

# THERATECHNOLOGIES ANNOUNCES FINANCIAL RESULTS FOR THE THIRD QUARTER OF FISCAL 2020

**Montreal, Canada – October 15, 2020** – Theratechnologies Inc. (Theratechnologies, or Company) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today announced its financial results for the third quarter of fiscal year 2020 ended August 31, 2020.

"Theratechnologies recently made a number of key business decisions that we expect will build a stronger foundation for growth. First, we announced our intention to pursue the development of tesamorelin for the treatment of NASH in the general population. This well-thought out decision was based on strong scientific evidence and feedback from some of the world's most renowned experts in this disease area. Additionally, we restructured our sales infrastructure to better align with the current environment and position our commercial medicines for growth. These strategic initiatives, along with our early development efforts in oncology, represent tremendous opportunities for the Company going forward," said Mr. Paul Lévesque, President and Chief Executive Officer, Theratechnologies.

# Revenue for Three- and Nine-Month Periods of Fiscal 2020 (in thousands of U.S. dollars)

	Three-month periods ended August 31,		Nine-month periods ended August 31,	
	2020	2019	2020	2019
EGRIFTA®, EGRIFTA SV® net sales	6,864	9,188	24,648	26,789
Trogarzo <sup>®</sup> net sales	7,185	6,923	22,282	20,027
Revenue	14,049	16,111	46,930	46,816

# **Key Business Highlights**

# Development of tesamorelin for the treatment of NASH in general population

- Announcement made on September 10, 2020 to move forward with a Phase 3 clinical trial evaluating tesamorelin for the potential treatment of nonalcoholic steatohepatitis (NASH) in the general population
- Protocol to be submitted to the U.S. Food and Drug Administration (FDA) and European regulatory agencies in the fourth quarter of 2020
- Once submitted, feedback from the regulatory agencies should be received within 30 to 60 days
- The Company aims to initiate the clinical trial in early 2021

## Trogarzo<sup>®</sup> IV Push

- A study evaluating a new method of administration of Trogarzo<sup>®</sup>, an IV push, is currently being conducted by TaiMed
- The study is progressing well and the recruitment of patients should be completed in the fourth quarter of 2020
- Under the terms of the in-licensing agreement with TaiMed, or TaiMed Agreement, Theratechnologies is entitled to commercialize the new method of administration of Trogarzo<sup>®</sup> if, and when, approved

# Transition to EGRIFTA SV®

- The transition to EGRIFTA SV® was completed in August 2020
- Subsequently, the transition had a non-recurrent impact on net revenue as vials of the original formulation were returned during the quarter. The Company expects corresponding revenue for the replacement vials to be recorded in the fourth quarter of 2020

## Impact of COVID-19

- COVID-19 continues to represent a challenge for sales representatives who, for the most part, cannot have face-to-face interactions with healthcare providers
- On September 21, 2020, the Company announced a change to its sales infrastructure and a reallocation of resources focused on increasing the number of virtual interactions and educational events with physicians. Theratechnologies expects these measures will support efforts to grow sales of Trogarzo<sup>®</sup> and EGRIFTA SV<sup>®</sup> in the U.S. going forward
- The Company continues to make progress toward advancing its research and development pipeline. All third-party service providers working with Theratechnologies on these programs remain active

## Research & Development Pipeline

Theratechnologies has established a robust and promising pipeline of investigational medicines in areas of high unmet need.

#### **Tesamorelin for the Treatment of NASH**

- On September 10, 2020, the Company announced its intention to pursue the development of tesamorelin for the treatment of NASH in the general population
- Theratechnologies intends to submit the Phase 3 study protocol to the FDA and European regulatory agencies in the fourth quarter of 2020
- Subject to feedback from regulatory agencies, enrollment of patients is planned to begin in the first quarter of 2021
- Theratechnologies plans to use a new formulation of tesamorelin, known as "F8 formulation", for the Phase 3 clinical trial in NASH. In addition, a supplemental Biologics License Application is expected to be filed with the FDA in early 2022 in HIV-associated lipodystrophy using the multi-dose pen injector currently being developed for this new formulation
- On October 13, 2020, the United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 10,799,562, which is directed to the treatment of NASH and/or Nonalcoholic Fatty Liver Disease (NAFLD) in patients using tesamorelin. This patent, which is scheduled to expire in 2040, stems from a patent application filed in March 2020 by Massachusetts General Hospital (MGH). Theratechnologies has an exclusive license with MGH to this patent

