is adequate to commercialize Trogarzo® in the EU; and the Company's business plan will not be substantially modified.

Forward-Looking Statements 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 Statements. These risks and uncertainties include, but are not limited to. those related to or arising from: the adverse impact of the COVID-19 pandemic on (a) the Company's sales efforts and sales initiatives, (b) the capacity of the Company's suppliers to meet their obligations vis-à-vis the Company, (c) the Company's research and development activities, (d) the health of the Company's employees and its capacity to rely on its resources, as well as (e) global trade; the Company's ability and capacity to grow the sales of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup> successfully in the United States and Trogarzo<sup>®</sup> in Europe; 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 U.S. and of Trogarzo<sup>®</sup> in Europe; 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 U.S.; 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; the Company's success in obtaining reimbursement for Trogarzo® in key European countries, together with the level of reimbursement, if at all; the Company's ability and capacity to commercialize Trogarzo® in key countries in the EU; the Company's ability to obtain the approval by the FDA of the F8 formulation and the multi-dose pen injector; the Company's ability to secure additional resources to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH; the Company's ability to successfully conduct its Phase 3 clinical trial using tesamorelin for the treatment of NASH and its Phase 1 clinical trial using TH1902 in various types of cancer; the Company's ability to find a partner on terms satisfactory to the Company; the Company's capacity to acquire or in-license new products and/or compounds; the discovery of a cure for HIV; 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.

In addition to the risks inherent to the conduct of clinical trials, there exist risks that the FDA will not approve tesamorelin for the treatment of NASH without the Company having substantial evidence and data from the conduct of Phase 2 clinical trials evaluating tesamorelin for the treatment of NASH in the general population and solely relying on data emanating from the conduct of one Phase 3 clinical trial. There is also risk that the FDA may require additional clinical trials to be conducted in order to obtain approval. Moreover, there exist risks that the EMA will not approve tesamorelin for the treatment of NASH because the trial design that the Company intends to pursue does not include the primary endpoint required under the current EMA guidelines.

We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 24, 2021 available on SEDAR at www.sedar.com and on EDGAR at <a href="www.sec.gov">www.sec.gov</a> as an exhibit to our report on Form 40-F dated February 25, 2021 under Theratechnologies' public filings for additional risks related to the Company. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on Forward-Looking Statements. Forward-Looking Statements reflect current expectations regarding future events and speak only as of the date of this MD&A and represent our expectations as of that date.

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

#### **BUSINESS OVERVIEW**

Theratechnologies is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. We have a promising pipeline of investigational medicines in oncology and NASH and two approved medicines ( $EGRIFTA\ SV^{\otimes}$ ) and Trogarzo for people living with HIV. The Company has a sales and marketing infrastructure to commercialize its products in the U.S. and Europe. We continue to assess the market for potential product acquisitions or in-licensing transactions that would be complementary to our business and further drive future sustainable growth and value creation.

