



Theratechnologies Reports Financial Results for the Second Quarter of Fiscal 2021 and Provides Update on Its Planned Phase 3 Clinical Trial in NASH

July 15, 2021

MONTREAL, July 15, 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 financial results for the second quarter ended May 31, 2021 (Q2 Fiscal 2021) and provided an update on its planned Phase 3 clinical trial evaluating tesamorelin for the treatment of nonalcoholic steatohepatitis (NASH).

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

	Three Months Ended		% change
	May 31, 2021	May 31, 2020	
EGRIFTA® , EGRIFTA SV® net sales	10,344	9,269	12%
Trogarzo® net sales	7,443	7,893	-6%
Revenue	17,787	17,162	4%

The Company also announced that discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) regarding its proposed trial design and protocol for its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH are complete. In addition, the Company has initiated a search for a potential partner to help launch the program.

"The first half of 2021 has been marked by progress across our R&D pipeline of novel compounds. Our Phase 1 clinical trial of TH1902 for the treatment of sortilin-expressing cancers progressed as planned during the quarter and we believe that we have developed a targeted peptide-drug conjugate that may potentially transform the way cancer is treated. In NASH, we concluded regulatory discussions in the U.S. and EU and now have a ready-to-proceed Phase 3 clinical trial design," said Paul Lévesque, President and Chief Executive Officer, Theratechnologies.

Update on Phase 3 clinical trial evaluating tesamorelin in NASH

- Discussions with the FDA and the EMA on the trial design are complete.
- The Phase 3 clinical trial will include participants in the U.S. and Europe.
- The Phase 3 clinical trial will be a multicenter, double-blind, placebo-controlled two-part study to evaluate the safety and efficacy of tesamorelin in liver-biopsy confirmed patients with NAS score of at least 4 and stage 2 or 3 fibrosis.
- The Phase 3 clinical trial will include a futility analysis that will be performed after approximately 400 patients have completed 18 months of treatment and have received a second liver biopsy.
- A supplemental Biologics Licence Application (sBLA) is expected to be filed after approximately 1,100 patients, including approximately 75 to 100 people living with HIV, have completed 18 months of treatment and have received a second liver biopsy.
- The primary endpoint will be NASH resolution and no worsening of fibrosis compared to placebo after 18 months as per FDA guidelines.
- Following potential approval, an additional 1,800 patients are expected to be enrolled, to continue measuring clinical outcomes over a period of five years.
- Based on regulatory discussions, the final Phase 3 clinical trial design will result in higher costs than what the Company had previously estimated.
- As a result of the total cost of the Phase 3 clinical trial, the Company is now evaluating its options to best execute its late-stage development program, including seeking a potential partner.
- An external U.S.-based biopharma advisory firm has been retained to assist in identifying a potential partner.
- Partner identification and negotiations will alter the initiation of the Phase 3 clinical trial that was previously expected to begin in the third quarter of calendar year 2021.

"Given the additional resources required to conduct the Phase 3 clinical trial in NASH, we are evaluating opportunities that will allow us to most

effectively execute this program, including seeking a potential partner for late-stage development. While this will alter the planned timing of the Phase 3 clinical trial initiation, finding a strong partner could potentially add additional resources and capabilities that will be of great value as we advance this exciting program toward a potential approval," added Mr. Lévesque.

