# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

July 23, 2021

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 Material Change Report Dated July 22, 2021.

#### **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: Vice President, Legal Affairs

Date: July 23, 2021

#### MATERIAL CHANGE REPORT FORM 51-102F3

#### Item 1 Name and Address of the Reporting Issuer

Theratechnologies. Inc. (the "Corporation" or "Theratechnologies" or "we/our")
2015 Peel Street, Suite 1100,
Montreal, Quebec H3A 1T8

#### Item 2 <u>Date of Material Change</u>

July 15, 2021

#### Item 3 News Release

A press release describing the material change was issued via GlobeNewswire on July 15, 2021.

A copy of the press release is also available on SEDAR at <u>www.sedar.com</u> under the Corporation's profile.

#### Item 4 Summary of Material Change

On July 15, 2021, Theratechnologies announced that discussions with the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency ("EMA") regarding its proposed trial design and protocol for its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH are complete and that the Corporation has initiated a search for a potential partner to help launch the program.

The Corporation announced that based on regulatory discussions, the final Phase 3 clinical trial design will result in higher costs than what the Corporation had previously estimated, and that as a result of the total cost of the Phase 3 clinical trial, the Corporation is now evaluating its options to best execute its late-stage development program, including seeking a potential partner. An external U.S.-based biopharma advisory firm has been retained to assist in identifying a potential partner. Partner identification and negotiations will alter the initiation of the Phase 3 clinical trial that was previously expected to begin in the third quarter of calendar year 2021.

#### Item 5 Full Description of Material Change

On July 15, 2021, Theratechnologies announced that discussions with the FDA and the EMA regarding its proposed trial design and protocol for its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH are complete and that the Corporation has initiated a search for a potential partner to help launch the program.

The Corporation announced that based on regulatory discussions, the final Phase 3 clinical trial design will result in higher costs than what the Corporation had previously estimated, and that as a result of the total cost of the Phase 3 clinical trial, the Corporation is now evaluating its options to best execute its late-stage development program, including seeking a potential partner. An external U.S.-

based biopharma advisory firm has been retained to assist in identifying a potential partner. Partner identification and negotiations will alter the initiation of the Phase 3 clinical trial that was previously expected to begin in the third quarter of calendar year 2021.

#### **Forward-Looking Information**

This document 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 document include, but are not limited to, statements regarding the conduct of our clinical trials with tesamorelin for the treatment of NASH, the potential approval by regulatory agencies of tesamorelin for the treatment of NASH, and the potential benefits to be derived from the addition of a partner for our Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH.

Although the Forward-Looking Statements contained in this document are based upon what the Corporation 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: the current COVID-19 pandemic will have limited adverse effect on the Corporation's operations and its business plan; and the Corporation will be able to secure additional resources to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH.

In addition, the Corporation assumes that the totality of evidence and data resulting from the conduct of its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH will demonstrate substantial evidence of efficacy and will be highly persuasive to the FDA given that the Corporation (i) has not conducted a Phase 2 clinical trial evaluating tesamorelin in the general population suffering from NASH prior to proceeding with its Phase 3 clinical trial as the FDA and EMA recommended; and (ii) is conducting one Phase 3 clinical trial as opposed to two. The Corporation also assumes that it will be successful in obtaining approval from the EMA for tesamorelin in the treatment of NASH based on the results obtained from its Phase 3 clinical trial despite the Corporation not following the current guidelines issued by the EMA for the approval of a drug for the treatment of NASH, which guidelines provide for both (i) NASH resolution and no worsening of fibrosis and (ii) improvement of fibrosis by one stage without worsening of NASH as a primary endpoint, whereas for the purposes of meeting the FDA's primary endpoint, only NASH resolution and no worsening of fibrosis will be relevant.

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, those related to or arising from: the adverse impact of the COVID-19 pandemic on (a) the Corporation's sales efforts and sales initiatives,

(b) the capacity of the Corporation's suppliers to meet their obligations vis-à-vis the Corporation, (c) the Corporation's research and development activities, (d) the health of the Corporation's employees and its capacity to rely on its resources, as well as (e) global trade; the Corporation's ability to secure additional resources to initiate its Phase 3 clinical trial evaluating tesamorelin for the treatment of NASH; the Corporation's ability to successfully conduct its Phase 3 clinical trial using tesamorelin for the treatment of NASH; and the Corporation's ability to find a partner on terms satisfactory to the Corporation.

In addition to the risks inherent to the conduct of clinical trials, there exist risks that the FDA will not approve tesamorelin for the treatment of NASH without the Corporation having substantial evidence and data from the conduct of Phase 2 clinical trials evaluating tesamorelin for the treatment of NASH in the general population and solely relying on data emanating from the conduct of one Phase 3 clinical trial. There is also risk that the FDA may require additional clinical trials to be conducted in order to obtain approval. Moreover, there exist risks that the EMA will not approve tesamorelin for the treatment of NASH because the trial design that the Corporation intends to pursue does not include the primary endpoint required under the current EMA guidelines.

We refer current and potential investors to the "Risk Factors" section of our Annual Information Form dated February 24, 2021 available on SEDAR at <a href="www.sedar.com">www.sedar.com</a> and on EDGAR at <a href="www.sec.gov">www.sec.gov</a> as an exhibit to our report on Form 40-F dated February 25, 2021 under Theratechnologies' public filings for additional risks related to the Corporation. 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.

#### Item 6 Reliance on subsection 7.1(2) of Regulation 51-102

Not applicable.

#### Item 7 Omitted Information

Not applicable.

#### Item 8 <u>Executive Officer</u>

Inquiries in respect of the material change referred to herein may be made to:

Jocelyn Lafond Vice President, Legal Affairs <a href="mailto:communications@theratech.com">communications@theratech.com</a> 514-336-7800

### Item 9 Date of Report

July 22, 2021