



Theratechnologies Reports Financial Results for the Third Quarter of Fiscal 2021 and Provides Business Update

October 13, 2021

- Q3 FY2021 consolidated sales grow 27% over Q3 FY2020 –

- Ongoing Part A of Phase 1 program evaluating TH1902 for sortilin-expressing cancers indicating better tolerability than docetaxel alone –

MONTREAL, Oct. 13, 2021 (GLOBE NEWSWIRE) -- Theratechnologies Inc. (Theratechnologies, or Company) (TSX: TH) (NASDAQ: THTX), a biopharmaceutical company focused on the development and commercialization of innovative therapies, today reported business highlights and financial results for its third quarter ended August 31, 2021 (Q3 Fiscal 2021).

"We are excited for the progress that has been achieved to date across our R&D and commercial portfolios," said Paul Lévesque, President and Chief Executive Officer at Theratechnologies. "Our Phase 1 program for TH1902 in oncology is progressing well. To date, we have dosed several patients with tumors for which no known effective therapies exist, with some participants receiving more docetaxel, when conjugated to TH1902, than the indicated dose of docetaxel alone. While our MTD has yet to be identified, this outcome is in line with trial expectations and seems to indicate that TH1902 is better tolerated than docetaxel alone."

"In line with our NASH development strategy, we continue to explore opportunities to best execute the Phase 3 clinical trial evaluating tesamorelin, including seeking a partnership for this program," continued Mr. Lévesque. "We remain committed to moving this exciting program through clinical development and toward a potential approval."

Third-Quarter 2021 Revenues (in thousands of U.S. dollars)

	Three Months Ended August 31,		% change
	2021	2020	
EGRIFTA [®] , EGRIFTA SV [®] net sales	11,224	6,864	64%
Trogarzo [®] net sales	6,628	7,185	-8%
Revenue	17,852	14,049	27%

"On the commercial front, we believe our operational improvements in digital marketing and disease education have created a springboard for growth for our approved medicines with sales increasing 27% over the year primarily supported by a 64% increase in EGRIFTA SV[®] sales. We have also made progress toward securing pricing and reimbursement for Trogarzo[®] in several European countries including Italy most recently, which is an integral part of growth for Trogarzo[®] going forward," concluded Mr. Lévesque.

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 nonalcoholic steatohepatitis (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 human immunodeficiency virus type 1 (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, a supplemental Biologics License Application (sBLA) is expected to be filed with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2021. Theratechnologies and TaiMed Biologics Inc. 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® Pricing Agreement in Italy:** Theratechnologies and the Italian Medicines Agency, AIFA, have reached a pricing and reimbursement agreement for Trogarzo®. 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 European Union (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.

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*® revenues, which increased 64% over the same quarter last year. The strong third-quarter performance for *EGRIFTA SV*® 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[®] 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[®] 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 \$277,000 and \$(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 impact 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 enough to finance the Company's operations for at least the next 12 months.

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-month periods ended August 31,		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)

Conference Call Details

A conference call and webcast will be held on October 13, 2021 at 8:30 a.m. (ET) to discuss the Q3 Fiscal 2021 results and recent business highlights. The call will be hosted by Paul Lévesque, President and Chief Executive Officer of Theratechnologies, and other members of the management team.

The conference call can be accessed by dialing 1-844-400-1697 (toll free) or 1-703-736-7400 (International). The conference call will also be accessible via webcast [here](#). An audio replay of the conference call will be available on the same day starting at 11:30 a.m. (ET) until October 20, 2021, by dialing 1-855-859-2056 (North America) or 1-404-537-3406 (International) and by entering the access code: 2420948. An archived webcast will also be available on the Company's Investor Relations website under '[Past Events](#)'.

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 www.theratech.com, on SEDAR at www.sedar.com and on EDGAR at www.sec.gov

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", "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 press release 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 an sBLA with the FDA and the beginning of the screening of patients for the IM study, and the growth of our revenues from sales of *EGRIFTA SV*[®] and Trogarzo[®].

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 adverse effect on the Company's operations; sales of *EGRIFTA SV*[®] and Trogarzo[®] in the United States will increase over time; the Company's commercial practices in the United States and the countries of the European Union 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 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*[®] 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; Trogarzo[®] will be reimbursed in key European countries; the FDA will approve the IV Push mode of administration of Trogarzo[®]; the Company will succeed in finding a partner or securing additional funding to initiate its Phase 3 clinical trial in NASH; the Company will be successful in finding the MTD for TH1902 in its Phase 1 clinical trial; the Company will be able to recruit patients to conduct its IM study using Trogarzo[®]; the Company's European infrastructure is adequate to commercialize Trogarzo[®] in Europe; 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 ability and capacity to grow the sales of *EGRIFTA SV*[®] and Trogarzo[®] successfully in the United States and Trogarzo[®] in Europe; the

Company's capacity to meet supply and demand for its products; the market acceptance of *EGRIFTA SV*[®] and Trogarzo[®] in the United States and of Trogarzo[®] 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 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 successfully conduct its Phase 3 clinical trial using tesamorelin for the treatment of NASH in the general population and its Phase 1 clinical trial using TH1902 in various types of cancer and delays that may occur in the timelines to complete such trials; 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.

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 www.sec.gov as an exhibit to our report on Form 40-F dated February 25, 2021 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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