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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 14, 2020

TRICIDA, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**001-38558**	**46-3372526**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

7000 Shoreline Court
Suite 201
South San Francisco, CA 94080
(Address of principal executive offices) (Zip Code)
(415) 429-7800
(Registrant's telephone number, including area code)
N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

Title of each class	**Trading Symbol(s)**	**Name of exchange on which registered**
Common stock, par value $0.001 per share	TCDA	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

Tricida, Inc. (the “Company”) submitted its New Drug Application (the “NDA”) for veverimer to the U.S. Food and Drug Administration (the “FDA”) through the Accelerated Approval Program in August 2019. The filing communication letter, also referred to as the Day 74 Letter, confirmed that the NDA had been accepted for review by the FDA through the Accelerated Approval Program and set a user fee goal date of August 22, 2020 under the Prescription Drug User Fee Act (the "PDUFA"). The Company is conducting an ongoing confirmatory postmarketing trial, VALOR-CKD (also known as TRCA-303), as part of the Accelerated Approval Program. On July 14, 2020, the Company received a notification from the FDA (the “Notification”) stating that, as part of its ongoing review of the Company’s NDA, the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The FDA stated that the Notification does not reflect a final decision on the information under review.

The Notification does not specify the deficiencies identified by the FDA. The Company plans to work with the FDA to identify and seek to resolve the deficiencies. The Company has no current plans to modify or suspend its ongoing confirmatory postmarketing trial, VALOR-CKD. However, at the time the Company is unable to evaluate whether it will be able to address the FDA's concerns.

On July 15, 2020, the Company issued a press release announcing its receipt of the Notification. A copy of the Company’s press release is filed herewith as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

By filing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report is intended to be considered in the context of the Company’s filings with the U.S. Securities and Exchange Commission (the “Commission”) and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Commission, through press releases or through other public disclosure.

Forward Looking Statements

This current report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 (“Exchange Act”). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as “projects,” “believes,” “anticipates,” “plans,” “expects,” “intends,” “may,” “will,” “could,” “should,” “would,” and similar words and expressions are intended to identify forward-looking statements. Any statements contained herein which do not describe historical facts, including, statements regarding the potential receipt and timing of the FDA’s approval of the NDA, the Company’s expectations with regard to its interactions and communications with the FDA, plans, and expectations as to the PDUFA date are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, without limitation, any deficiencies the FDA may identify with respect to veverimer and whether the Company will be able to address the issues that may relate to those deficiencies, the receipt of regulatory approval for veverimer, the Company’s ability to market and sell veverimer, if approved, the Company’s ability to manufacture veverimer, and risks associated with our business prospects, financial results and business operations. These and other factors that may affect our future business prospects, results and operations are identified and described in more detail in our filings with the Securities and Exchange Commission (the “SEC”), including the Company’s most recent Annual Report filed on Form 10-K and our subsequently filed Quarterly Report(s) on Form 10-Q. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this filing. Except as required by applicable law, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

Item 9.01 **Financial Statements and Exhibits.**

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release, dated July 15, 2020, issued by the Company.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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 hereunto duly authorized.

Dated: July 15, 2020

TRICIDA, INC.

By: /s/ Geoffrey M. Parker

Name: Geoffrey M. Parker

Title: Chief Financial Officer and Executive Vice President

EXHIBIT 99.1

FOR IMMEDIATE RELEASE

Tricida Provides Regulatory Update on Veverimer

SOUTH SAN FRANCISCO, Calif., July 15, 2020 (Business Wire) — Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with chronic kidney disease (CKD), announced today that on July 14, 2020, the Company received a notification from the U.S. Food and Drug Administration (FDA) stating that, as part of its ongoing review of the Company's New Drug Application (NDA), the FDA has identified deficiencies that preclude discussion of labeling and postmarketing requirements/commitments at this time. The FDA stated that the notification does not reflect a final decision on the information under review.

The notification does not specify the deficiencies identified by the FDA. The Company plans to work with the FDA to identify and seek to resolve the deficiencies. The Company has no current plans to modify or suspend its ongoing confirmatory postmarketing trial, VALOR-CKD. However, at this time the Company is unable to evaluate whether it will be able to address the FDA's concerns.

"We are surprised and disappointed by this news," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We continue to believe in the potential of veverimer to be disease modifying and our goal is to work with FDA to identify and resolve the issues in order to bring veverimer to patients."

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its drug candidate, veverimer (TRC101), a non-absorbed, orally-administered polymer designed to treat metabolic acidosis in patients with CKD. Metabolic acidosis is a condition commonly caused by CKD that is believed to accelerate the progression of kidney deterioration. It is estimated to pose a health risk to approximately three million patients with CKD in the United States. Tricida is currently conducting its confirmatory postmarketing trial, VALOR-CKD, of veverimer. The Tricida NDA for veverimer has been accepted for review by the FDA through the Accelerated Approval Program. The FDA has assigned a PDUFA goal date of August 22, 2020.

For more information about Tricida, please visit www.Tricida.com.

Cautionary Note on Forward-Looking Statements

This current report on Form 8-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 (“Exchange Act”). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as “projects,” “believes,” “anticipates,” “plans,” “expects,” “intends,” “may,” “will,” “could,” “should,” “would,” and similar words and expressions are intended to identify forward-looking statements. Any statements contained herein which do not describe historical facts, including, statements regarding the potential receipt and timing of the FDA’s approval of the NDA, the Company’s expectations with regard to its interactions and communications with the FDA, plans, and expectations as to the PDUFA date are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include, without limitation, any deficiencies the FDA may identify with respect to veverimer and whether the Company will be able to address the issues that may relate to those deficiencies, the receipt of regulatory approval for veverimer, the Company’s ability to market and sell veverimer, if approved, the Company’s ability to manufacture veverimer, and risks associated with our business prospects, financial results and business operations. These and other factors that may affect our future business prospects, results and operations are identified and described in more detail in our filings with the Securities and Exchange Commission (the “SEC”), including the Company’s most recent Annual Report filed on Form 10-K and our subsequently filed Quarterly Report(s) on Form 10-Q. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this filing. Except as required by applicable law, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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