

## MANAGEMENT'S DISCUSSION AND ANALYSIS

FOR THE THREE AND NINE-MONTH PERIOD ENDED AUGUST 31, 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 three- and nine-months period ended August 31, 2022, compared to the three- and nine-months period ended August 31, 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 October 11, 2022, was approved by our Audit Committee on October 12, 2022, and should be read in conjunction with our unaudited interim consolidated financial statements and the notes thereto as at August 31, 2022 ("Interim Financial Statements"), as well as the MD&A and audited annual consolidated financial statements, including the notes thereto, as at November 30, 2021.

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, or 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*<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 (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 our forecasted revenues for the 2022 full fiscal year, the conduct of our clinical trials with TH1902, the availability to us of the whole amount of \$100 million under the terms of the Credit Agreement (as defined below), our ability to successfully complete the HFS (as defined below) for both *EGRIFTA SV*<sup>®</sup> and the F8 formulation, the timelines associated with the filing of a supplemental biologic application ("sBLA") with the FDA (as defined below) for the F8 formulation and the launch thereof, our discussions with potential partners in NASH and in Greater China for our

oncology platform, and the benefits to be derived from the approval of the IV push method of administration of Trogarzo®.

Although the forward-looking information contained in this MD&A is based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on this information since actual results may vary from the forward-looking information. 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; the Company's 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; the Company's relations with third-party suppliers of *EGRIFTA SV*® and Trogarzo® will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA SV*® and Trogarzo® to meet market demand on a timely basis; no biosimilar version of *EGRIFTA SV*® will be approved by the FDA; the Company's intellectual property will prevent companies from commercializing biosimilar versions of *EGRIFTA SV*® in the United States; the Company will meet all conditions under the Credit Agreement to draw down all amounts thereunder; the Company will succeed in finding a commercial partner in Greater China for its oncology platform and for its NASH program; the timelines associated with the filing of a sBLA with the FDA for the F8 formulation and the launch thereof will be met; the Company will be able to recruit patients for its clinical trial using TH1902; no material manufacturing issues will be encountered in connection with the manufacture of TH1902; results observed and obtained from the Phase 1 clinical trial using TH1902 will be at least as good as those observed in preclinical studies and will allow the pursuit of this clinical study; the market will accept the new method of administration of Trogarzo®; and the Company's business plan will not be substantially modified.

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*® and Trogarzo® successfully in the United States; the Company's capacity to meet supply and demand for its products; the market acceptance of *EGRIFTA SV*® and Trogarzo® in the United States, including the IV push method of administration of Trogarzo®; 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*® and Trogarzo® by third-party payors in the United States; the success and pricing of other competing drugs or therapies that are or may become available 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 Credit Agreement resulting in an event of default and preventing

the Company from accessing the full amount of the term loan; inconclusive results from the conduct of the Company's Phase 1 clinical trial using 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 in the territory of Greater China; 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 23, 2022, available on SEDAR at [www.sedar.com](http://www.sedar.com) and on EDGAR at [www.sec.gov](http://www.sec.gov) as an exhibit to our report on Form 40-F dated February 24, 2022, 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.

## **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*<sup>®</sup> and Trogarzo<sup>®</sup>) for people living with HIV. The Company has a sales and marketing infrastructure to commercialize its products in the U.S. We are winding down commercial operations in Europe in connection with the commercialization and distribution of Trogarzo<sup>®</sup> as we will forfeit our rights to commercialize and distribute such products in November 2022. 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 HIGHLIGHTS AND PROGRAM UPDATES**

### **Pipeline Updates**

- **TH1902 Phase 1 Trial Update:** On July 14, 2022, the Company issued an update on the dose escalation portion of the TH1902 Phase 1 clinical safety study. TH1902 is Theratechnologies' first-in-human study of its investigational lead peptide drug conjugate ("PDC") for the treatment of sortilin-expressing cancers. It has received Fast Track designation from the United States Food and Drug Administration ("FDA").