#### **RECENT AND NOTABLE UPDATES**

### **Pipeline Updates**

- **TH1902 Study Update**: The Company's Phase 1 study evaluating its novel investigational proprietary peptide-drug conjugate (PDC) TH1902 for the treatment of sortilin-positive cancers is progressing as planned. To date, the study has dosed several patients with tumors for which no known effective therapies exist, with some receiving more docetaxel, when conjugated to TH1902, than the indicated dose of docetaxel alone (80-100mg/m²). Patients that have received up to 300mg/m² of TH1902 (the equivalent of 130mg/m² of docetaxel), or approximately 1.5 times the indicated dose of docetaxel, have not experienced any grade 2 adverse events. The last patient dosed received 420mg/m² of TH1902, or approximately 2 times the indicated dose of docetaxel, and experienced a grade 4 adverse event (neutropenia). The Company is awaiting all safety information to assess the next dosing level and to pursue the study as per the protocol. Part A of the Phase 1 trial is ongoing until the maximum tolerated dose (MTD) is identified. Theratechnologies' expects to provide another update on the Phase 1/Part A study when it has reached MTD of TH1902.
- Phase 3 Development of Tesamorelin for NASH: The Company continues to evaluate its opportunities to most effectively execute its Phase 3 development program evaluating tesamorelin for the treatment of NASH, including seeking a potential partner. Theratechnologies previously announced that an external U.S.-based biopharma advisory firm was retained to assist in identifying a potential partnership for this program. On September 13, 2021, Theratechnologies hosted a virtual NASH event featuring key opinion leaders (KOLs) in hepatology and NASH, which was well-attended.
- Lifecycle Management for Treatment of HIV: Based on an internal data assessment, the TMB-302 study evaluating an intravenous (IV) Push mode of administration of Trogarzo® for the treatment of HIV-1 infection achieved consistent and statistically significant results demonstrating that there was no difference in pharmacokinetics (PK) between IV Push and IV Infusion. This more convenient IV Push mode of administration may offer patients a rapid infusion time and requires only two quick infusions per month potentially increasing patient compliance and thereby allowing patients to benefit from long-acting protection against HIV-1 when Trogarzo® is administered with other antiretrovirals. Based on these results, an sBLA is expected to be filed with the FDA in the fourth quarter of 2021. Theratechnologies and TaiMed Biologics Inc. (TaiMed) are also evaluating an intramuscular (IM) method of administration for Trogarzo® within the TMB-302 study. Patient screening for the IM study is planned for the fourth quarter of Fiscal 2021.
- TH1902 Preclinical Data Published in Peer-Reviewed Journal, Cancer Science: Preclinical research of TH1902 for the treatment of sortilin-positive triple negative breast cancer (TNBC) was published in the peer-reviewed journal Cancer Science, confirming the in vivo efficacy and safety of TH1902 against TNBC through a SORT1 receptor-mediated mechanism. This research also further supports sortilin as a potential targetable biomarker for hard-to-treat cancers.
- New Preclinical Findings for TH1902 for Potential Treatment of Metastatic Cancers: In June 2021, the Company announced new preclinical in vivo findings

on the anti-metastatic effect and tolerability of TH1902. If confirmed in humans, the Company believes TH1902 could be used in the treatment of metastasis.

### **Commercial Updates**

- Trogarzo<sup>®</sup> Pricing Agreement in Italy: Theratechnologies and the Italian Medicines Agency, AIFA, have reached a pricing and reimbursement agreement for Trogarzo<sup>®</sup>. The Company expects Trogarzo to be commercially available to all eligible patients in Italy before the end of 2021.
- Trogarzo® PROMISE Study: The Company is initiating a post-authorization study in the EU evaluating the real-world long-term efficacy and safety of Trogarzo® in combination with other antiretrovirals. The study, named Prospective and Retrospective, Observational Multicenter Ibalizumab Study of Efficacy (PROMISE), is expected to enroll patients in the EU in the fourth quarter of 2021. A similar study which is intended to collect real-world clinical data of Trogarzo® in the U.S. (PROMISE-US), is expected to begin in the U.S. in the first quarter of 2022.

### **Corporate Updates**

- Appointment of Mace Rothenberg, M.D. as Oncology Advisor: Theratechnologies recently appointed Mace Rothenberg, M.D. as a scientific advisor for the Company's SORT1+ Technology™ oncology platform. Dr. Rothenberg brings more than 30 years of experience across government, academia and the biopharmaceutical industry, most recently serving as Chief Medical Officer (CMO) at Pfizer before his retirement earlier this year. During his time at Pfizer as CMO, the company initiated, completed and obtained emergency use authorization for its COVID-19 vaccine and obtained regulatory approval for 11 new cancer medicines. Dr. Rothenberg is a Fellow of the American College of Physicians and the American Society of Clinical Oncology.
- New At-The-Market Facility Established: On July 23, 2021, the Company announced that it established an at-the-market (ATM) equity program allowing Theratechnologies to issue and sell up to US \$50 million of common shares from treasury to the public at the Company's sole discretion and at the prevailing market price.
- New Board Member Appointed: In June 2021, the Company appointed Mr. Frank
  Holler as an independent member to its Board of Directors. Mr. Holler is a
  recognized biotechnology industry leader with expertise in capital markets.

