



Theratechnologies Reports Second Quarter and First Half Fiscal 2022 Financial Results and Provides Business Update

July 14, 2022

- Q2 2022 Consolidated Sales Growth of 8.3% to \$19.3 million
- Year-to-Date Revenue Growth of 13.9% or \$37.8 million
- Year-to-Date EGRIFTA SV[®] Revenue Growth of 21.5%
- TH1902 Basket Trial Initiated
- Binding Commitment for a Non-Dilutive Term Loan up to \$100 Million
- FY2022 Revenue Guidance \$79 - \$82 million

MONTREAL, July 14, 2022 (GLOBE NEWSWIRE) -- **Theratechnologies Inc. (Theratechnologies, or the 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 second quarter and first half of fiscal year 2022 ended May 31, 2022. All figures are in U.S. dollars unless otherwise stated.

"This past quarter, we executed on strategic plans including our decision to focus our sales efforts on the United States. We also initiated the very promising TH1902 Basket Trial, while we diligently worked on improving our financial position. We are pleased with the results of these efforts as our commercial businesses remain on track to meet our fiscal 2022 guidance which now reflects the shift in focus. Onboarding of our dedicated commercial field force in the United States has now been fully completed. Our capital allocation framework continues to prudently support our investment thesis and ability to generate long term value," said Paul Lévesque, President and Chief Executive Officer. "Despite the challenging environment of the biotech capital markets, we have successfully extended the financial runway to support Theratechnologies' strategic commercial and development activities. The recently announced transaction with Marathon Asset Management will allow us to rapidly retire more than half of the Company's convertible notes due in 2023 and has significantly strengthened our balance sheet," concluded Mr. Lévesque.

Revenue Summary for Second Quarter and First Half Fiscal 2022

(in thousands of U.S. dollars)

	Three months ended May 31		% change	Six months ended May 31		% change
	2022	2021		2022	2021	
EGRIFTA [®] , EGRIFTA SV [®] net sales	11,416	10,344	10.4%	23,120	19,032	21.5%
Trogarzo [®] net sales	7,852	7,443	5.5%	14,705	14,185	3.7%
Revenue	19,268	17,787	8.3%	37,825	33,217	13.9%

RECENT HIGHLIGHTS AND PROGRAM UPDATES

Pipeline Updates

TH1902 Basket Trial Update:

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

A total of 18 heavily pre-treated patients, who received an average of 8 prior cancer treatments, were enrolled in the dose escalation portion of the study. Two of those patients remain on treatment. Following the safety observations at 420 mg/m² including grade 3 neuropathy, grade 4 neutropenia, grade 3 ocular changes (visual acuity, keratitis and ocular surface dryness) and grade 2 skin toxicities (rash, pruritis and inflammation), the dose of TH1902 was decreased to 300 mg/m² for the next dose level and was expanded to a total of 6 patients. No Dose Limiting Toxicities were observed during the first cycle, therefore, the dose of 300 mg/m² was selected for continuation of the basket part of the study. In addition, the levels of free docetaxel are low, at only 11% of those observed at docetaxel treatment dosage of 75 mg/m². Thus far 300 mg/m² appears to be a well-tolerated dose level, which continues to be evaluated in the larger basket portion of the TH1902 study.

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

- Confirmed partial response in one prostate cancer patient with 53% overall reduction in target lesions after three cycles of TH1902 at 300 mg/m², PSA continued to progress.
- Stabilized disease observed in a prostate cancer patient with measurable reduction in target lesion sizes (single digit percentages), including one PSA response. The patient was treated with mixed cycles of TH1902 from 420 mg/m² to 300

mg/m².

- Stabilized disease observed in an endometrial cancer patient with measurable reduction in target lesion sizes (single digit percentages). Notably, she received a total of 11 cycles. Her dose was escalated from 60 mg/m² to 360 mg/m².