In this update, we announced a total of 18 heavily pre-treated patients, who received an average of 8 prior cancer treatments, were enrolled in the dose escalation portion of the study. Following the safety observations at 420 mg/m<sup>2</sup> 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/m<sup>2</sup> for the next dose level and was expanded to a total of 6 patients. No Dose Limiting Toxicities were observed during the first cycle, therefore, the dose of 300 mg/m<sup>2</sup> was selected for continuation of the basket part of the study. In addition, the levels of free docetaxel are low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m<sup>2</sup>. Thus far 300 mg/m<sup>2</sup> appears to be a well-tolerated dose level, which continues to be evaluated in the larger basket portion of the TH1902 study.

Signs of efficacy have been observed in three heavily pretreated patients in the dose escalation trial, and recorded results include:

- Confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m<sup>2</sup>, PSA (*Prostate-specific Antigen*) continued to progress.
- Stabilized disease observed 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/m<sup>2</sup> to 300 mg/m<sup>2</sup>.
- Stabilized disease observed in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages). Notably, the patient received a total of 11 cycles. The dose was escalated from 60 mg/m<sup>2</sup> to 360 mg/m<sup>2</sup>.

In an effort to optimize and ensure success of this clinical research program, the Company has currently enrolled six active trial sites across the United States. The plan is to enroll additional sites in the United States, the European Union and Canada.

### **TH1902 Study in *Pharmaceutics* Journal**

Subsequent to the end of the quarter, the Company announced the publication of a preclinical study demonstrating the *in vitro* and *in vivo* efficacy of TH1902, an investigational sortilin (SORT1)-targeted peptide-drug conjugate, in inhibiting ovarian cancer and triple-negative breast cancer (TNBC) stem-like cells' (CSCs) tumor growth. The study, published as part of the special issue of [\*Pharmaceutics\*](#) "Targeting Drug Resistance and Metastatic Pathways for Cancer Therapy", reports that TH1902 appears to exert anticancer activity that is superior to unconjugated docetaxel in preclinical models, in part by circumventing the chemoresistance phenotype that is often responsible for treatment failure and cancer recurrence.

In the *Pharmaceutics* paper, researchers at Theratechnologies and the Molecular Oncology Laboratory at Université du Québec à Montréal (UQAM) describe the activity of TH1902 against CSCs and its ability to circumvent some of the known resistance phenotypes associated with CSCs. Their findings suggest that TH1902 targets cancer cells overexpressing the sortilin receptor – an effect that is absent in healthy cells. Additionally, at doses equivalent to docetaxel, single-agent TH1902 exhibited superior efficacy against breast and ovarian CSCs, compared to docetaxel alone. Finally, when combined with carboplatin in an ovarian tumor model, the efficacy of TH1902 was also superior to that of paclitaxel- or docetaxel-

carboplatin combinations. In TNBC and ovarian CSCs animal models, TH1902 decreased tumor growth by 80%, compared to roughly 35% in docetaxel-treated mouse models.

### **Trogarzo® Lifecycle Management**

On October 3, the Company received notice of approval from the FDA for the 30-Second Intravenous (“IV”) Push method of administration of Trogarzo®.

The FDA originally approved Trogarzo® a novel, long-acting monoclonal antibody, in March 2018 to be administered intravenously as a single loading dose followed by a 15-minute maintenance dose, every two weeks. Following this approval, the maintenance dose can be administered as an undiluted IV push over 30 seconds.

The Company believes this simplified method of administration will improve patient compliance and will provide a broader number of access points for patients.

The Company is also conducting a study assessing an intramuscular method of administration of Trogarzo®. This study is now fully enrolled, with the last patient visit scheduled for November 2022. If approved, we believe that this new method of administration will give patients an even more convenient form of administration, and further potentially improving access and compliance to the regimen.

### **Trogarzo® Data at AIDS 2022 Shows Potential for Improved Treatment Regimens**

On July 28, Theratechnologies announced data from two poster presentations at the 24th International AIDS Conference (“AIDS 2022”) held in Montreal that provided key understandings on the potential of Trogarzo® (ibalizumab) to evolve treatment paradigms for heavily treatment-experienced HIV populations on complex regimens.