#### **OUR MEDICINES**

The Company has two approved medicines for people living with HIV, namely Trogarzo® in the U.S., EU, and United Kingdom (UK), and EGRIFTA SV® in the U.S. EGRIFTA® is commercially available in Canada, but sales of EGRIFTA® in Canada are not material to our business.

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

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

Trogarzo® was approved by the FDA in March 2018 for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant (MDR) HIV-1 infection failing their current antiretroviral regimen. Trogarzo® was also approved by the EMA in September 2019 for the treatment of adults infected with MDR HIV-1 for whom it is otherwise not possible to construct a suppressive antiviral regimen. Trogarzo® is currently commercially available in Germany and in the fourth quarter of 2021, the Company secured a pricing agreement for Trogarzo® in Italy. A number of patients are also being treated with Trogarzo® in other European countries through early access programs. Trogarzo® will be launched on a country-by-country basis across Europe as it gains reimbursement in each individual country. In addition, the Company has received regulatory approval in Israel for Trogarzo® and is working to secure pricing and reimbursement.

In March 2016, we obtained the rights to commercialize Trogarzo® in the U.S. 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® in the EU and in other countries such as Israel, Norway, Russia and Switzerland (TaiMed Agreement).

The Company's commercial strategy for the 2021 fiscal year is to generate revenue growth through increased sales of its medicines in the U.S. while working on securing an appropriate price and widespread reimbursement for Trogarzo<sup>®</sup> in key European countries and pursue the launch of Trogarzo<sup>®</sup> in those key European countries.

#### OUR PIPELINE

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

#### SORT1+ Technology™

The Company is currently developing a platform of new proprietary peptides for cancer drug development targeting SORT1 receptors called SORT1+ Technology<sup>™</sup>. 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. It is estimated that the SORT1 receptor is expressed in 40% to 90% of cases of endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

The Company's innovative PDCs generated through our SORT1+ Technology™ demonstrate distinct pharmacodynamic and pharmacokinetic properties that differentiate them from traditional chemotherapy. In contrast to traditional chemotherapy, our proprietary PDCs are designed to enable selective delivery of certain anti-cancer drugs within the tumor microenvironment, and more importantly, directly inside SORT1 cancer cells. Commercially available anticancer drugs, like docetaxel, doxorubicin or tyrosine kinase inhibitors are conjugated to our PDC to specifically target SORT1 receptors. This could potentially improve the efficacy and safety of those agents.

In preclinical data, the Company's lead investigational PDC, TH1902, derived from our SORT1+ Technology<sup>™</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 of chemotherapy treatment. TH1902 combines our proprietary peptide to the cytotoxic drug docetaxel.

In December 2020, we filed an IND application with the FDA for the Phase 1 first-in-human clinical trial evaluating TH1902 for the treatment of various cancers. The FDA granted fast track designation to TH1902 as a single agent for the treatment of all sortilin-positive recurrent advanced solid tumors that are refractory to standard therapy. In March 2021, a Phase 1 clinical trial was initiated evaluating TH1902 for the treatment of cancers where the sortilin receptor is expressed. The Phase 1 clinical trial design includes a Part A dose escalation study to evaluate the safety, pharmacokinetics, MTD and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies. Once the MTD is determined, the Company expects a total of 40 additional patients will be enrolled in a Part B study to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

See "Recent and Notable Updates – TH1902 Study Update" above for a description of the status of the Phase 1 study.

The Company has retained the services of a global, large-scale CRO to assist with the conduct of its Phase 1 clinical trial. The detailed study protocol is available at ClinicalTrials.gov under the identifier number: NCT04706962.

The Company is also evaluating TH1904 in preclinical research, its second PDC derived from its SORT1+ Technology<sup>™</sup>. TH1904 is conjugated to the cytotoxic drug doxorubicin.