In an effort to optimize and ensure success of this clinical research program, the company has enrolled six active trial sites across the United States, including Cedars-Sinai in California, Karmanos Cancer Institute and START Midwest in Michigan, Pennsylvania Cancer Specialists Research Centre, Mary Crowley Cancer Research and University of Texas MD Anderson Cancer Center, both in Texas.

TH1902 China Out-licensing and Partnership Strategy: Out-licensing development and commercialization rights for TH1902 in Greater China continues. Discussions are moving forward with an expanding number of potential partners.

EGRIFTA SV[®] Human Factors Study: Following complaints received from patients relating to the reconstitution of EGRIFTA SV[®] after its launch in 2019, we have submitted an amendment to the Instructions For Use (“IFU”)s included in the EGRIFTA SV[®] Patient Information in March 2021, and per the timelines set forth in the regulation, we implemented these changes, which included amended IFUs. We also provided patients with detailed training through our call center, Thera Patient Support[®], related to that change and the number of complaints have since been reduced to almost nil. The FDA responded to our amendment with a Complete Response Letter, asking the Company to carry out a Human Factors Study (“HFS”) to ensure that patients reconstitute the product in the proper manner. We have recently initiated such study, which we believe will be carried out to the FDA’s satisfaction, within their imposed timeframe of one year.

F8 sBLA filing: As previously announced, our intention was to file a supplemental Biologic License Application (“sBLA”) for the F8 formulation by the end of the first quarter of calendar 2022. Currently, the issue around the global supply for bacteriostatic water for injection (“BWFI”) required for the reconstitution of the F8 formulation, has not been resolved. As per the FDA website, the estimated recovery of supply of BWFI is scheduled for October 2022.

In addition, since the FDA has asked us to perform an HFS for the reconstitution of EGRIFTA SV[®], we have proactively decided to carry out such a study before filing the sBLA for the F8 formulation. As such, we will be filing the sBLA for the F8 once we have consistent sourcing of the BWFI and completed the HFS.

NASH: After internal discussions and further risk assessments on this program, in order to further de-risk the Phase 3 trial, the Company has submitted an amended protocol to the FDA. The new protocol will include a Phase 2b/3 seamless study design where the first 350 or so patients’ data will be analyzed by a data monitoring committee to assess the efficacy of tesamorelin on a smaller subset of patients. This amended protocol will allow us to generate hard end point data on NAS score and fibrosis. A decision will then be made whether to continue the study until full number of patients (1,094) have completed 18 months of treatment. The FDA has agreed to this redesigned protocol.

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

VAMOS Study: The Company continues its study titled Visceral Adiposity Measurement and Observation Study (“VAMOS”) to reflect our commitment to improve the health outcomes of people living with HIV. VAMOS is an epidemiologic cross-sectional study to answer the unknown associations between visceral fat and cardiovascular disease risk, liver fat, liver fibrosis, pericardial fat, and muscle fat in HIV patients.

These associations are being measured across a diversity of weights, BMIs, genders, and races so that the impact of visceral fat can be understood with external validity to the results. Additionally, the performance of anthropometric measurements like waist circumference and hip circumference are being assessed in a modern HIV population. The aim of the study is two-fold: (1) to determine the utility of WC’s ability to predict cardiovascular risk scores, liver fat, liver fibrosis, and abnormal glucose homeostasis across the full VAMOS population and subgroups; and (2) to identify common clinical data points in today’s standard of care that can be used to assess a patient’s risk of having excess visceral fat. The VAMOS study results are expected to direct clinicians on why and which patients in their practice should be screened for excess visceral fat and treatment.

Trogarzo[®] Lifecycle Management: An sBLA was filed with the FDA in the fourth quarter of 2021 for the Company’s Intravenous (“IV”) Push mode of administration of Trogarzo[®] for the treatment of human immunodeficiency virus type 1 (“HIV-1”). The FDA has accepted our filing and has provided a target action date of October 3, 2022, in accordance with the Prescription Drug User Fee Act (“PDUFA”). Theratechnologies and TaiMed are also evaluating an intramuscular (“IM”) mode of administration for Trogarzo[®] within the TMB-302 study. This trial is now fully enrolled, and we expect completion of the study in the second half of 2022.