In summary, the poster presentation entitled “***ibalizumab long-term efficacy is not impacted by partially active antiretrovirals***” demonstrated that in clinical trial patients, long-term viral suppression is not influenced by partially active agents; and the poster presentation entitled “***Pharmacokinetic modeling and simulation of intramuscular and subcutaneous ibalizumab delivery***” revealed that Predictive pharmacokinetic modelling shows that new methods of administration, intramuscular and subcutaneous, could be maintained through concentrations greater than 0.3 µg/mL, which has been previously correlated with efficacy with the intravenous infusion.

The two AIDS 2022 scientific presentations followed on data presented at the Italian Conference on AIDS and Antiviral Research (ICAR) entitled ***Evaluation of the in vitro combinatorial activity of Ibalizumab and HIV-1 antivirals***, which was supported by an independent grant. In vitro combination activity between Trogarzo® and nine other ARVs, seven commercially available and two investigational, demonstrated the additive or synergistic effects seen between each pairing. Of note, synergistic activities were seen with dolutegravir, etravirine, tenofovir alafenamide and lenacapavir, a long-acting investigational ARV.

## **TH1902 China Out-licensing and Partnership Strategy**

Discussions around out-licensing the development and commercialization rights for TH1902 in Greater China continue. The Company is optimistic about the prospects as the TH1902 basket trial continues to enroll patients.

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

As previously announced, the FDA requested that the Company carry out a Human Factors Study (“HFS”) to ensure that patients are administering *EGRIFTA SV<sup>®</sup>* in the appropriate manner. The study has been initiated and is progressing as planned.

## **F8 sBLA Filing**

The Company had planned on filing a supplemental biologic licence application (“sBLA”) for its F8 formulation of tesamorelin by the end of the first quarter of calendar 2022. As the FDA asked us to do a HFS for *EGRIFTA SV<sup>®</sup>*, we have proactively decided to do one also for the F8 formulation. This study has been initiated and will be completed shortly after the *EGRIFTA SV<sup>®</sup>* HFS study.

Furthermore, given the current uncertainty around the supply of Bacteriostatic Water For Injection (“BWF1”), we have signed an agreement with a contract manufacturer to produce our own supply. We believe this proactive step will ensure we have access to BWF1 upon launch of the F8 formulation, if approved. With these decisions made, we are currently on track to deliver the filing of this new formulation in the fourth quarter of 2023, with an approval and launch expected around the first quarter of 2024.

## **NASH**

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

## **Corporate and Commercial Updates**

### **\$100 million Credit Agreement with Marathon Asset Management and Closing of first tranche of \$40 million**

On July 13, 2022, the Company announced it received a binding commitment with respect to a credit agreement (the “Credit Agreement”) for a non-dilutive term loan with an affiliate of Marathon Asset Management for up to \$100 million.

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

noteholders, while the remainder was allocated to working capital. All amounts drawn under the Credit Agreement bear interest at SOFR plus 9.5%.

## **2022 Revenue Guidance**

Fiscal year 2022 revenue guidance is on track to be in the range of \$79 million - \$82 million, or growth of the commercial portfolio to be in the range of 13% and 17%, as compared to the 2021 fiscal year.

## **OUR MEDICINES**

The Company has two approved medicines for people living with HIV, namely Trogarzo® in the United States, European Union, and United Kingdom, and *EGRIFTA SV*® in the United States.

Trogarzo® 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. Trogarzo® was also approved by the European Medicines Agency (“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.

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

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

## **OUR PIPELINE**

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

### **Tesamorelin**

During the 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 the tesamorelin formulation. The F8 formulation has a number of advantages over the current formulation of *EGRIFTA SV*®. Specifically, it is two times more concentrated resulting in a smaller volume of administration and is intended to be presented in a multi-dose vial that can be reconstituted once per week. Similar to the current formulation of *EGRIFTA SV*®, the F8 formulation is stable at room temperature, even once reconstituted.

