



Theratechnologies Reports First Quarter 2021 Financial Results and Recent Business Highlights

April 14, 2021

MONTREAL, April 14, 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 the first quarter ended February 28, 2021 (Q1 Fiscal 2021).

"Theratechnologies is at a unique point in its evolution, and we have a tremendous opportunity ahead of us," said Paul Levesque, President and Chief Executive Officer at Theratechnologies. "We are particularly pleased with the swift advancement of our Phase 1 oncology program, which has dosed its first patient, and the continued progress we have made toward advancing our Phase 3 trial in NASH.

"We believe we are well-positioned for growth when we begin to emerge from the COVID-19 pandemic. Inline with these efforts is our continued focus on strengthening our business with the addition of key talent and resources. While first-quarter revenues were relatively flat year-over-year, we believe that we have aligned our organization to provide an optimal landscape to further validate and drive value for our commercial and R&D opportunities," concluded Mr. Levesque.

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

	Three Months Ended February,		% change
	28, 2021	29, 2020	
EGRIFTA [®] , EGRIFTA SV [®] net sales	8,688	8,515	2.0
Trogarzo [®] net sales	6,742	7,204	(6.4)
Revenue	15,430	15,719	(1.8)

Recent Highlights and Program Updates

- Additional data for TH1902 at AACR support broad applicability:** On April 10, 2021, new positive preclinical data on TH1902 were presented in two posters at the American Association for Cancer Research (AACR). These data demonstrated sustained tumor regression, better anti-tumor activity and tolerability with TH1902 compared to docetaxel alone in all cancer types studied, namely melanoma, pancreatic, ovarian, endometrial, colorectal and triple-negative breast cancers. The anti-tumor effect of TH1902 also persisted longer post-treatment than with docetaxel alone. Furthermore, these data showed that in all cancers studied, neutropenia was absent after six consecutive treatments with TH1902 at an equivalent dose of the maximum tolerated dose (MTD) of docetaxel, whereas a single treatment of docetaxel strongly reduced neutrophil counts. These new data further support the development of TH1902 for the potential treatment in various cancers as well as highlight its broad applicability in potentially treating all sortilin-expressing solid tumors that are refractory to standard therapy.
- Strategic additions to commercial organization:** On March 29, 2021, Theratechnologies announced the addition of two new senior leaders to support the Company's commercial and pipeline operations. John Leasure joined the Company as the Global Commercial Officer and Peter Kowal joined as Vice President, HIV-U.S. Commercial Operations. John and Peter bring to Theratechnologies sales and marketing expertise in HIV, endocrinology and oncology.
- Phase 1 trial of TH1902 for the treatment of cancer initiated:** In March 2021, the Company initiated a Phase 1 clinical trial evaluating TH1902, its investigational lead peptide-drug conjugate (PDC), for the treatment of sortilin positive (SORT1+) solid tumors. The Phase 1 clinical trial includes a dose-escalating part 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. Once the MTD is determined, it is planned that a total of 40 additional patients will be enrolled to evaluate the potential anti-tumor activity of TH1902 in patients with endometrial, ovarian, colorectal, pancreatic and triple negative breast cancers. The Company received fast track designation from the U.S. Food and Drug Administration (FDA) for TH1902 in February 2021.
- Planned Phase 3 trial of tesamorelin for the treatment of nonalcoholic steatohepatitis (NASH):** The initiation of a Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH is on track to begin in the third quarter of calendar year 2021. Per the FDA's recommendation, the Company has confirmed a date to meet with the agency and discuss the proposed trial design and protocol. The Company received a "Study May Proceed" letter for the Phase 3 trial from the FDA in January 2021 and has retained the services of a global, large-scale contract research organization (CRO) with experience in implementing large and late-stage clinical trials to assist with the execution of the trial.