Corporate and Commercial Updates

Binding Commitment for a Non-Dilutive Term Loan of up to \$100 Million: On July 13, 2022, the Company announced it received a binding commitment letter with respect to a non-dilutive term loan with Marathon Asset Management for up to \$100 million. The term loan will make it possible to buy back and cancel \$30 million principal amount of convertible notes due June 2023, through private agreements with certain US noteholders.

Commercialization Activities Focused on the United States: The Company has decided to focus its commercialization activities in the United States and, as a result, will cease its Trogarzo[®] commercialization operations in Europe. A notice of termination was sent to TaiMed Biologics Inc. (“TaiMed”) and will return the European commercialization rights to Trogarzo[®] to TaiMed by the end of October 2022.

CQDM provides new cancer research grant: The CQDM – a Quebec biopharmaceutical research consortium - has provided a new cancer research grant to validate the anti-metastatic potential of TH1902. The CQDM together with the Quebec Breast Cancer Foundation and Mitacs announced close to 1 million Canadian dollars for a new research project at l’Université du Québec à Montréal focused on several metastatic cancer models. This public-private partnership complements Theratechnologies’ annual investment in the development of our targeted oncology platform in breast cancer and could increase the spectrum of cancer patients who might ultimately benefit from this new therapy. This new sum

will further expand our knowledge in advanced metastatic breast cancer.

2022 Revised Revenue Guidance

Fiscal year 2022 revenue guidance tightened to be in the range of \$79 million - \$82 million, or growth of the commercial portfolio to be in the range of 13% and 17%, as compared to the 2021 fiscal year. The adjustments reflect our updated expectations from Europe, as announced earlier in the quarter and first half results.

Second Quarter Fiscal 2022 Financial Results

The financial results presented in this press release are taken from the Company's Management's Discussion and Analysis (MD&A) and our unaudited consolidated financial statements as at May 31, 2022 (Second Quarter Fiscal 2022) which have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). The MD&A and the Unaudited Financial Statements can be found at www.sedar.com, on EDGAR at www.sec.gov and at www.theratech.com. Unless specified otherwise, all amounts in this press release are in U.S. dollars and all capitalized terms have the meaning ascribed thereto in our MD&A.

Revenue

For the three- and six-month periods ended May 31, 2022, consolidated revenue was \$19,268,000 and \$37,825,000, compared to \$17,787,000 and \$33,217,000 for the same periods ended May 31, 2021, representing a year-over-year increase of 8.3% and 13.9%, respectively.

For the second quarter of fiscal 2022, net sales of *EGRIFTA SV*[®] were \$11,416,000 compared to \$10,344,000 in the second quarter of fiscal 2021, representing an increase of 10.3% year-over-year. Net sales for the six-month period ended May 31, 2022, were \$23,120,000 compared to \$19,032,000 in the same period in 2021. Higher *EGRIFTA SV*[®] sales are the result of increased unit and a higher net selling price per unit.

Trogarzo[®] net sales in the second quarter of fiscal 2022 amounted to \$7,852,000 compared to \$7,443,000 for the same quarter of 2021, representing an increase of 5.5% year-over-year. For the six-month period ended May 31, 2022, Trogarzo[®] net sales were \$14,705,000 compared to \$14,185,000 in the same period in 2021. Higher sales of Trogarzo[®] were a result of a stronger performance in the United States, where we recorded 14% growth compared to the same quarter of last year, and were hampered by lower sales in Europe, as a result of a weaker overall pricing environment.