### ***Human Factors Study***

As previously announced, the FDA requested that the Company carry out a Human Factors Study (“HFS”) to ensure that patients are administering *EGRIFTA SV*<sup>®</sup> in the appropriate manner. The study has been initiated and is progressing as planned.

The Company had planned on filing a supplemental biologic licence application (“sBLA”) for its F8 formulation of tesamorelin by the end of the first quarter of calendar 2022. As the FDA asked us to do a HFS for *EGRIFTA SV*<sup>®</sup>, we have proactively decided to do one also for the F8. This study has been initiated and will be completed shortly after the *EGRIFTA SV*<sup>®</sup> HFS study.

### ***Bacteriostatic Water for Injection (“BWFI”)***

Furthermore, given the current uncertainty around the supply of BWFI, we have signed an agreement with a contract manufacturer to produce our own supply. We believe this proactive step will ensure we have access to BWFI upon launch of the F8 formulation, if approved. With these decisions made, we are currently on track to deliver the filing of this new formulation in the fourth quarter of 2023, with an approval and expected launch around the first quarter of 2024.

### ***PEN for the F8 Formulation***

The Company is currently working on the development of a pen to be used in conjunction with the F8 formulation. To date, its development is not completed, and we are still working on the pen. As a result, no timeline has been set for the filing of an sBLA with the FDA in relation to the pen.

### ***NASH***

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

The Company received an approval in connection with a Phase 3 trial design for tesamorelin for the treatment of NASH.

After internal discussions and further risk assessments on this program, in order to further de-risk the Phase 3 trial, the Company has submitted an amended protocol to the FDA. The new protocol will include a Phase 2b/3 seamless study design where the first 350 or so patients’ data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. This amended protocol will allow us to generate hard endpoint data on NAS score and fibrosis. A decision will then be made whether to continue the study until full number of patients (1,094) have completed 18 months of treatment. This does not change the total number of patients required to seek accelerated approval of tesamorelin for the treatment of NASH.



In the third quarter of 2022, the Company received questions from the FDA on the redesigned protocol. These questions were received after the normal regulatory timelines. The Company is confident that it will be able to address all of the questions. As of the date of this MD&A, the Company confirms that the redesigned protocol has not been accepted by the FDA.

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

### **SORT1+ Technology™**

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

Our SORT1+ Technology™ was acquired in February 2019 as part of the acquisition of Katana Biopharma, Inc. (“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.

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 included a Part A dose escalation study to evaluate the safety, pharmacokinetics, maximum tolerated dose (“MTD”) and preliminary anti-tumor activity of TH1902 administered once every three weeks in patients with advanced solid tumors refractory to available anti-cancer therapies.

The Corporation’s Phase 1 study evaluating its novel investigational proprietary PDC TH1902 for the treatment of sortilin positive cancers is progressing as planned. The Company has completed the dose escalation portion of the Phase 1 trial (Part A). See “Recent Highlights and Program Updates – Pipeline Updates – TH1902 Phase 1 Trial Update” above. We have now initiated enrollment of the larger open label basket trial, which will further assess the safety and tolerability of TH1902. The preliminary anti-tumor activity of TH1902 will be evaluated for all patients as per the response evaluation criteria in solid tumors. Part B of the Phase 1 trial will include the following solid tumor types: Hormone Receptor-Positive (HR+) Breast Cancer, Triple Negative Breast Cancer, Ovarian Cancer, Endometrial Cancer, Melanoma (10 patients per tumor type). In addition, one arm will be added to include Thyroid, Small Cell Lung, Prostate and potential other high Sortilin expressing cancers (15 patients in total). The plan is to enroll a total of approximately 70 patients in the basket trial to evaluate the potential anti-tumor activity of TH1902.

## **Ibalizumab for HIV**

The Company is also conducting a study assessing an intramuscular method of administration of Trogarzo®. This study is now fully enrolled, with the last patient visit scheduled for November 2022.

## **2022 Revenue Guidance**

Fiscal year 2022 revenue guidance is on track to be in the range of \$79 million - \$82 million, or growth of the commercial portfolio to be in the range of 13% and 17%, as compared to the 2021 fiscal year.