# Investigational SORT1+ Technology<sup>™</sup> for the Treatment of Cancer

- The Company is pursuing the development of a unique targeted oncology technology. The SORT1+ Technology<sup>™</sup> consists of proprietary peptide-drug conjugates, or PDCs, that specifically target various cancers where the sortilin receptor (SORT1) is overexpressed
- Based on positive preclinical data, Theratechnologies plans to submit an investigational new drug application, or IND, to the FDA for a first-in-human clinical trial evaluating its first investigational PDC, TH1902, before the end of 2020. Following IND approval, the Company expects to initiate a Phase 1 clinical trial in early 2021
- Theratechnologies plans to submit an IND for TH1904, the Company's second investigational PDC, once manufacturing scale-up is completed, which is expected to occur following the initiation of the Phase 1 clinical trial of TH1902

#### **Third-Quarter 2020 Financial Results**

Consolidated revenue for the three and nine-month periods ended August 31, 2020 was \$14,049,000 and \$46,930,000 compared to \$16,111,000 and \$46,816,000 for the same periods ended August 31, 2019.

Revenue for the third quarter of 2020 were impacted by one-time items, such as tighter inventory controls at the distributor level and higher than anticipated rebates and chargebacks. Also impacting revenues for the quarter were returns of original  $EGRIFTA^{\otimes}$  vials, as this formulation has been removed from the market, and vials still in circulation were pulled from pharmacies; the Company expects that the corresponding revenue for replacement vials of  $EGRIFTA\ SV^{\otimes}$  will be recorded in the fourth quarter of 2020. Finally, prescription growth was impacted by the Covid-19 pandemic.

COVID-19 has changed the pharmaceutical sales and marketing paradigm. Hospitals and clinics have become less accessible to sales representatives due to pandemic-related restrictions which led to fewer face-to-face interactions with healthcare professionals. As a result, we implemented the appropriate actions to address these challenges. Through a

different sales structure and the reallocation of resources, as announced on September 21, 2020, we are increasing the number of virtual interactions and educational events with physicians and ensuring that we have an overall larger presence in the healthcare community. We believe these measures will support our efforts to grow sales of Trogarzo® and EGRIFTA SV® in the U.S.

## **Cost of Sales**

For the three- and nine-month periods ended August 31, 2020, cost of sales was \$6,111,000 and \$20,252,000 compared to \$6,437,000 and \$19,087,000 for the same periods ended August 31, 2019, or Fiscal 2019. Cost of goods sold was \$4,611,000 and \$15,780,000 in the three and nine-month periods of 2020 compared to \$5,215,000 and \$15,371,000 for the same periods in the previous year. The decrease in cost of goods sold was mainly due to lower sales of *EGRIFTA*® which was offset by a higher proportion of Trogarzo® sales. Cost of sales also included the amortization of the other asset of \$1,220,000 and \$3,661,000 for the three and nine-month periods ended August 31, 2020. In addition, cost of sales includes write-downs of \$282,000 and \$676,000 to recognize inventories at net realizable value for the three- and nine-month periods ended August 31, 2020, respectively (\$nil and \$3,000 for the corresponding periods in the prior year), which includes 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.

## **R&D Expenses**

R&D expenses for the three- and nine-month periods ended August 31, 2020 amounted to \$4,183,000 and \$11,224,000 compared to \$2,152,000 and \$6,964,000 in the comparable periods of Fiscal 2019.

The increase was largely due to the development of our oncology platform, 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® launch.

#### Selling Expenses

Selling expenses increased to \$7,025,000 and \$20,327,000 for the three- and nine-month periods ended August 31, 2020 compared to \$6,389,000 and \$18,809,000 for the same periods last year.

The increase was mainly associated with increased activities in Europe.

The amortization of the intangible asset value for the *EGRIFTA®*, *EGRIFTA SV®* and Trogarzo® commercialization rights was also included in selling expenses. As such, we recorded an expense of \$796,000 for the third quarter of Fiscal 2020 compared to \$641,000 for the same quarter last year and \$2,155,000 for the nine-month period ended August 31, 2020 and \$1,770,000 for the same period last year.

## **General and Administrative Expenses**

General and administrative expenses in the three- and nine-month periods ended August 31, 2020 amounted to \$2,699,000 and \$8,975,000 compared to \$1,772,000 and \$5,072,000 reported in the comparable periods of Fiscal 2019.