Cost of Sales

For the three- and six-months ended May 31, 2022, cost of sales increased to \$8,979,000 and \$15,078,000 compared to \$5,934,000 and \$11,345,000 for the same periods in fiscal 2021, primarily due to an increase in other production related costs.

Cost of goods sold was \$7,759,000 and \$12,637,000 in the three- and six-month periods of 2022 compared to \$4,714,000 and \$8,904,000 for the same periods in 2021. The increase in cost of goods sold was mainly due to a charge arising from the non-production of scheduled batches of *EGRIFTA SV*[®] that were cancelled due to the planned transition to the F8 formulation of tesamorelin. Cost of goods sold was also impacted by higher sales of both *EGRIFTA SV*[®] and Trogarzo[®].

Cost of sales also included the amortization of the other asset of \$1,220,000 in both Q2 fiscal 2022 and Q2 fiscal 2021, and of \$2,441,000 for the six-month periods of 2022 and 2021.

R&D Expenses

R&D expenses in the three- and six-month periods ended May 31, 2022, amounted to \$11,056,000 and \$19,059,000 compared to \$6,417,000 and \$11,300,000 in the comparable periods of fiscal 2021.

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

Selling Expenses

Selling expenses increased to \$15,371,000 and \$23,178,000 for the three- and six-month periods ended May 31, 2022, compared to \$6,901,000 and \$13,059,000 for the same periods last year. The increase is due in part to one-time costs related to setting up of our internal field force in the United States, as well as spending on new initiatives implemented in 2022 to increase awareness of our products on the North American market.

The amortization of the intangible asset value for the *EGRIFTA SV*[®] and Trogarzo[®] commercialization rights is also included in selling expenses. As such, we recorded expenses of \$7,102,000 and \$7,897,000 for the three- and six-month periods ended May 31, 2022, compared to \$795,000 and \$1,590,000 in 2021. The increase is related to the accelerated amortization of the Trogarzo[®] commercialization rights for the European territory following our decision to cease commercialization activities in that territory in Q2 2022.

General and Administrative Expenses

General and administrative expenses in the three- and six-month periods ended May 31, 2022, amounted to \$4,823,000 and \$9,191,000 compared to \$3,884,000 and \$7,446,000 reported in the comparable periods of fiscal 2021. The increase in General and Administrative expenses is largely due to increased overall business activities in 2022 compared to 2021, as well as key hires in North America to support the implementation and management of our internal field force in the United States.

Net Finance Costs

Net finance costs for the three- and six-month periods ended May 31, 2022, were \$1,644,000 and \$2,929,000 compared to \$1,023,000 and \$2,355,000 for the comparable periods of 2021. Net finance costs in the second quarter of 2022 and 2021 included interest of \$833,000 (\$1,635,000 in the corresponding six-months periods) on the senior convertible notes issued in June 2018.

Net finance costs for the three- and six-month periods ended May 31, 2022, also included accretion expense of \$544,000 and \$1,061,000, compared to \$608,000 and \$1,189,000 for the comparable periods in 2021.

Net Loss

Given the increase in revenue and the increased expenses and the impairment of the Trogarzo[®] commercialization rights for the European Territory, net loss for the three- and six-month periods ended May 31, 2022, amounted to \$22,727,000 and \$31,759,000, compared to \$6,392,000 and \$12,314,000, for the same periods last year.

Liquidity and Financial Position

We ended the second quarter of fiscal 2022 with \$32,491,000 in cash, bonds and money market funds. The Company believes that its cash position and future operating cash flows will be sufficient to finance its operations and capital needs for at least the next 12 months from the consolidated statement of financial position date. Furthermore, subsequent to May 31, 2022, (please refer to the Subsequent Events section in the MD&A for details) the Company secured a new financing.

For the three-month period ended May 31, 2022, cash flows used by operating activities were \$11,736,000 compared to \$2,812,000 in the same period of fiscal 2022.