Update on SORT1+ Technology in oncology

- **New preclinical findings for TH1902 in metastatic cancers:** On June 21, 2021, the Company announced new preclinical *in vivo* findings on the anti-metastatic effect and tolerability of its novel investigational proprietary peptide-drug conjugate (PDC), TH1902. These results demonstrated that TH1902 had better anti-metastatic activity when compared to docetaxel alone when administered at an equimolar concentration in a lung metastasis cancer model expressing the sortilin (SORT1) receptor. In conjunction with the announcement, the Company hosted a webinar on its SORT1+ Technology™ featuring Richard Bélineau, Ph.D., Université du Québec à Montréal, who discussed the science of receptor-mediated cancer therapy and the discovery of sortilin as a novel target in cancer treatment. The archived webcast event can be accessed on the Theratechnologies website under '[Past Events](#)'.
- **Phase 1 clinical trial of TH1902 for the treatment of sortilin-expressing cancers progressing:** Following fast track designation from the FDA, the Phase 1 clinical trial evaluating TH1902 in sortilin-expressing solid tumors is progressing as planned. At this time, the Company expects to obtain interim safety and efficacy information from the Phase 1 Part A study in the fourth quarter of calendar year 2021.

Key talent recruitment

- **New member of Board of Directors:** The Company welcomed Frank Holler as a new independent member to its Board of Directors. Mr. Holler brings extensive knowledge and experience in North American capital markets and has a well-established track record in the biotechnology industry.
- **Human Resources Leader:** Theratechnologies announced that Mr. André Dupras joined the Company as Vice President, Human Resources. Mr. Dupras brings more than 25 years of experience in talent recruitment and development to the Company, and he will play a pivotal role in building and retaining an industry-leading team to support Theratechnologies' commercial and R&D growth.
- **Business development management:** The Company welcomed Daniel Böck as Senior Director of Business and Corporate Development. Mr. Böck will lead efforts to support the Company's commercial and R&D strategic partnerships and alliances within the life sciences industry.

Second-Quarter Fiscal 2021 Financial Results

Revenue

For the three- and six-month periods ended May 31, 2021 consolidated revenue was \$17,787,000 and \$33,217,000, compared to \$17,162,000 and \$32,881,000 for the same periods ended May 31, 2020, representing a year-over-year increase of 4% and 1%, respectively.

For the second quarter of fiscal 2021, net sales of *EGRIFTA SV®* were \$10,344,000 compared to \$9,269,000 in the second quarter of fiscal 2020, representing an increase of 12% year-over-year. Net sales for the six-month period ended May 31, 2021 were \$19,032,000 compared to \$17,784,000 in the same period in 2020. While unit sales of *EGRIFTA SV®* were relatively flat compared to the same period in 2020, net sales increased due to a higher selling price and lower rebates to government payers.

Trogarzo® net sales in the second quarter of fiscal 2021 amounted to \$7,443,000 compared to \$7,893,000 for the same quarter of 2020, representing a decrease of 6% year-over-year. For the six-month period ended May 31, 2021, Trogarzo® net sales were \$14,185,000 compared to \$15,097,000 in the same period in 2020. Lower sales of Trogarzo® were a result of a decrease in unit sales, the effect of the ongoing COVID-19 pandemic resulting in the difficulty for patients to visit health care facilities to meet with physicians and obtain their intravenous infusion, competitive pressures and higher rebates, and were partially offset by a higher selling price. Net sales of Trogarzo® in the comparative period were positively impacted by unusually large orders by pharmacies at the beginning of the COVID-19 pandemic in March 2020.

Cost of Sales

For the three- and six-months ended May 31, 2021, cost of sales decreased to \$5,934,000 and \$11,345,000 compared to \$7,380,000 and \$14,141,000 for the same periods in fiscal 2020, primarily due to the decrease in cost of goods sold. Cost of goods sold was \$4,714,000 and \$8,904,000 in the three- and six-month periods of 2021 compared to \$5,769,000 and \$11,169,000 for the same periods in 2020.

The decrease in cost of goods sold was mainly due to a combination of lower Trogarzo® sales, a lower cost for Trogarzo® and a lower cost of *EGRIFTA SV®* compared to *EGRIFTA®*. Cost of sales also included the amortization of the other asset of \$1,220,000 in both Q2 fiscal 2021 and Q2 fiscal 2020, and of \$2,441,000 for the six-month periods of 2021 and 2020.

