

# Theratechnologies Reports Financial Results and Business Updates for First Quarter 2023

April 12, 2023

- Q1 2023 Consolidated Revenue Grew 7%, Supported by 9% Growth in EGRIFTA SV<sup>®</sup> Revenue and 5% Growth in Trogarzo<sup>®</sup> Revenue
  - Revised Sudocetaxel Zendusortide (TH1902) Phase 1 Trial Protocol Expected to be Filed by End of April
- FY2023 Revenue Guidance Range Confirmed Between \$90 million and \$95 million; Growth of the Commercial Portfolio in the Range of 13% and 19%

MONTREAL, April 12, 2023 (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 first quarter of fiscal year 2023 ended February 28, 2023 (Q1 2023). All figures are in US dollars unless otherwise stated.

"The first quarter of 2023, which for us commenced on December 1 <sup>st</sup>, 2022, was impacted by our decision to voluntarily halt patient enrollment in our TH1902 basket trial. Following expert advice from the Scientific Advisory Committee on March 22, an optimized path forward was agreed upon and the amended protocol is expected to be filed with the FDA by the end of April. The SAC has agreed with our assessment that the three key required changes include an adjustment in the patient dosing regimen of TH1902, the narrowing of tumor types based on current results, in addition to refined patient selection criteria for the trial. We look forward to once again enrolling patients and will update the market on our progress as we proceed. We remain strongly committed to the success of this promising oncology program through a sensible, stage-gated approach to drug development. Once back in the clinic, we feel we will be in a good position to accelerate the outreach to potential partners," said President and CEO, Mr. Paul Lévesque.

"Our first quarter revenue growth was impacted by variability in inventories at the specialty pharmacy level and set against an unusually strong Q1 2022. However, new patient enrollments, a leading indicator for our revenues, were significantly ahead in the first quarter of 2023, as compared to the first quarter of 2022, and are indicative of a stronger performance for the remainder of our fiscal year. Consistent with our previously stated objective of becoming Adjusted EBITDA positive in the latter part of this year, we will endeavor to manage expenses tightly without compromising top line revenue," concluded Mr. Levesque.

# First-Quarter 2023 Revenues

(in thousands	of U.S. dollars)	

	Three Months Ended February 28,		Change
	2023	2022	
EGRIFTA <sup>®</sup> , EGRIFTA SV <sup>®</sup> net sales	12,711	11,704	8.6%
Trogarzo <sup>®</sup> net sales	7,197	6,853	5.0%
Revenue	19,908	18,557	7.3%

# **Recent Highlights:**

# Sudocetaxel Zendusortide ("TH1902") Development Pathway

On December 1, 2022, Theratechnologies announced the decision to voluntarily pause the enrollment of patients in its Phase 1 clinical trial of TH1902, the Company's lead investigational peptide drug conjugate ("PDC") for the treatment of sortilin-expressing cancers.

Following the voluntary pause, the Company formed a Scientific Advisory Committee ("SAC") to help determine the best developmental path forward for TH1902. A meeting was held on March 22, with several medical oncologists from across the United States, who are leading experts in the end-to-end lifecycle of oncology drug development.

Theratechnologies presented the pre-clinical and clinical data gathered thus far to the SAC, which made recommendations to modify the frequency of administration, selection of tumor types and refined criteria for patient selection to further improve our chances of a successful outcome. The Company is finalizing adjustments to the protocol and aims to submit to the FDA before the end of April 2023.

Consistent with the Company's 2023 objective of generating positive Adjusted EBITDA by fiscal year end, any new investments in TH1902 will be stage-gated. Once the Phase 1 clinical trial has resumed, Theratechnologies will also evaluate potential partnerships for TH1902.

# Amendment to Term Loan Facility with Affiliates of Marathon Asset Management

On February 28<sup>th</sup>, the Company announced that it entered into a first amendment to its credit agreement dated July 20, 2022 (the "Loan Facility") with certain funds and accounts for which Marathon Asset Management, L.P. acts as investment manager (collectively, "Marathon").

The Company and Marathon agreed to amend the terms of the Loan Facility by removing the condition related to the submission to the FDA of its human factors study ("HFS") related to *EGRIFTA SV®* in order to access a US\$20 million second tranche of the Loan Facility, and by allowing the

inclusion of a going concern note in the auditor's report to shareholders for the fiscal year ended November 30, 2022, without triggering an event of default.

