
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 6-K

**Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
under the Securities Exchange Act of 1934**

January 4, 2023

Commission File Number 001-35203

THERATECHNOLOGIES INC.

(Translation of registrant's name into English)

2015 Peel Street, Suite 1100
Montréal, Québec, Canada H3A 1T8
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes No

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes No

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____.

THERATECHNOLOGIES INC.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release Dated January 4, 2023

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

THERATECHNOLOGIES INC.

By: /s/ Jocelyn Lafond

Name: Jocelyn Lafond

Title: General Counsel

Date: January 4, 2023



Open Letter to Shareholders from CEO Paul Levesque

Theratechnologies Announces Fiscal Year 2023 Guidance and Operating Plan's Key Objectives

- FY2022 top line revenue expected to end the year at ~\$80 million, in line with previously announced revenue guidance
- FY2023 revenue guidance range set between \$90 million and \$95 million, ending the new year on a solid path to positive cash flow from operating activities
- FY2023 operating plan to focus on achieving positive EBITDA¹ in the near-term based on commercial business growth and new asset opportunities
 - Scientific Advisory Committee formed to optimize Protocol Amendment for our Phase 1 clinical trial of TH1902
 - The U.S. Food and Drug Administration ("FDA") confirmed they will review the Protocol Amendment within thirty days of submission

This news release constitutes "a designated news release" for the purposes of the Company's prospectus supplement dated December 16, 2021 to its short form base shelf prospectus dated December 14, 2021.

MONTREAL, January 4, 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 announced that President and CEO, Paul Lévesque has issued an open letter to shareholders. All amounts are in U.S. dollars unless otherwise stated.

The letter provides a summary of the Company's 2022 fiscal year results, details key business objectives of the Company's 2023 operating plan which is aimed to accelerate revenue growth and cash flow and sets out next steps for our Phase 1 clinical trial of TH1902.

The full letter is available on the Company's website, and is published below:

Dear Shareholders,

With nearly a month left before we report our full fiscal year 2022 results, I am pleased to note that we have met our previously announced guidance and expect to report ~\$80 million in top line revenues. Our full year results represent approximately 15% in year-over-year growth in the commercial business. We are also pleased to outline our fiscal year 2023 key objectives and strategies.

¹ This is a non-IFRS measure. See "Non-IFRS Information" below.

In guiding our focus for the new year, we are placing a strong emphasis on maintaining the solid growth of our commercial business, while allocating financial resources thoughtfully to achieve positive EBITDA by the end of 2023.

Under these principles of value creation, we aim to further strengthen our vibrant commercial businesses, while continuing to assess our TH1902 clinical trial and SORT1+ Technology™ platform.

We believe these strategic steps will position us for top line growth for the foreseeable future.

Fiscal Year 2022 in Summary

We have been especially pleased with our FY2022 results, having worked to position our product portfolio for commercial success. We built out a dedicated salesforce in-house, removing our reliance on external contract organizations. This move has resulted in accelerated sales growth.

We are working towards driving long-term, sustainable, double-digit sales growth with an eye on achieving positive cash flow from operations in the near-term. Our medicines are also becoming more and more embedded in the workflow of prescribers as an option of choice that can play a major impact in the lives of people living with HIV.

During 2022, we also worked diligently to further improve Trogarzo®'s method of administration and now have FDA approval for Trogarzo®'s 30-Second Intravenous (IV) Push administration, simplifying the method of administration for heavily treatment-experienced populations. We are also working closely with our partner, TaiMed Biologics, in completing the development of an intra-muscular method of administration for Trogarzo®, and subsequent filing of a new supplemental Biologics License Application (“sBLA”) with the FDA. These projects will serve to ensure lifecycle management of Trogarzo® for years to come.

In HIV-associated lipodystrophy, we are on track to complete the Human Factors Study for *EGRIFTA SI*® in the first half of 2023, and we are diligently completing the work associated to the sBLA filing for the F8 formulation of Tesamorelin with the FDA. We are also confident in successfully addressing the shortage of bacteriostatic water for injection by placing the sourcing of this drug component under our own control via the services of a third-party manufacturer. The further development of Tesamorelin allows Theratechnologies to maintain its positioning as one of the few options for drug developers to immediately partner with a company in order to launch a Phase 2b/3 NASH clinical trial.

Operationally, we made the difficult decision to withdraw our business from Europe in order to focus sales in the United States, a territory with optimal conditions for growing our commercial assets. Withdrawing from Europe was a difficult but necessary decision as it represents a region with unfavorable pricing regimes across many territories.

Both the NASH and HIV markets in the United States have considerable opportunity, and we believe that we are well positioned to capture market share in the future.

2023 Revenue Guidance

Having confidently developed the right strategy for commercial success, we have set full fiscal year 2023 revenue guidance to be in the range of \$90 million and \$95 million, representing growth of between 13% and 19% as compared to 2022. More encouragingly, in our commitment to hold fast to fiscal responsibility and also based on the strength of our commercial portfolio, we expect to end 2023 on a strong path to positive cash flow from operations, setting the stage for even more leverage in years to come. The commercial infrastructure we have built in the United States will also serve as a platform to grow both our current products, as well as potential new accretive product acquisitions or in-licensing of commercial assets.

TH1902 Development Pathway

Now, let me address what has been top of mind for many. We were disappointed to voluntarily pause enrollment in the Phase 1 clinical trial of TH1902; however, we believe it was the right decision for patients, the Company and our shareholders.