The SORT1+ Technology™ was acquired in February 2019 as part of the acquisition of Katana Biopharma Inc., (Katana). Through the acquisition, Theratechnologies obtained the worldwide rights to this platform based on an exclusive royalty-bearing license entered into between Katana and Transfer Plus L.P. The Canadian Cancer Society and the Government of Quebec, through the Consortium Québécois sur la découverte du médicament (CQDM), will contribute a total of 1.4 million dollars towards some of the research currently being conducted for the development of our targeted oncology platform.

### Tesamorelin

In fiscal year 2020, the Company completed the evaluation and development of the F8 formulation, which based on internal studies, is bioequivalent to the original commercialized formulation of tesamorelin (F1 formulation). The F8 formulation has a number of advantages over the current formulation of  $EGRIFTA\ SV^{@}$ . Specifically, it is twice as concentrated resulting in a smaller volume of administration and is intended to be presented in a multi-dose vial that can be reconstituted once per week. Similar to the current formulation of  $EGRIFTA\ SV^{@}$ , the F8 formulation is stable at room temperature, even once reconstituted.

The F8 formulation is patent protected in the U.S. until 2033 and until 2034 in major European countries.

The Company is currently working on the development of a multi-dose pen injector to be used in conjunction with the F8 formulation and we intend to seek marketing approval of the pen. We plan to file an sBLA for the F8 formulation in early 2022 for the treatment of lipodystrophy in people living with HIV. An sBLA filing of the multi-dose pen injector is expected to be filed later in 2022.

In November 2020, the Company filed an IND with the FDA for the Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH and received a "Study May Proceed" letter for the Phase 3 clinical trial from the FDA in December 2020. The IND filing followed our announcement made in September 2020 regarding our intent to develop tesamorelin for the treatment of NASH in the general population.

On July 15, 2021, the Company announced that it had completed discussions with the FDA and the EMA 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.

Based on regulatory discussions, the final Phase 3 clinical trial design will result in higher costs than what the Company had previously estimated. As a result of the total cost of the Phase 3 clinical trial, the Company is evaluating its options to best execute its late-

stage development program, including seeking a potential partner. An external U.S.-based biopharma advisory firm was retained to assist in identifying a potential partner.

#### **Ibalizumab for HIV**

Based on an internal data assessment, the TMB-302 study evaluating an intravenous (IV) Push mode of administration of Trogarzo® for the treatment of HIV-1 infection achieved consistent and statistically significant results demonstrating that there was no difference in pharmacokinetics (PK) between IV Push and IV Infusion. This more convenient IV Push mode of administration may offer patients a rapid infusion time and requires only two quick infusions per month potentially increasing patient compliance thereby allowing patients to benefit from long-acting protection against HIV-1 when Trogarzo® is administered with other ARVs. Based on these results, an sBLA is expected to be filed with the FDA in the fourth quarter of 2021. The study was conducted and funded by the Company's partner, TaiMed.

Theratechnologies and TaiMed are also evaluating an intramuscular (IM) method of administration for Trogarzo® within the TMB-302 study. A protocol amendment was approved by the FDA and patient screening is planned for the fourth quarter of 2021. The study will be conducted and funded by Theratechnologies with support from TaiMed. Under the terms of the TaiMed Agreement, we are entitled to commercialize the new methods of administration of Trogarzo® if, and when, approved.

In connection with the September 2019 approval of Trogarzo® in Europe, the Company is initiating a post-authorization efficacy study (Registry) in the EU to evaluate the real-world long-term efficacy and safety of Trogarzo® in combination with other ARVs, at the EMA's request. The study, named Prospective and Retrospective, Observational Multicenter Ibalizumab Study of Efficacy (PROMISE), is expected to have sites activated in the EU in the fourth quarter of 2021. A similar study, which is intended to collect real-world clinical data of Trogarzo® in the U.S. (PROMISE-US), is expected to begin in the first quarter of 2022.