- **Intellectual property position strengthened in NASH:** On March 16, 2021, the U.S. Patent and Trademark Office (USPTO) issued a new U.S. Patent, No. 10,946,073, covering among other things, a method for preventing or delaying the onset of liver fibrosis or reducing liver fibrosis or its progression in a subject suffering from nonalcoholic fatty liver disease (NAFLD) or NASH, wherein said subject has a hepatic fat fraction of at least about 10%, through the administration of an effective amount of tesamorelin. This patent is scheduled to expire in 2040 and adds to the Company's strong intellectual property position in NASH. Theratechnologies has an exclusive license with Massachusetts General Hospital (MGH) to this patent. Combined with previously announced patents, the Company is well-positioned in the development and potential commercialization of tesamorelin for the treatment of NASH and other liver diseases.
- **Lifecycle management of tesamorelin for the treatment of HIV:** The Company has developed a new formulation of tesamorelin known as the "F8 formulation". The F8 formulation has a number of significant improvements over our current F4 formulation, which is currently commercialized as *EGIRFTA SV*[®] for the treatment of HIV-associated lipodystrophy. The F8 formulation is twice as concentrated as the F4 formulation 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. A multi-dose pen injector is also being developed for the administration of the F8 formulation. The Company plans to file an sBLA for the F8 formulation and multi-dose pen injector in early 2022 for the treatment of HIV-associated lipodystrophy and plans to use the F8 formulation for its planned Phase 3 clinical trial in NASH.
- **Lifecycle management of ibalizumab for the treatment of HIV:** Enrollment is complete in a study evaluating an intravenous (IV) push administration of Trogarzo[®] for the treatment of human immunodeficiency virus type 1 (HIV-1) infection. The study is evaluating the drug levels of Trogarzo[®] using the IV push administration versus the approved IV infusion method and is expected to be completed in the third quarter of 2021. The IV study is being conducted and funded by the Company's partner, TaiMed Biologics (TaiMed). Theratechnologies and TaiMed are also planning to evaluate an intramuscular (IM) method of administration for Trogarzo[®] and the study will be conducted and funded by Theratechnologies.

First-Quarter Fiscal 2021 Financial Results

Revenue

Consolidated revenue for the three-month period ended February 28, 2021 was \$15,430,000 compared to \$15,719,000 for the same period ended February 29, 2020.

For the first quarter of fiscal 2021, net sales of *EGRIFTA SV*[®] reached \$8,688,000 compared to \$8,515,000 in the first quarter of the prior year, representing an increase of 2.0% over the first quarter of 2020, which included sales of both *EGRIFTA SV*[®] and *EGRIFTA*[®].

In the first quarter of fiscal 2021, Trogarzo[®] net sales amounted to \$6,742,000 compared to \$7,204,000 for the same quarter of 2020, representing a decrease of 6.4%. Lower sales of Trogarzo[®] were a result of a decrease in unit sales, and higher rebates, which were offset by a higher selling price.

Cost of Sales

For the three months ended February 28, 2021, cost of sales was \$5,411,000 compared to \$6,761,000 for the same quarter in fiscal 2020, primarily due to the lower cost of goods sold. Cost of goods sold was \$4,190,000 in the first quarter of 2021 compared to \$5,400,000 for the same quarter the previous year. 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 \$1,221,000 in both Q1 fiscal 2021 and Q1 fiscal 2020.

R&D Expenses

R&D expenses amounted to \$4,883,000 in the three-month period ended February 28, 2021 compared to \$3,419,000 for the same period in 2020. The increase was largely due to higher spending in our oncology and NASH programs, increased spending in medical and patient education, as well as increased medical affairs spending in Europe.

Selling Expenses

Selling expenses amounted to \$6,158,000 for the first quarter of 2021 compared to \$6,361,000 for the same three-month period last year, reflecting a realignment of spending as a result of a lower headcount in our salesforce.

The amortization of the intangible asset value for the *EGRIFTA*[®] and Trogarzo[®] commercialization rights is also included in selling and market development expenses. As such, we recorded an expense of \$795,000 for the first quarter of fiscal 2021 compared to \$642,000 for the same quarter last year.