The increase in general and administrative expenses was mainly associated with business growth, increased activity in Europe, increased administrative expenses as a result of our

US registration and listing of our common shares on NASDAQ in October 2019 and the transition to a new CEO.

#### Finance Income

Finance income, consisting of interest income, for the three- and nine-month periods ended August 31, 2020 was \$32,000 and \$278,000 compared to \$253,000 and \$880,000 in the comparable periods of Fiscal 2019.

Lower finance income was due in large part to a decrease in the average interest rates and a decreased liquidity position in Fiscal 2020 compared to Fiscal 2019.

#### **Finance Costs**

Finance costs for the three- and nine-month periods ended August 31, 2020 were \$831,000 and \$3,548,000 compared to \$1,253,000 and \$3,805,000 in the comparable periods of Fiscal 2019. Finance costs in the third quarter of 2020 and for the nine-month period ended August 31, 2020 represent interest of \$838,000 and \$2,482,000, respectively on the senior convertible notes issued in June 2018, compared to \$847,000 and \$2,493,000 for the same periods last year. Finance costs for the third quarter ended August 31, 2020 were partially offset by a foreign currency gain of \$496,000.

Finance costs also included accretion expense, which was \$485,000 for the third quarter of 2020 and \$1,508,000 for the nine-month period ended August 31, 2020 compared to \$428,000 and \$1,233,000 for the same periods last year.

## **Adjusted EBITDA**

For the reasons noted above, Adjusted EBITDA for the three- and nine- month periods ended August 31, 2020 was \$(3,149,000) and \$(5,676,000) compared to \$1,566,000 and \$3,540,000 in the comparable periods of Fiscal 2019. See "Non-IFRS Financial Measures" below.

#### **Net Loss**

Taking into account the revenue and expense variations described above, we recorded a net loss of \$6,768,000 or \$(0.09) per share in the third quarter of Fiscal 2020 and a net loss of \$17,118,000 or \$(0.22) per share for the nine-month period ended August 31, 2020 compared to a net loss of \$1,639,000 or \$(0.02) per share in the three-month period ended August 31, 2019 and a net loss of \$6,041,000 or \$(0.08) per share compared to the nine-month period ended August 31, 2019.

## **Financial Position**

For the three- and nine-month periods ended August 31, 2020, cash flow generated/(used) in operating activities was \$277,000 and \$(7,648,000) compared to \$5,945,000 and \$(631,000) for the same periods last year.

In the third quarter of Fiscal 2020, changes in operating assets and liabilities had a positive impact on cash flow of \$3,521,000. These changes are mainly due to a decrease in trade and other receivables of \$3,967,000.

In the nine months of Fiscal 2020, changes in operating assets and liabilities negatively affected cash flow by \$1,872,000 compared to \$4,150,000 in the comparable period of fiscal 2019.

As at August 31, 2020, cash, bonds and money market funds amounted to \$26,847,000. Based on management's estimate and current level of operations, we believe that our current liquidity position is sufficient to finance our operations in the foreseeable future.

#### Non-IFRS Financial Measures

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

Adjusted EBITDA is a non-IFRS financial measure. A reconciliation of the Adjusted EBITDA to net profit (loss) is presented in the table below. We use adjusted financial measures to assess our operating performance. Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than IFRS do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. We use Adjusted EBITDA to measure operating performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends in our business, and because we believe it provides meaningful information on our 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, lease inducements and amortization and income taxes. We also exclude the effects of certain non-monetary transactions recorded, such as share-based compensation for the stock option plan 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-month periods ended August 31,		Nine-month periods ended August 31,	
	2020¹	2019	2020¹	2019
	\$	\$	\$	\$
Net loss	(6,768)	(1,639)	(17,118)	(6,041)
Add (deduct):				
Depreciation and amortization	2,189	1,929	6,328	5,565
Lease inducements and amortization	-	5	-	233
Finance costs	831	1,253	3,548	3,805
Finance income	(32)	(253)	(278)	(880)
Share-based compensation	349	271	1,168	855
Write-down of inventories	282	-	676	3
Adjusted EBITDA	(3,149)	1,566	(5,676)	3,540

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. As a result, adjusted EBITDA includes adjustments for additional depreciation related to the right-of-use asset of \$111,000 for the three-month period ended August 31, 2020 and of \$329,000 for the nine-month period of Fiscal 2020, and an accretion expense on lease liabilities, included in finance costs, of \$53,000 and \$162,000 for the three- and nine-month periods respectively ended August 31, 2020.