R&D Expenses

R&D expenses in the three- and six-month periods ended May 31, 2021 amounted to \$6,417,000 and \$11,300,000 compared to \$3,622,000 and \$7,041,000 in the comparable periods of fiscal 2020.

The increases in both periods were largely due to higher spending related to the initiation of the Phase 1 trial in oncology and spending related to the NASH program (including spending on the new F8 formulation of tesamorelin), increased spending in medical and patient education, and increased

medical affairs spending in Europe.

Selling Expenses

Selling expenses were relatively stable and amounted to \$6,901,000 and \$13,059,000 for the three- and six-month periods ended May 31, 2021 compared to \$6,941,000 and \$13,302,000 for the same periods last year.

General and Administrative Expenses

General and administrative expenses in the three- and six-month periods ended May 31, 2021 amounted to \$3,884,000 and \$7,446,000 compared to \$3,706,000 and \$6,276,000 reported in the comparable periods of fiscal 2020. The increase in General and Administrative expenses is largely due to increased overall business activities in 2021 compared to 2020.

Finance Income

Finance income, consisting of interest income and foreign exchange gains, for the three- and six-month periods ended May 31, 2021 was \$432,000 and \$481,000 compared to \$80,000 and \$246,000 in the comparable periods of fiscal 2020. Interest income for the three- and six-month periods ended May 31, 2021 was \$54,000 and \$79,000, respectively, compared to \$80,000 and \$246,000 in the comparable periods of fiscal 2020. Lower interest income was due in large part to a decreased liquidity position and a decrease in interest rates. We also recorded a foreign exchange gain of \$378,000 and \$402,000 in the three- and six-month periods ended May 31, 2021.

Finance Costs

Finance costs for the three- and six-month periods ended May 31, 2021 were \$1,455,000 and \$2,836,000 compared to \$1,399,000 and \$2,717,000 in the comparable periods of fiscal 2020. Finance costs in the three- and six-month periods ended May 31, 2021 mostly represent interest of \$833,000 and \$1,635,000, respectively on the senior convertible notes issued in June 2019, compared to \$842,000 and \$1,644,000 for the same periods last year.

Adjusted EBITDA

Adjusted EBITDA for the three- and six-month periods ended May 31, 2021 was \$(2,616,000) and \$(4,437,000) compared to \$(1,533,000) and \$(2,527,000) 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, net loss for the second quarter of fiscal 2021 was \$6,392,000, or \$(0.07) per share, and a net loss of \$12,314,000, or \$(0.14) per share, for the six-month period ended May 31, 2021 compared to a net loss of \$5,806,000, or \$(0.08) per share, in the three months ended May 31, 2020 and a net loss of \$10,350,000, or \$(0.13) per share, compared to the six-month period ended May 31, 2020.

Financial Position

At period-end May 31, 2021, the Company had \$56,714,000 in cash, bonds and money market funds, and remained virtually unchanged from February 28, 2021. At this time, the current cash, bonds and money market funds are sufficient to fund the Company's operations to meet its current obligations for at least the next twelve months.

For the three-month period ended May 31, 2021, operating activities used cash of \$716,000 compared to \$3,100,000 in the comparable period of fiscal 2020, primarily due to the positive impact of changes in operating assets and liabilities, partially offset by the increased loss in 2021.

In the second quarter of fiscal 2021, changes in operating assets and liabilities had a positive impact on cash flow of \$2,096,000 (2020-negative impact of \$1,561,000). These changes were mostly due to a positive impact from accounts payables and accrued liabilities, provisions, trade and other receivables as well as prepaid expenses and deposits and were negatively impacted by inventories.