## **Term Loan Financing**

In the third quarter of 2022, the Company announced that it had entered into the Credit Agreement. Highlights of the Credit Agreement are as follows:

- Senior secured term loan of up to \$100 million across four tranches;
- \$40 million funded on July 27, 2022 (“Tranche 1 Loan”);
- \$20 million 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 million for the 12-month period immediately preceding the funding of the tranche (“Tranche 2 Loan”);
- \$15 million 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 million for the 12-month period immediately preceding the funding of the tranche (“Tranche 3 Loan”);
- Up to an additional \$25 million to be made available no later than December 31, 2024, if the Company has had at least \$110 million in net revenues for the 12-month period immediately preceding the funding of the tranche and at least \$20 million in EBITDA (as defined in the Credit Agreement) (“Tranche 4 Loan”);
- The facility has an initial term of five years (six years if Tranche 3 is drawn), provides for an interest-only period of 24 months (36 months if Tranche 3 is drawn), and bears interest at the Secured Overnight Financing Rate (SOFR) plus 9.5%;
- The proceeds from the Tranche 1 Loan were used to purchase \$30 million principal amount of issued and outstanding convertible unsecured senior notes through private agreements with certain noteholders 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.

## **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 August 31, 2022:

<i>In millions</i>	<b>Estimated Use of Proceeds</b>	<b>Actual Use of Proceeds</b>	<b>Variance</b>
Nash Phase 3 clinical trial	\$30.5	\$2.8	\$(27.7)
Oncology R&D	7.0	6.5	(0.5)
Commercial and marketing activities	3.5	--	(3.5)
Other	1.5	1.9	0.4
Net Proceeds	\$42.5	\$11.2	\$(31.3)

As at August 31, 2022, approximately \$2,845,000 had been used in connection with the NASH Phase 3 clinical trial.

As at August 31, 2022, approximately \$6,462,000 had been used in connection with oncology research and development activities and the variance between the amount reserved and the amount used as at August 31, 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.

## Third Quarter Fiscal 2022 Financial Results

### Revenue

For the three- and nine-month periods ended August 31, 2022, consolidated revenue was \$20,811,000 and \$58,636,000, compared to \$17,852,000 and \$51,069,000 for the same periods ended August 31, 2021, representing a year-over-year increase of 16.6% and 14.8%, respectively.

For the third quarter of fiscal 2022, net sales of *EGRIFTA SV*<sup>®</sup> were \$12,876,000 compared to \$11,224,000 in the third quarter of fiscal 2021, representing an increase of 14.7% year-over-year. Net sales for the nine-month period ended August 31, 2022, were \$35,996,000 compared to \$30,256,000 in the same period in 2021. Higher *EGRIFTA SV*<sup>®</sup> sales are the result of increased unit sales and a higher net selling price per unit.

Trogarzo<sup>®</sup> net sales in the third quarter of fiscal 2022 amounted to \$7,935,000 compared to \$6,628,000 for the same quarter of 2021, representing an increase of 19.7% year-over-year. For the nine-month period ended August 31, 2022, Trogarzo<sup>®</sup> net sales were \$22,640,000 compared to \$20,813,000 in the same period in 2021. Higher sales of Trogarzo<sup>®</sup> were a result of a stronger performance in the United States, where we recorded 26.0% growth compared to the same quarter of last year, and were hampered by lower sales in Europe, as a result of a weaker overall pricing environment.

### Cost of Sales

For the three-month period ended August 31, 2022, cost of sales decreased to \$5,292,000 from \$5,504,000 in the same period in fiscal 2021. The decrease is mostly related to the end of the amortization of the Other Asset.

For the nine-months ended August 31, 2022, cost of sales increased to \$20,370,000 from \$16,849,000, this increase is mostly related to the increase in revenues. The increase is also due to a charge, in the second quarter of 2022, arising from the non-production of scheduled batches of *EGRIFTA SV*<sup>®</sup> that were cancelled due to the planned transition to the F8 formulation of tesamorelin.