#### **Conference Call Details**

A conference call and webcast will be held on October 15, 2020 at 8:30 a.m. (ET) to discuss the results. The call will be hosted by Paul Lévesque, President and Chief Executive Officer of Theratechnologies, and other members of the management team.

To access the call, please dial 1-877-223-4471 (North America) or 1-647-788-4922 (International). The conference call will also be webcast live at <a href="https://onlinexperiences.com/Launch/QReg/ShowUUID=3EDEAF73-D2A7-43DB-9EC2-8806F955FECC">https://onlinexperiences.com/Launch/QReg/ShowUUID=3EDEAF73-D2A7-43DB-9EC2-8806F955FECC</a>. An audio replay of the conference call will be available by dialing 1-800-585-8367 (North America) or 1-416-621-4642 (International) and by entering the playback code 2181409.

## **About Theratechnologies**

Theratechnologies (TSX: TH) (NASDAQ: THTX) is a biopharmaceutical company focused on the development and commercialization of innovative therapies addressing unmet medical needs. Further information about Theratechnologies is available on the Company's website at <a href="www.theratech.com">www.theratech.com</a>, on SEDAR at <a href="www.sedar.com">www.sedar.com</a> and on EDGAR at <a href="www.sedar.com">www.sedar.com</a> and <a href="www.sedar.com">w

# **Forward-Looking Information**

This press release contains forward-looking statements and forward-looking information, or, 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", "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 press release include, but are not limited to, statements regarding the progress of our research and development activities, the various timelines to achieve certain milestones or to complete certain activities, including those related to the filing with regulatory agencies of a Phase 3 study protocol, an investigator new drug application, or IND, and the beginning of clinical trials as part of our research and development activities, revenue growth from sales of *EGRIFTA SV*® and Trogarzo®, the securing of an appropriate pricing and widespread reimbursement for Trogarzo® in key European countries, the launch of Trogarzo® in Europe and potential product acquisitions or in-licensing transactions.

Although the forward-looking information contained in this press release 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: the current COVID-19 pandemic will have limited effect on the Company's operations; 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 United States. Canada and the countries of the European Union will not be found to be in violation of applicable laws; the long-term use of EGRIFTA®, EGRIFTA SV® and Trogarzo® will not change their respective current safety profile; no recall or market withdrawal of EGRIFTA®, 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® and Trogarzo® in countries where such products are commercialized; continuous supply of EGRIFTA SV® and Trogarzo® will be available; the Company's relations with third-party suppliers of 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<sup>®</sup> 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; Trogarzo® will be reimbursed in European countries; the FDA will approve the F8 formulation; the FDA and the European regulatory agencies will approve the Phase 3 study protocol for the Corporation's Phase 3 clinical trial to develop tesamorelin for the treatment of NASH in the general population; the Company will succeed in conducting such Phase 3 clinical trial: the Company's research and development activities using peptides derived from its oncology platform will yield positive results allowing for the development of new drug for the treatment of cancer; the data obtained from the Company's market research on the potential market size for the Company's products are accurate; the Company's European infrastructure is adequate to commercialize Trogarzo® in Germany and in other European countries; 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 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 expectations regarding the commercialization of EGRIFTA SV® and Trogarzo®; 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 United States 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® 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; 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 countries of the European Union, together with the level of reimbursement, if at all; the Company's ability and capacity to commercialize Trogarzo® in Germanv and to launch Trogarzo® in other countries of the European Union; the Company's ability to obtain the approval by the FDA of the F8 formulation; the Company's ability to obtain approval from regulatory agencies for its Phase 3 study protocol for the development of tesamorelin in the NASH general population without conducting a Phase 2b or earlier study in such population; the Company's ability to successfully conduct a Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population and the timeline to complete such trial; the Company's capacity to develop its proprietary oncology platform and obtain positive results therefrom; the Company's capacity to acquire or in-licence new products and/or compounds; 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 24, 2020 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, 2020 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 press release and represent our expectations as of that date.

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

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For media inquiries: Denis Boucher Vice President, Communications and Corporate Affairs

# $\frac{communications@the ratech.com}{514\text{-}336\text{-}7800}$

For investor inquiries: Leah Gibson Senior Director, Investor Relations Igibson@theratech.com 617-356-1009