#### 2021 BUSINESS STRATEGY AND OBJECTIVES

### Our 2021 Business Strategies and Objectives are as follows:

- Continue to grow our revenues in the United States from increased sales of EGRIFTA SV<sup>®</sup> and Trogarzo<sup>®</sup>;
- Successfully obtain reimbursement for Trogarzo<sup>®</sup> in key European countries and launch Trogarzo<sup>®</sup> in some of these countries;
- Initiate a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH by the end of the third quarter of calendar year 2021; (new trial initiation timeframe to be determined following securing additional resources or potential partnership agreement)
- Initiate a Phase 1 clinical trial evaluating TH1902 for the treatment of various cancer types in the second quarter of calendar year 2021 (achieved in Q1'21 ahead of target);
- Seek and pursue potential product acquisitions, in-licensing transactions or other opportunities complementary to our business; and,
- Manage our financial position to ensure we can successfully execute on our business strategy and objectives.

#### Third-Quarter Fiscal 2021 Financial Results

#### Revenue

Consolidated revenue for the three and nine-month periods ended August 31, 2021 was \$17,852,000 and \$51,069,000 compared to \$14,049,000 and \$46,930,000 for the same periods ended August 31, 2020.

Revenue for the third quarter of 2021 were up 27% compared to the third quarter of 2020. Most of that growth was attributable to strong  $EGRIFTA\ SV^{\otimes}$  revenues, which increased 64% over the same quarter last year. The strong third-quarter performance for  $EGRIFTA\ SV^{\otimes}$  was related to higher unit sales and a higher selling price and were also supported by stronger new prescriptions, a sign of a return to pre-COVID-19 levels. Sales of Trogarzo were down 7.8% compared to the third quarter of last year. Lower unit sales were somewhat offset by a higher selling price and were the result of lower patient access to hospitals and clinics because of COVID-19, as well as the impact of a new competitor.

#### **Cost of Sales**

For the three- and nine-month periods ended August 31, 2021, cost of sales was \$5,504,000 and \$16,849,000 compared to \$6,111,000 and \$20,252,000 for the same periods ended August 31, 2020. Cost of goods sold was \$4,283,000 and \$13,187,000 in the three and nine-month periods of 2021 compared to \$4,611,000 and \$15,780,000 for the same periods in the previous year. The decrease in cost of goods sold was mainly due to lower cost of *EGRIFTA SV*® and lower unit sales of Trogarzo®, as well as a lower average cost for Trogarzo®. Cost of sales also included the amortization of the other asset of \$1,221,000 and \$3,662,000 for the three and nine-month periods ended August 31, 2021. In addition, cost of sales for the three- and nine-month periods ended August 31, 2020, include write-downs of \$280,000 and \$811,000 to recognize inventories at net realizable value, which included write-downs of \$422,000 during the nine-month period ended August 31, 2020 on excess stock of *EGRIFTA*® mainly due to the Company's decision to switch patients to and only actively commercialize *EGRIFTA SV*® in the U.S. No such amounts were recorded for the three- and nine-month periods ended August 31, 2021.

### **R&D Expenses**

R&D expenses for the three- and nine-month periods ended August 31, 2021 amounted to \$8,296,000 and \$19,596,000 compared to \$4,183,000 and \$11,224,000 in the comparable periods of Fiscal 2020.

The increase was largely due to the development of our oncology platform, the preparation of our Phase 3 trial for tesamorelin in the treatment of NASH, the F8 formulation and the multi-dose pen injector, as well as regulatory expenses and increased medical education initiatives in Europe in preparation for the Trogarzo<sup>®</sup> launch.

#### Selling Expenses

Selling expenses increased to \$7,669,000 and \$20,728,000 for the three- and nine-month periods ended August 31, 2021 compared to \$7,025,000 and \$20,327,000 for the same periods last year.

The increase was mainly associated with increased activities in Europe in preparation for the Trogarzo<sup>®</sup> launch.

### **General and Administrative Expenses**

General and administrative expenses in the three- and nine-month periods ended August 31, 2021 amounted to \$3,633,000 and \$11,079,000 compared to \$2,699,000 and \$8,975,000 reported in the comparable periods of Fiscal 2020.