General and Administrative Expenses

General and administrative expenses amounted to \$3,562,000 for the three months ended February 28, 2021 compared to \$2,570,000 for the first quarter of 2020. The increase in general and administrative expenses was mainly associated with an overall increase in business activities and increased activity in Europe.

Finance Income

Finance income, consisting of interest income, amounted to \$25,000 during the first quarter of 2021 compared to \$166,000 in the first quarter of last year. Lower finance income was due in large part to a decreased liquidity position and a decrease in interest rates.

Finance Costs

Finance costs for the three months ended February 28, 2021 were \$1,357,000 compared to \$1,318,000 for the comparable period of 2020. Finance costs in the first quarter of 2021 and 2020 included interest of \$802,000 on the senior convertible notes issued in June 2018.

Finance costs also included accretion expense of \$581,000, compared to \$502,000 for the comparable period in 2020.

Adjusted EBITDA

Adjusted EBITDA was \$(1,821,000) for the first quarter of fiscal 2021 compared to \$(994,000) for the same period of 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 \$5,922,000 or \$0.07 per share in the first three months of fiscal 2021 compared to a net loss of \$4,544,000 or \$0.06 per share for the same period last year.

Financial Position

We ended the first quarter of fiscal 2021 with \$56,716,000 in cash, bonds and money market funds.

During the first quarter of fiscal 2021, the Company completed a public offering for the sale and issuance of 16,727,900 units of the Company for a gross cash consideration of \$46,002,000 including the full exercise of the over-allotment option. Share issue costs amounted to \$3,385,000 resulting in net proceeds of \$42,617,000.

Each unit is comprised of one common share of the Company and one-half of one common share purchase warrant of the Company (each whole warrant, a “Warrant”). Each Warrant entitles the holder to purchase one common share of the Company at an exercise price of \$3.18 until January 19, 2024.

Our current cash, bond and money market funds will be sufficient to fund the Company’s operations for the foreseeable future.

For the three-month period ended February 28, 2021, operating activities used \$5,228,000 compared to \$4,825,000 in the comparable period of fiscal 2020, primarily due to the increased loss in 2021, partially offset by a smaller negative impact of changes in operating assets and liabilities.

In the first quarter of fiscal 2021, changes in operating assets and liabilities had a negative impact on cash flow of \$3,332,000 (2020-negative impact of \$3,832,000). These changes included a negative impact from accounts payables and accrued liabilities and inventories, and were offset by a decrease in trade and other receivables and an increase in provisions.

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 February,	
	28, 2021	29, 2020
Net loss	(5,922)	(4,544)
Add (deduct):		
Depreciation and amortization	2,185	2,030
Finance costs	1,357	1,318
Finance income	(25)	(166)
Income taxes	6	-
Share-based compensation	578	365
Write-down of inventories	-	3
Adjusted EBITDA	(1,821)	(994)

Conference Call Details

A conference call and webcast will be held on April 14, 2021 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.

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 at <https://edge.media-server.com/mmc/p/yiqvqmdq>. Audio replay of the conference call will be available on the same day

starting at 11:30 a.m. (ET) until April 21, 2021, by dialing 1-855-859-2056 (North America) or 1-404-537-3406 (International) and by entering the access code: 7982427. The audio replay is also available until April 14, 2022 on <https://edge.media-server.com/mmc/p/yiqvgmdq>.

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 those clinical trials, the development of a multi-dose pen injector using the F8 formulation, the growth of our revenues and the value generated from our commercial and research and development activities.

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 F8 formulation and the multi-dose pen injector; the FDA and the European regulatory agencies will approve a common design for the Phase 3 clinical trial studying tesamorelin for the treatment of NASH in the general population; the Company will succeed in conducting such Phase 3 clinical trial and its Phase 1 clinical trial using TH1902 in various types of cancer; the Company's 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.

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 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 obtain an agreement with the FDA for its Phase 3 clinical trial design studying tesamorelin in the NASH general population; 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.

For media inquiries:

Denis Boucher

Vice President, Communications and Corporate Affairs

communications@theratech.com

514-336-7800

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