These amendments were entered into in consideration of the issuance of an aggregate of 5,000,000 common share purchase warrants (the "Marathon Warrants") to Marathon. Each Marathon Warrant entitles the holder thereof to purchase one common share of the Company at a price of US\$1.45 per share until February 27, 2030.

## Conference on Retroviruses and Opportunistic Infections ("CROI")

On February 22, Theratechnologies announced a presentation at the 30<sup>th</sup> Conference on Retroviruses and Opportunistic Infections ("CROI"), highlighting new Tesamorelin data demonstrating improvement of metabolic syndrome in people with HIV. The presentation demonstrated association between excess visceral abdominal fat ("EVAF") reduction and decreased prevalence of metabolic syndrome with tesamorelin treatment. These data provided further evidence of potential utility of tesamorelin in addressing metabolic syndrome and complements research in fatty liver diseases.

#### American Association for Cancer Research ("AACR")

On March 14, subsequent to the end of the first quarter, Theratechnologies announced that it will have three presentations at the annual meeting of the American Association for Cancer Research ("AACR"), on April 18, 2023. These new data, to be presented in three poster sessions highlight a synergistic effect of TH1902 in combination with programmed death-ligand 1 ("PD-L1"), checkpoint inhibitor therapy in a melanoma mouse model; high expression of the sortilin ("SORT1") receptor in multiple tumor types compared to healthy tissues; and the rationale for using TH1902 as a potential therapeutic approach in SORT1-positive triple-negative breast cancer ("TNBC") and HER2-positive breast cancers.

#### 2023 Revenue Guidance

The Company's anticipated FY2023 revenue guidance range is confirmed between \$90 million and \$95 million, or growth of the commercial portfolio in the range of 13% and 19%, as compared to the 2022 fiscal year results.

# First Quarter Fiscal 2023 Financial Highlights

The financial results presented in this press release are taken from the Company's Management's Discussion and Analysis ("MD&A") and interim consolidated financial statements ("Interim Financial Statements") for the three-month period ended February 28, 2023 ("First Quarter Fiscal 2023") 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 Interim 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

Consolidated revenue for the three months ended February 28, 2023, amounted to \$19,908,000 compared to \$18,557,000 for the same period last year, representing an increase of 7.3%.

For the first quarter of Fiscal 2023, sales of *EGRIFTA*  $SV^{\textcircled{R}}$  reached \$12,711,000 compared to \$11,704,000 in the first quarter of the prior year, representing an increase of 8.6%. Growth in sales of *EGRIFTA*  $SV^{\textcircled{R}}$  was mostly the result of increased unit sales and a higher net selling price but were offset by greater rebates to government payers.

In the first quarter of Fiscal 2023, Trogarzo<sup>®</sup> sales amounted to \$7,197,000 compared to \$6,853,000 for the same quarter of 2022, representing an increase of 5.0%. Trogarzo<sup>®</sup> unit sales in the first quarter of 2023 were up marginally and were positively impacted by a higher net selling price and more favorable government rebates and chargebacks.

#### **Cost of Sales**

For the three-month period ended February 28, 2023, cost of sales was \$4,693,000 compared to \$6,099,000 in the comparable period of Fiscal 2022. In the first quarter of 2022, cost of sales included an amortization charge of \$1,221,000 in connection with the settlement of the future obligation which has been accounted as "Other asset" on the consolidated statement of the financial position. The Other asset was fully amortized during the first half of Fiscal 2022, and thus this charge was Nil in the first quarter of Fiscal 2023.

Cost of goods sold decreased to \$4,693,000 compared to \$4,878,000 for the same period last year. Cost of goods sold for the first quarter of last year was higher because of an adjustment to the cost of goods sold for Trogarzo in Europe related to the provision for rebates to the French government.

#### **R&D Expenses**

R&D expenses in the three-month period ended February 28, 2023 amounted to \$9,356,000 compared to \$8,003,000 in the comparable period of Fiscal 2022. The increase during the first quarter of Fiscal 2023 was largely due to expenses related to the production of the validation batches of BWFI (\$536,000) and \$838,000 in expenses related to the production of clinical batches of TH1902. Other project spending included the *EGRIFTA SV*<sup>®</sup> Human Factors Study and spending on the TH1902 Phase 1 trial.