The increase in general and administrative expenses was mainly associated with an overall increase in business activities, senior hires to support our sales activities in the U.S., and increased activity in Europe.

#### **Net Finance Costs**

Net finance costs for the three- and nine-month periods ended August 31, 2021 were \$(2,254,000) and \$(4,609,000) compared to \$(799,000) and \$(3,270,000) in the comparable periods of Fiscal 2020.

The change in finance income and finance costs in 2021 versus the comparable periods in 2020 was mostly due to foreign currency variations. We recorded a net foreign currency loss of \$851,000 in the three-month period ended August 31, 2021, versus a net foreign currency gain of \$496,000 in the same period in 2020. For the nine-month period ended August 31, 2021, we recorded a net foreign currency loss of \$449,000 versus a net foreign currency gain of \$471,000 in the same period in 2020.

Finance costs also included accretion expense, which was \$612,000 for the third quarter of 2021 and \$1,801,000 for the nine-month period ended August 31, 2021 compared to \$485,000 and \$1,508,000 for the same periods last year.

#### **Adjusted EBITDA**

For the reasons noted above, Adjusted EBITDA, which is a non-GAAP measure, for the three- and nine- month periods ended August 31, 2021 was \$(4,648,000) and \$(9,085,000) compared to \$(3,149,000) and \$(5,676,000) in the comparable periods of Fiscal 2020. See "Non-IFRS Financial Measures" below.

#### **Net loss**

Taking into account the revenue and expense variations described above, we recorded a net loss of \$9,510,000 or \$(0.10) per share in the third quarter of Fiscal 2021 and a net loss of \$21,824,000 or \$(0.24) per share for the nine-month period ended August 31, 2021 compared to a net loss of \$6,768,000 or \$(0.09) per share in the three-month period ended August 31, 2020 and a net loss of \$17,118,000 or \$(0.22) per share compared to the nine-month period ended August 31, 2020.

#### **Financial Position**

For the three- and nine-month periods ended August 31, 2021, cash flow generated/(used) in operating activities was (3,133,000) and (9,077,000) compared to (7,648,000) for the same periods last year.

In the third quarter of Fiscal 2021, changes in operating assets and liabilities had a positive impact on cash flow of \$1,421,000. These changes were mainly due to an increase in accounts payables and accrued liabilities of \$2,843,000, a decrease in inventories of

\$1,157,000, which were offset by an increase in trade and other receivables of \$2,800,000.

In the first nine months of Fiscal 2021, changes in operating assets and liabilities positively affected cash flow by \$185,000 and negatively impacted cash flow by \$1,872,000 in the comparable period of fiscal 2020.

As of August 31, 2021, cash, bonds and money market funds amounted to \$51,584,000. Based on management's estimate and current level of operations, the current liquidity position is sufficient to finance the Company's operations for at least the next 12 months.

## **Quarterly Financial Information**

The following table is a summary of our unaudited consolidated operating results for the last eight quarters.

(in thousands of dollars, except per share amounts)

	2021			2020				2019 <sup>1</sup>
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Revenue Operating expenses	17,852	17,787	15,430	19,123	14,049	17,162	15,719	16,400
Cost of sales Cost of	4,283	4,714	4,190	5,190	4,611	5,769	5,400	5,754
goods sold Other production- related costs	-	-	-	240	280	391	140	14
Amortization of other asset	1,221	1,220	1,221	1,220	1,220	1,220	1,221	1,221
R&D	8,296	6,417	4,883	6,795	4,183	3,622	3,419	3,877
Selling	7,657	6,901	6,158	6,532	7,025	6,941	6,361	7,673
General and administrative	3,633	3,884	3,562	3,255	2,699	3,706	2,570	3,258
Total operating expenses	25,090	23,316	20,014	23,232	20,018	21,649	19,111	21,797
Net finance costs	(2,254)	(1,023)	(1,332)	(1,424)	(799)	(1,319)	(1,152)	(1,058)
Income taxes	(18)	(20)	(6)	(16)	-	-	-	-
Net loss	(9,510)	(6,392)	(5,922)	(5,549)	(6,768)	(5,806)	(4,544)	(6,455)
Basic and diluted loss per share	(0.10)	(0.07)	(0.07)	(0.07)	(0.09)	(0.08)	(0.06)	(0.08)