Cost of goods sold was \$5,292,000 and \$17,929,000 in the three- and nine-month periods of 2022 compared to \$4,283,000 and \$13,187,000 for the same periods in 2021. The increase in cost of goods sold was mainly due to higher unit sales of both *EGRIFTA SV*<sup>®</sup> and Trogarzo<sup>®</sup>.

### R&D Expenses

R&D expenses in the three- and nine-month periods ended August 31, 2022, amounted to \$8,425,000 and \$27,484,000 compared to \$8,296,000 and \$19,596,000 in the comparable periods of fiscal 2021.

The increases in both periods were largely due to higher spending related to the ongoing Phase 1 trial of TH1902. In 2022, we have also initiated important studies related to medical education and follow-up studies in the HIV field. Increased spending in R&D is also related to the on-going trial evaluating the intra-muscular form of administration of

Trogarzo®. The increase is also explained by severance costs related to our decision to exit the European market for Trogarzo®.

### **Selling Expenses**

Selling expenses increased to \$8,404,000 and \$31,582,000 for the three- and nine-month periods ended August 31, 2022, compared to \$7,657,000 and \$20,716,000 for the same periods last year. The increase is due in part to one-time costs related to setting up of our internal field force in the United States, as well as spending on new initiatives implemented in 2022 to increase awareness of our products on the North American market. The increase is also explained by severance costs related to our decision to exit the European market for Trogarzo®.

The amortization of the intangible asset value for the *EGRIFTA SV*® and Trogarzo® commercialization rights is also included in selling expenses. As such, we recorded expenses of \$642,000 and \$8,539,000 for the three- and nine-month periods ended August 31, 2022, compared to \$795,000 and \$2,745,000 in 2021. The increase in the nine-month period ended August 31, 2022, is related to the accelerated amortization of the Trogarzo® commercialization rights for the European territory following our decision in the second quarter of 2022 to cease commercialization activities in that territory.

### **General and Administrative Expenses**

General and administrative expenses in the three- and nine-month periods ended August 31, 2022, amounted to \$4,209,000 and \$13,400,000 compared to \$3,633,000 and \$11,079,000 reported in the comparable periods of fiscal 2021. The increase in General and Administrative expenses is largely due to increased overall business activities in 2022 compared to 2021, as well as key hires in North America to support the implementation and management of our internal field force in the United States. General and administrative expenses for Q3 of 2022 also include severance costs and fees associated to our realignment in Europe.

### **Net Finance Costs**

Net finance costs for the three- and nine-month periods ended August 31, 2022, were \$1,879,000 and \$4,808,000 compared to \$2,254,000 and \$4,609,000 for the comparable periods of 2021. Net finance costs in the third quarter of 2022 and 2021 included interest of \$554,000 and \$847,000 respectively (\$2,189,000 and \$2,482,000 in the corresponding nine-months periods, respectively) on the senior convertible notes issued in June 2018, as well \$490,000 interest on our new term loan. (Please refer to note 7 of the Interim Consolidated Financial Statements).

Net finance costs for the three- and nine-month periods ended August 31, 2022, also included accretion expense of \$456,000 and \$1,517,000, compared to \$612,000 and \$1,801,000 for the comparable periods in 2021.

### **Net Loss**

Given the increase in revenue and the smaller increase in expenses in the third quarter of 2022, net loss improved to \$7,549,000 from \$9,510,000 in the third quarter of 2021. During the nine-month period ended August 31, 2022, net loss increased to \$39,308,000 from \$21,824,000 in the corresponding period of 2021, mostly due to the accelerated amortization of the Trogarzo® commercialization rights for the European Territory in the second quarter of 2022 of \$6,356,000. Net loss in the third quarter of 2022 was also impacted by severance costs and fees related to our decision to exit the European market for Trogarzo® of approximately \$900,000. Net loss for the nine-month period ended August 31, 2022 was further impacted by a charge, in the second quarter of 2022, 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.

## **Liquidity and Financial Position**

We ended the third quarter of fiscal 2022 with \$36,462,000 in cash, bonds and money market funds. The Company believes that its cash position and future operating cash flows will be sufficient to finance its operations for at least the next 12-months from the consolidated statement of financial position date. (See Note 1c) to the Interim Financial Statements).