# Selling Expenses

Selling expenses in the three-month period ended February 28, 2023, amounted to \$6,814,000 compared to \$7,807,000 in the comparable period of Fiscal 2022 or a 12.7% decrease.

The decrease in selling expenses is largely associated to the decision to exit the European market in 2022 and is partially offset by higher spending in the United States.

#### **General and Administrative Expenses**

General and administrative expenses in the first quarter of Fiscal 2023 amounted to \$4,452,000, compared to \$4,368,000 reported in the same period of Fiscal 2022. The slight increase is due to an overall increase in activity to reflect the growth of our business in North America related to the on boarding of our field force during 2022 and is offset by lower spending in Europe.

## **Net Finance Costs**

Net finance costs for the three-month period ended February 28, 2023, were \$4,940,000 compared to \$1,285,000 in the same period last year. The increase in net finance cost is mostly due to the loss on debt modification of \$2,650,000 related to the issuance of the Marathon Warrants issued in connection to the amendments to the Credit Agreement as well as the higher interest expense on the company's outstanding long-term debt due to the new Loan Facility entered into in Q3 of Fiscal 2022.

# Adjusted EBITDA

Adjusted EBITDA was \$(3,892,000) for the first quarter of fiscal 2023 compared to \$(4,094,000) for the same period of 2022. Adjusted EBITDA in the first quarter of 2023 was negatively affected by certain production costs, namely an expense related to the production of the validation batches of BWFI of \$536,000, and \$838,000 in expenses related to production batches of TH1902. Adjusted EBITDA is a Non-IFRS measure. See "Non-IFRS and Non-US-GAAP Measure – Reconciliation of Adjusted EBITDA" below for the composition of this measure and a reconciliation to net loss for the relevant periods.

#### Net loss

Taking into account the revenue and expense variations described above, we recorded a net loss of \$10,443,000, or \$0.11 per share, in the first quarter of Fiscal 2023 compared to a net loss of \$9,032,000, or \$0.09 per share, in the first quarter of Fiscal 2022.

# **Financial Position, Liquidity and Capital Resources**

### Going Concern Uncertainty

As part of the preparation of the interim financial statements, management is responsible for identifying any event or situation that may cast doubt on the Company's ability to continue as a going concern. Substantial doubt regarding the Company's ability to continue as a going concern exists if events or conditions, considered collectively, indicate that the Company may be unable to honor its obligations as they fall due during a period of at least, but not limited to, 12 months from February 28, 2023. If the Company concludes that events or conditions cast substantial doubt on its ability to continue as a going concern, it must assess whether the plans developed to mitigate these events or conditions will remove any possible substantial doubt.

For the three-month period ended February 28, 2023, the Company incurred a net loss of \$10,443,000 (2022 – \$9,032,000) and had positive operating cash flows of \$2,361,000 (2022 - \$42,000). The Company's total current liabilities exceeded total current assets at February 28, 2023. The Company's outstanding \$27,467,000 convertible unsecured senior notes mature in June 2023 (refer to Note 7 of the Interim Financial Statements) requiring the Company to use its cash balance and draw the Tranche 2 Loan (as defined in Note 18 of the annual consolidated financial statements as at November 30, 2022) of its Loan Facility to repay the principal and the interest thereon. The Loan Facility is available in four tranches and contains various covenants, including minimum liquidity covenants whereby the Company needs to maintain significant cash, cash equivalent and eligible short-term investments balances in specified accounts, which restricts the management of the Company's liquidity (refer to notes 18 and 24 of the annual consolidated financial statements as at November 30, 2022). There are also operational milestones and required revenue targets in order for the Company to comply with the conditions of the Loan Facility or to be able to borrow money forming part of the various tranches.