We believe there is a path forward for the development of TH1902, and to ensure we are heading in the right direction, we have formed a Scientific Advisory Committee comprised of internal and external independent experts in the development of oncology candidates. The mandate of this Scientific Advisory Committee is to optimize the protocol amendment for the development of TH1902.

Since announcing our decision to pause enrollment in the basket trial, we have had discussions with the FDA, and the agency has indicated that it agreed with our voluntary pause.

Further to our discussions with the FDA, we received a letter indicating that our Phase 1 clinical trial was placed on a partial clinical hold subject to our responses to a list of questions. We intend to respond to their questions along with the filing of the amended protocol. Questions raised by the FDA were already being addressed by our team as part of our sub-analysis of the data accumulated so far, and we are confident that we will be able to address all of their questions. Finally, the FDA indicated that their review of the protocol amendment would be completed within thirty days of submission.

The further development of TH1902 will be stage-gated and depend on the analysis of the data generated, and decisions will be carefully taken in the context of our goal to become EBITDA positive in 2023 and beyond.

Path to Positive Cash Flow from Operations in 2023 and Beyond

While we refine our plans around TH1902, our priority will be to rein in costs associated with its development and deploy those resources towards the Company's path to positive cash flow from operations in 2023. In doing so, we believe that we will be able to generate increasing cash flow throughout the year, which will give us further leverage to build upon our commercial portfolio.

For future consideration, we have tasked our business development team to explore opportunities for additional commercialized assets which can be incorporated into our existing product portfolio, leveraging the strength of our commercial infrastructure in the United States.

We will remain laser-focused on continuing to build out our strong commercial portfolio, significantly improving patient care in the HIV space along the way, while continuing to pursue development opportunities in a financially responsible manner.

On behalf of the Theratechnologies team, I wish everyone a very happy and successful new year and look forward to our upcoming earnings call.

Sincerely,

Paul Lévesque
President and Chief Executive Officer

About SORT1+ Technology™ and TH1902

Theratechnologies is currently developing a platform of proprietary peptides called SORT1+ Technology™ for cancer drug development targeting SORT1 receptors. The SORT1 receptor plays a significant role in protein internalization, sorting and trafficking. It is highly expressed in cancer cells compared to healthy tissue, which makes SORT1 an attractive target for cancer drug development. Expression of SORT1 is associated with aggressive disease, poor prognosis and decreased survival. It is estimated that the SORT1 receptor is expressed in 40% to 90% of cases of endometrial, ovarian, colorectal, triple-negative breast and pancreatic cancers.

TH1902 is currently Theratechnologies' lead investigational peptide drug conjugate candidate for the treatment of cancer derived from its SORT1+ Technology™. It is the Company's proprietary peptide linked to docetaxel – a commonly used cytotoxic agent used to treat many cancers. The FDA granted fast track designation to TH1902 as a single agent for the treatment of all sortilin-positive recurrent advanced solid tumors that are refractory to standard therapy.

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.

Non-IFRS Information

This press release includes measures that are not determined in accordance with International Financial Reporting Standards ("IFRS") or U.S. generally accepted accounting principles ("U.S. GAAP") including the financial measure "EBITDA", that is used by us as an indicator of financial performance. EBITDA is obtained by adding to net profit or loss, finance income and costs, depreciation and amortization, and income taxes. Management believes that EBITDA can be considered as a useful indicator of our operating performance from one period to another and our ability to generate liquidity through cash flows from operating activities that may be used to fund future working capital needs. This measure 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.

Non-IFRS and non-U.S. GAAP financial measures do not have standardized meanings prescribed under IFRS or U.S. GAAP and our computation may differ from similarly-named computations as reported by other entities and, accordingly, may not be comparable. These financial measures should not be considered as an alternative to, or more meaningful than, measures of financial performance as determined in accordance with IFRS or U.S. GAAP as an indicator of performance. Non-IFRS measures also provide investors with insight into our decision making as we use these non-IFRS measures to make financial, strategic and operating decisions.

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 2022 fiscal year results, our 2023 fiscal year revenue guidance, our 2023 objectives and strategies, the development of an intra-muscular method of administration of Trogarzo[®], the filing of an sBLA for the F8 Formulation of Tesamorelin, the finding of a partner and the launch of a Phase 2b/3 clinical trial in NASH, the development of TH1902 and the SORT1+ Technology[™] platform and the addition of commercial assets as part of our commercial infrastructure in the United States. 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) there will not occur any event which would lead us to amend our fiscal year 2022 results; (ii) sales of our products will continue to grow in 2023 and beyond; (iii) 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; (iv) the development of an intra-muscular method of administration of Trogarzo[®] will yield positive results and such method of administration will be approved by the FDA when filed; (v) we will timely file an sBLA for the F8 Formulation of Tesamorelin; (vi) we will be successful in finding a partner for the conduct of a Phase 2b/3 clinical trial in NASH using Tesamorelin; (vii) we will successfully find a path forward for the development of TH1902 and the FDA will approve an amended protocol related to the conduct of a Phase 1 clinical trial using TH1902; (viii) we will be successful in identifying and entering into a transaction to add one or more commercial assets as part of our commercial infrastructure in the United States; and (ix) no event will occur that would prevent us from the executing 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, the occurrence of events that would require us to amend our fiscal year 2022 results, 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 EBITDA position, the inability to answer to the satisfaction of the FDA to all questions raised by them resulting in a hold in our clinical trial, the non-approval of our protocol amendment by the FDA, our incapacity to identify a commercial asset or our inability to enter into a commercial agreement regarding same on terms satisfactory to us, unsatisfactory results derived from the conduct of an intra-muscular method of administration study of Trogarzo[®], 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 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 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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