For the three-month period ended August 31, 2022, cash flows used by operating activities were \$4,372,000 compared to \$4,554,000 in the same period of fiscal 2021.

In the third quarter of fiscal 2022, changes in operating assets and liabilities had a positive impact on cash flow of \$3,176,000, as compared to \$1,500,000 in 2021. These changes were mostly attributable to positive impacts from lower accounts receivable (\$1,059,000), inventories (\$1,536,000) and prepaid expenses (\$1,135,000) and were offset by lower accounts payables and accrued liabilities (\$1,333,000).

Our financial position was also positively impacted by the net proceeds from the first tranche of the term loan facility (\$36,892,000, including deferred financing costs), which were offset by funds used to repurchase \$30,000,000 principal amount of convertible notes outstanding (\$28,746,000), as well as by the interest paid on the convertible notes.

## **Subsequent Event**

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 its commercialization agreement for Trogarzo®, the Company has additional contingent cash-based milestones based on the attainment of commercial milestones. Accordingly, a probable cash payment totalling \$3,000,000 will be accrued in the fourth quarter of fiscal 2022.

## **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)*

	2022			2021			2020	
	Q3	Q2	Q1	Q4	Q3	Q2	Q1	Q4
Revenue	20,811	19,268	18,557	18,754	17,852	17,787	15,430	19,123
Operating expenses								
Cost of sales								
Cost of goods sold	5,292	7,759	4,878	5,191	4,283	4,714	4,190	5,190
Other production-related costs	-	-	-	-	-	-	-	240
Amortization of other asset	-	1,220	1,221	1,220	1,221	1,220	1,221	1,220
R&D	8,425	11,056	8,003	8,678	8,296	6,417	4,883	6,795
Selling	8,404	15,371	7,807	8,193	7,657	6,901	6,158	6,532
General and administrative	4,209	4,823	4,368	3,537	3,633	3,884	3,562	3,255
Total operating expenses	26,330	40,229	26,277	26,819	25,090	23,136	20,014	23,232
Net finance costs	(1,879)	(1,644)	(1,285)	(1,817)	(2,254)	(1,023)	(1,332)	(1,424)
Income taxes	(151)	(122)	(27)	(19)	(18)	(20)	(6)	(16)
Net loss	(7,549)	(22,727)	(9,032)	(9,901)	(9,510)	(6,392)	(5,922)	(5,549)
Basic and diluted loss per share	(0.08)	(0.24)	(0.09)	(0.1)	(0.1)	(0.07)	(0.07)	(0.07)

### 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.

The increase in cost of goods sold in Q2 2022 was mainly due to a charge arising from the non-production of scheduled batches of *EGRIFTA SV*<sup>®</sup> that were cancelled due to the planned transition to the F8 formulation of tesamorelin.

The increase in selling expenses in Q2 2022 was related to the accelerated amortization of the Trogarzo<sup>®</sup> commercialization rights for the European territory following our decision to cease commercialization activities in that territory.

### Recent Changes in Accounting Standards

There were no changes in accounting standards during the third quarter of fiscal 2022.

### Outstanding Share Data

As of October 11, 2022, the Company had 95,141,639 common shares issued and outstanding, 8,130,550 warrants outstanding, and 5,424,820 outstanding options. We also had \$27,500,000 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 remaining outstanding notes would result in the issuance of 1,851,852 common shares.

### **Contractual Obligations**

The Company has entered into the Credit Agreement. See “Term Loan Financing” above. Other than the Credit Agreement and the buy-back of \$30 million principal amount of the convertible notes, there was no material change in contractual obligations during the three- and nine-month periods ended August 31, 2022.

### **Economic and Industry Factors**

In the three months ended August 31, 2022, there were no material economic and industry factors affecting our business.

### **Internal Control**

There was no change in the Company’s internal control over financial reporting (“ICFR”) that occurred during the period beginning on June 1, 2022, and ending on August 31, 2022, that has materially affected, or is reasonably likely to materially affect, the Company’s ICFR.