The Company's ability to continue as a going concern for a period of at least, but not limited to, 12 months from February 28, 2023 involves significant judgement and is dependent on its ability to increase revenues and manage expenses to generate sufficient positive cash flows from operations and/or find alternative source of funding to respect all the various covenants of its Loan Facility, including obtaining the approval from the FDA for its F8 formulation of tesamorelin on or before March 31, 2024, and/or to obtain the continued support of its lender. On February 27, 2023, the lender removed the condition related to the submission to the FDA of the results from the human factors validation study by no later than June 30, 2023, in order to access the Tranche 2 Loan under the Loan Facility (refer to Note 30 of the annual consolidated financial statements as at November 30, 2022). Management believes its plans will comply with all of the other various covenants of the Loan Facility to draw the Tranche 2 Loan, repay all the convertible unsecured senior notes due June 30, 2023, and to comply with the covenants for the foreseeable future. However, there can be no assurance that management's plans will be realized since some elements of these plans are outside of management's control and cannot be predicted at this time. Should management's plans not materialize, the Company may be forced to reduce or delay expenditures and capital additions, seek additional financing through the issuance of equity or obtain from the lender waivers of these covenants, if available. Raising additional equity capital is subject to market conditions. As a result, there is material uncertainty related to events or conditions that cast substantial doubt about the Company's ability to continue as a going concern.

Furthermore, the Loan Facility includes a covenant prohibiting having a going concern explanatory paragraph in the annual report of the independent registered public accounting firm but the lender amended the Loan Facility on February 27, 2023 to exclude the fiscal year ended November 30, 2022. The term loan has been reclassified from current at November 30, 2022 to long-term at February 28, 2023 as a result of the waiver received within the first quarter. There is no assurance that the lender will agree to amend or to waive potential future covenant breaches, if any.

The interim financial statements have been prepared assuming the Company will continue as a going concern, which assumes the Company will continue its operations in the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. The interim financial statements do not include any adjustments to the carrying values and classification of assets and liabilities and reported expenses that might result from the outcome of this uncertainty and that may be necessary if the going concern basis was not appropriate for these interim financial statements. If the Company was unable to continue as a going concern, material impairment of the carrying values of the Company's assets, including intangible assets, could be required.

#### Analysis of cash flows

We ended the first quarter of fiscal 2023 with \$29,156,000 in cash, bonds and money market funds. Available cash is invested in highly liquid fixed income instruments including governmental and municipal bonds, and money market funds.

The Company voluntarily changed its accounting policy in Fiscal 2022 to classify interest paid and received as part of cash flows from operating activities, which were previously classified as cash flow from financing activities and interest received as cash flows from investing activities. The Fiscal 2022 amounts presented herein have been recasted to reflect the change in policy.

For the three-month period ended February 28, 2023, cash used in operating activities was relatively stable at \$3,339,000, compared to \$5,690,000 in the comparable period of Fiscal 2022.

In the first quarter of fiscal 2023, changes in operating assets and liabilities had a positive impact on cash flow of \$2,361,000 (2022-positive impact of \$42,000). These changes included a positive impact from lower accounts receivable (\$2,085,000), a decrease in inventories (\$4,578,000), lower prepaid expenses (\$1,644,000) and deposits and also include a negative impact from lower accounts payable (\$6,545,000). The decrease in inventories is mainly due to a planned reduction of Trogarzo<sup>®</sup> inventory levels.

During Fiscal 2022, the Company realized net proceeds from the issuance of a long-term loan of \$37,715,000. We also received net proceeds for the issuance of common stock to an institutional investor in the amount of \$2,871,000 under its ATM program. Significant uses of cash for financing activities during Fiscal 2022 included the purchase of convertible notes for \$28,819,000 (including costs related to the purchase), and \$1,527,000 in deferred financing costs related to the establishment of the Loan Facility.

On January 19, 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 of \$3,394,000 resulted in net proceeds of \$42,608,000.

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 "Public Offering Warrant"). Each Public Offering Warrant entitles the holder to purchase one common share of the Company at an exercise price of \$3.18 until January 19, 2024.

During the first quarter of 2023, cash used in investing activities included \$222,000 for the acquisition of research equipment, and financing activities used \$162,000 in cash.

# **Conference Call Details**

The conference call will be held on Wednesday, April 12, 2023, hosted by Mr. Paul Lévesque, President and Chief Executive Officer, and begin at 8:30 a.m. ET. Joining Mr. Lévesque on the call will be other members of the management team, including Chief Financial Officer Mr. Philippe Dubuc, Chief Medical Officer Dr. Christian Marsolais, and Global Commercial Officer Mr. John Leasure, who will be available to answer questions from participants following prepared remarks.