<sup>1</sup> The Company adopted IFRS 16 – Leases, using the modified retrospective approach, effective for Fiscal 2020, beginning on December 1, 2019. Accordingly, comparative figures for Fiscal 2019 have not been restated and continue to be reported under IAS 17–. See note 1 in the Audited Financial Statements for the year ended November 30, 2020.

### Factors Affecting the Variability of Quarterly 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.

#### Subsequent Event

Stock options

Between September 1, 2021 and October 11, 2021, no options were exercised.

### **Recent Changes in Accounting Standards**

There were no changes in accounting standards during Q3 Fiscal 2021.

#### **Outstanding Share Data**

As of October 11, 2021, the Company had 95,121,639 common shares issued and outstanding, 8,130,550 warrants outstanding, and 3,598,171 outstanding options. We also had \$57,500,000 aggregate principal amount of 5.75% convertible unsecured senior notes due June 30, 2023 issued and outstanding as a result of the Offering. These notes are convertible into common shares at the option of the holder at a conversion price of \$14.85, representing a conversion rate of approximately 67.3401 common share per \$1,000 principal amount of notes. The conversion of all of the outstanding notes would result in the issuance of 3,872,055 common shares.

### **Contractual Obligations**

There was no material change in contractual obligations during the three-month period ended August 31, 2021.

#### **Economic and Industry Factors**

The WHO declared a global pandemic on March 11, 2020. Authorities around the world implemented confinement measures designed to curb the spread of the COVID-19. Those measures have severely limited face-to-face access to healthcare providers. The industry as a whole has had to adapt to this new reality and uncertainty remains.

#### **Internal Control**

There was no change in the Company's internal control over financial reporting, or ICFR, that occurred during the three-month period ending August 31, 2021 that has materially affected, or is reasonably likely to materially affect, the Company's ICFR.

#### **Non-IFRS Financial Measures**

Reconciliation of net profit or loss to adjusted earnings before interest, taxes, depreciation and amortization (Adjusted EBITDA)

Adjusted EBITDA is a non-IFRS financial measure. A reconciliation of the Adjusted EBITDA to net loss is presented in the table below. We use adjusted financial measures to assess our operating performance. Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than IFRS do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. We use

Adjusted EBITDA to measure operating performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends in our business, and because we believe it provides meaningful information on our financial condition and operating results.

We obtain our Adjusted EBITDA measurement by adding to net profit or loss, finance income and costs, depreciation and amortization, and income taxes. We also exclude the effects of certain non-monetary transactions recorded, such as share-based compensation and write-downs (or related reversals) of inventories, for our Adjusted EBITDA calculation. We believe it is useful to exclude these items as they are either non-cash expenses, items that cannot be influenced by management in the short term, or items that do not impact core operating performance. Excluding these items does not imply they are necessarily nonrecurring. Share-based compensation costs are a component of employee remuneration and can vary significantly with changes in the market price of the Company's shares. In addition, other items that do not impact core operating performance of the Company may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of our operating results over a period of time. Our method for calculating Adjusted EBITDA may differ from that used by other companies.

# **Adjusted EBITDA**

(In thousands of U.S. dollars)

	Three-mont ended Au	-	Nine-month periods ended August 31,		
	2021	2020	2021	2020	
Net loss	(9,510)	(6,768)	(21,824)	(17,118)	
Add (deduct):					
Depreciation and amortization	2,189	2,189	6,559	6,328	
Net finance costs	2,254	799	4,609	3,270	
Share-based compensation	401	349	1,527	1,168	
Write-down of inventories	-	282	-	676	
Income taxes	18	-	44	-	
Adjusted EBITDA	(4,648)	(3,149)	(9,085)	(5,676)	