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

November 26, 2024

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.

Exhibit	Description
99.1	Press Release Dated November 26, 2024

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 and Corporate Secretary

Date: November 26, 2024

Theratechnologies Submits Updated Tesamorelin F8 Formulation sBLA for FDA Review

Resubmission addresses questions raised in January 2024 Complete Response Letter

F8 formulation intended to replace EGRIFTA SV® with simplified dosing for the treatment of excess abdominal fat in adults with HIV and lipodystrophy

MONTREAL, November 26, 2024 (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 the resubmission of its supplemental Biologics License Application (sBLA) to the U.S. Food and Drug Administration (FDA) for the F8 formulation of tesamorelin, the only medication approved in the U.S. for the reduction of excess abdominal fat in adults with HIV who have lipodystrophy.

Theratechnologies has filed the resubmission to address concerns raised in the FDA’s Complete Response Letter (CRL) to the initial F8 formulation sBLA filing. In the CRL, which was issued in January 2024, the FDA requested clarifications largely related to chemistry, manufacturing and controls (CMC), as well as further information on immunogenicity risk.

“We are confident in our sBLA resubmission after discussing our response approach with the FDA in a Type A meeting,” said Christian Marsolais, Ph.D., Senior Vice President and Chief Medical Officer at Theratechnologies. “The F8 formulation of tesamorelin would simplify dosing for people with HIV who face the clinical challenges of excess abdominal fat. We look forward to further collaboration with the FDA as the agency reviews our updated application.”

The FDA will review the updated sBLA within four months of submission. Theratechnologies therefore expects a decision around the end of March 2025. The new formulation is patent protected in the U.S. until 2033.

About *EGRIFTA SV®* (tesamorelin for injection)

EGRIFTA SV® is approved in the U.S. for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy*. *EGRIFTA SV®* is a growth hormone releasing factor (GHRF) analog that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone.

* Limitations of Use:

- Long-term cardiovascular safety of *EGRIFTA SV®* has not been established. Consider risk/benefit of continuation of treatment in patients who have not had a reduction in visceral adipose tissue.

- *EGRIFTA SV®* is not indicated for weight loss management as it has a weight neutral effect.
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking *EGRIFTA SV®*.

Do not use *EGRIFTA SV®* if a patient:

- Has a pituitary gland tumor, has had pituitary gland surgery, has other problems related to their pituitary gland, or has had radiation treatment to their head or head trauma.
- Has active cancer.
- Is allergic to tesamorelin or any of the ingredients in *EGRIFTA SV®.*
- Is pregnant or planning to become pregnant.

The most commonly reported adverse reactions to *EGRIFTA SV®* include: hypersensitivity reactions, hyperglycemia, injection site reactions, arthralgia, pain in extremity, myalgia and peripheral edema.

Refer to www.egriftasv.com for the full prescribing information, patient information and instructions for use for further details about this product.

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.sedarplus.ca and on EDGAR at www.sec.gov. Follow Theratechnologies on Linkedin and X (formerly Twitter).

Forward-Looking Information

This press release contains forward-looking statements and forward-looking information (collectively, the "Forward-Looking Statements") within the meaning of applicable securities laws, that are based on management's beliefs and assumptions and on information currently available to it. 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: (i) the time period related to the review of the sBLA by the FDA; and (ii) the benefits to patients associated with the use of the F8 formulation, if approved. 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 contained in this press release. Certain assumptions made in preparing the Forward-Looking Statements include that: (i) the FDA will complete its review within the timelines set forth in the press release; (ii) the Company's responses to the issues raised by the FDA in its CRL will be satisfactory to the FDA; (iii) the FDA will approve the sBLA for the F8 formulation; and (iv) if approved, health care providers and patients will adopt the F8 formulation.

Forward-Looking Statements assumptions are subject to a number of risks and uncertainties, many of which are beyond the Company's 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: (i) the review period of the sBLA which could be longer than the timelines set forth in this press release, ; (ii) the non-approval of the sBLA by the FDA, or the issuance of another CRL; and (iii) the negative reception by the marketplace of the F8 formulation, if approved. The Company refers current and potential investors to the "Risk Factors" section of the Company's annual information form filed under Form 20-F dated February 21, 2024 available on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov 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 the Company's expectations as of that date.

The Company undertakes 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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