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 May 31,		Six-month periods ended May 31,	
	2021	2020	2021	2020
Net loss	(6,392)	(5,806)	(12,314)	(10,350)
Add (deduct):				
Depreciation and amortization	2,185	2,109	4,370	4,139

Finance costs	1,455	1,399	2,836	2,717
Finance income	(432)	(80)	(481)	(246)
Share-based compensation	548	454	1,126	819
Income taxes	20	-	26	-
Write-down of inventories	-	391	-	394
Adjusted EBITDA	(2,616)	(1,533)	(4,437)	(2,527)

Conference Call Details

A conference call and webcast will be held on July 15, 2021 at 8:30 a.m. (ET) to discuss the second quarter 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 July 22, 2021, by dialing 1-855-859-2056 (North America) or 1-404-537-3406 (International) and by entering the access code: 7943345. 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", "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 timelines associated to the Phase 1 clinical trial using TH1902, the filing of an sBLA evaluating tesamorelin for the treatment of NASH with the FDA, the potential approval by regulatory agencies of tesamorelin for the treatment of NASH, the development of a multi-dose pen injector using the F8 formulation, the growth of our revenues, the value generated from our commercial and research and development activities, and the potential benefits to be derived from the addition of a partner for our Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH.

Although the Forward-Looking Statements contained in this press release are based upon what the Company believes are reasonable assumptions in light of the information currently available, investors are cautioned against placing undue reliance on these statements since actual results may vary from the Forward-Looking Statements. Certain assumptions made in preparing the Forward-Looking Statements include that: the current COVID-19 pandemic will have limited adverse effect on the Company's operations and its business plan; sales of *EGRIFTA SV®* 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 relationships 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 F8 formulation and the multi-dose pen injector; the Company will succeed in pursuing the conduct of its Phase 1 clinical trial using TH1902; the Company will be able to secure additional resources to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH; research and development activities using peptides derived from its oncology platform will yield positive results allowing for the development of new drugs for the treatment of cancer; the Company's European infrastructure is adequate to commercialize *Trogarzo®* in Germany and in other European countries; and the Company's business plan will not be substantially modified.

In addition, the Company assumes that the totality of evidence and data resulting from the conduct of its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH will demonstrate substantial evidence of efficacy and will be highly persuasive to the FDA given that the Company (i) has not conducted a Phase 2 clinical trial evaluating tesamorelin in the general population suffering from NASH prior to proceeding with its Phase 3 clinical trial as the FDA and EMA recommended; and (ii) is conducting one Phase 3 clinical trial as opposed to two. The Company also assumes that it will be successful in obtaining approval from the EMA for tesamorelin in the treatment of NASH based on the results obtained from its Phase 3 clinical trial despite the Company not following the current guidelines issued by the EMA for the approval of a drug for the treatment of NASH, which guidelines provide for both (i) NASH resolution and no worsening of fibrosis and (ii) improvement of fibrosis by one stage without worsening of NASH as a primary endpoint, whereas for the purposes of meeting the FDA's primary endpoint, only NASH resolution and no worsening of fibrosis will be relevant.

Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond Theratechnologies' control that could cause actual results to differ materially from those that are disclosed in or implied by such Forward-Looking Statements. These risks and uncertainties include, but are not limited to, those related to or arising from: the adverse impact of the COVID-19 pandemic on (a) the Company's sales efforts and sales initiatives, (b) the capacity of the Company's suppliers to meet their obligations vis-à-vis the Company, (c) the Company's research and development activities, (d) the health of the Company's employees and its capacity to rely on its resources, as well as (e) global trade; the Company's ability and capacity to grow the sales of *EGRIFTA SV®* 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 *EGR/IFTA 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 Germany and to launch Trogarzo® in other key countries of the European Union; the Company's ability to obtain the approval by the FDA of the F8 formulation and the multi-dose pen injector; the Company's ability to secure additional resources to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH; the Company's ability to successfully conduct its Phase 3 clinical trial using tesamorelin for the treatment of NASH and its Phase 1 clinical trial using TH1902 in various types of cancer; the Company's ability to find a partner on terms satisfactory to the Company; the Company's capacity to acquire or in-license new products and/or compounds; the discovery of a cure for HIV; the Company's expectations regarding its financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and the Company's estimates regarding its capital requirements.

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

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