In the second quarter of fiscal 2022, changes in operating assets and liabilities had a positive impact on cash flow of \$10,589,000 (2021- \$2,096,000). These changes were mostly attributable to positive impacts from lower accounts receivable (\$1,077,000) and prepaid expenses (\$1,097,000), and higher accounts payables and accrued liabilities (\$7,095,000).

Conference Call Details

A conference call will be held on July 14, 2022 at 8:30 a.m. (ET) to discuss the results and recent business updates. The call will be hosted by Paul Lévesque, President and Chief Executive Officer. Joining Mr. Lévesque on the call will be other members of the management team, including Chief Financial Officer Philippe Dubuc and Chief Medical Officer Christian Marsolais, who will be available to answer questions from participants following prepared remarks.

Participants are encouraged to join the call ten minutes in advance to secure access.

Conference call dial-in and replay information is below:

CONFERENCE CALL INFORMATION	
Conference Call Date:	July 14, 2022
Conference Call Time:	8:30 AM ET
North America Dial-in:	1- 877-513-4119
International Dial-in:	1- 412-902-6615
Access Code:	5742327
CONFERENCE CALL REPLAY	
North America Dial-in:	1- 877-344-7529
International Dial-in:	1- 412-317-0088
Replay Access Code:	7192794
Replay End Date	July 21, 2022

The live conference call will be accessible via webcast at:

<https://edge.media-server.com/mmc/p/98pvag4g>.

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 availability of the term loan, our forecasted revenues for the 2022 full fiscal year, the conduct of our clinical trials with TH1902, the timelines associated with the completion of the HFS, with the filing of an sBLA with the FDA for the F8 formulation and the IM mode of administration study using Trogarzo[®], and our discussions with potential partners in NASH and in Greater China for our oncology platform.

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 Company will meet all the terms and conditions of the term loan; 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 the United States; continuous supply of *EGRIFTA SV*[®] and Trogarzo[®] will be available; the Company's relations with third-party suppliers of *EGRIFTA SV*[®] and Trogarzo[®] will be conflict-free and such third-party suppliers will have the capacity to manufacture and supply *EGRIFTA SV*[®] and Trogarzo[®] to meet market demand on a timely basis; no biosimilar version of *EGRIFTA SV*[®] will be approved by the FDA; the Company's intellectual property will prevent companies from commercializing biosimilar versions of *EGRIFTA SV*[®] in the United States; the FDA will approve the IV Push mode of administration of Trogarzo[®] by the target action date of October 3, 2022; the Company will succeed in finding a commercial partner in Greater China for its oncology platform and for its NASH program; the timelines associated with the completion of the HFS, the filing of an sBLA with the FDA for the F8 formulation and the completion of the IM mode of administration for Trogarzo[®] will be met; 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: non-compliance by the Company with the terms and conditions of the term loan; the occurrence of an event of default under the term loan triggering the accelerated reimbursement of any outstanding drawn down amounts; the Company's ability and capacity to grow the sales of *EGRIFTA SV*[®] and Trogarzo[®] successfully in the United States; the Company's capacity to meet supply and demand for its products; the market acceptance of *EGRIFTA SV*[®] and Trogarzo[®] in the United States; 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 ability to successfully meet the timelines set forth herein; the discovery of a cure for HIV; the Company's failure to meet the terms and conditions set forth in the credit agreement resulting in an event of default and preventing the Company from accessing the full amount of the term loan; the Company's expectations regarding its financial performance, including revenues, expenses, gross margins, profitability, liquidity, capital expenditures and income taxes; and the Company's estimates regarding its capital requirements.

We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 23, 2022, available on SEDAR at www.sedar.com and on EDGAR at www.sec.gov as an exhibit to our report on Form 40-F dated February 24, 2022, under Theratechnologies' public filings. The reader is cautioned to consider these and other risks and uncertainties carefully and not to put undue reliance on forward-looking statements. Forward-looking statements reflect current expectations regarding future events and speak only as of the date of this 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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