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

Conference call dial-in and replay information is below:

CONFERENCE CALL INFORMATION	
Conference Call Date:	April 12, 2023
Conference Call Time:	8:30 AM ET
North America Dial-in:	1-877-513-4119
International Dial-in:	1-412-902-6615
Access Code:	4314981
CONFERENCE CALL REPLAY	
North America Dial-in:	1- 877-344-7529
International Dial-in:	1- 412-317-0088
Replay Access Code:	8857934
Replay End Date	April 19, 2023

The live conference call will be accessible via webcast at: https://edge.media-server.com/mmc/p/nt9j2fgg

## **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 <u>www.theratech.com</u>, on SEDAR at <u>www.sedar.com</u> and on EDGAR at <u>www.sec.gov</u>.

# NON-IFRS AND NON-US GAAP MEASURE

The information presented in this press release includes a measure that is not determined in accordance with International Financial Reporting Standards ("IFRS") or U.S. generally accepted accounting principles ("U.S. GAAP"), being the term "Adjusted EBITDA". "Adjusted EBITDA" is used by the Corporation as an indicator of financial performance and is obtained by adding to net profit or loss, finance income and costs, depreciation and amortization, income taxes, share-based compensation from stock options, and certain write-downs (or related reversals) of inventories. "Adjusted EBITDA" excludes the effects of items that primarily reflect the impact of long-term investment and financing decisions rather than the results of day-to-day operations. The Corporation believes that this measure can be a useful indicator of its operational performance from one period to another. The Corporation uses this non-IFRS measure to make financial, strategic and operating decisions. Adjusted EBITDA is not a standardized financial measure under the financial reporting framework used to prepare the financial statements of the Corporation to which the measure relates and might not be comparable to similar financial measures disclosed by other issuers. The Corporation has reinstated its use of Adjusted EBITDA starting this quarter and has included Adjusted EBITDA for the comparative period. A quantitative reconciliation of the Adjusted EBITDA is presented in the table below:

# **Reconciliation of Adjusted EBITDA**

(In thousands of U.S. dollars)

Three-month periods ended February 28,

2023	2022
(10,443)	(9,032)
939	2,184
4,940	1,285
96	27
576	1,442
(3,892)	(4,094)
	(10,443) 939 4,940 96 576

# FORWARD-LOOKING INFORMATION

This press release contains forward-looking statements and forward-looking information (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 our 2023 fiscal year revenue guidance, our 2023 objectives and strategies, , the filing and the approval of an amended protocol with the FDA to resume the Phase 1 clinical trial using TH1902 and the timelines related thereto, and the control of our expenses to achieve a positive adjusted EBITDA by year end. 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 (i) sales of our products will continue to grow in 2023 and beyond; (ii) we will control expenses as planned and no unforeseen events will occur which would have the effect of increasing our expenses in 2023 and beyond; (iii) we will file an amended protocol to resume the Phase 1 clinical trial studying TH1902 and the FDA will approve such amended protocol allowing us to resume such study; (iv) we will have access to the second tranche of US\$20 million under the Loan Facility and will be in compliance with the terms and conditions of the Loan Facility; and (viii) no event will occur that would prevent us from executing the objectives set forth in this press release. 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, a decrease or stagnation in sales of our products in 2023 and beyond, product recalls or change in the regulation that would adversely impact the sale of our products, the occurrence of events which would lead us to spend more cash than anticipated, the effect of which could result in a negative Adjusted EBITDA position by the fiscal year-end and beyond, defaults under the Loan Facility triggering an increase of 300 basis points on the loaned amount and a decision by the lenders to declare all amounts owed under the Loan Facility as immediately due and payable, the non-approval by the FDA of our amendments to our protocol to resume our Phase 1 clinical trial using TH1902, financial difficulties in meeting our contractual obligations or default under contractual covenants, and changes in our business plan. We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 27, 2023, 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 28, 2023, 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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<sup>1</sup> Includes depreciation of property and equipment, amortization of intangible, other assets and right-of-use assets.

<sup>2</sup> Includes all finance income and finance costs consisting of: Foreign exchange, interest income, accretion expense and amortization of deferred financing costs, interest expense, bank charges, gain or loss on financial instruments carried at fair value and loss on debt modification.