

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): September 4, 2019

TRICIDA, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-38558

(Commission File Number)

46-3372526

(I.R.S. Employer Identification Number)

**7000 Shoreline Court
Suite 201**

South San Francisco, CA 94080
(Address of principal executive offices)

(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))
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Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

On September 4, 2019, Tricida, Inc., issued a press release announcing that it has submitted a New Drug Application to the U.S. Food and Drug Administration under the Accelerated Approval Program for approval of veverimer (TRC101) for the treatment of metabolic acidosis in patients with chronic kidney disease. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release



Tricida Announces Submission of New Drug Application for Veverimer for the Treatment of Metabolic Acidosis in Patients with Chronic Kidney Disease

NDA Submitted under the FDA's Accelerated Approval Program

SOUTH SAN FRANCISCO, Calif., September 4, 2019 (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 it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) under the Accelerated Approval Program for approval of veverimer for the treatment of metabolic acidosis in patients with CKD.

The NDA submission is supported by data from Tricida's successful Phase 3 clinical trials that were recently published in back-to-back publications in *The Lancet* (March 2019 and June 2019).

"This submission under the FDA's Accelerated Approval Program could provide the first and only FDA-approved therapy to this underserved population of patients with chronic kidney disease and metabolic acidosis," said Gerrit Klaerner, PhD, Tricida's Founder, Chief Executive Officer and President. "We are grateful for the patients who participated in our clinical trials, our clinical investigators and the entire Tricida team who have made this journey possible. It is notable that the process from generating the idea to treat metabolic acidosis to the in-house discovery, development and NDA submission of veverimer was achieved in less than 6 years. We now look forward to the potential approval and launch of veverimer next year."

About Metabolic Acidosis

Metabolic acidosis is a chronic condition commonly caused by CKD and is believed to accelerate the progression of kidney deterioration. Metabolic acidosis is estimated to pose a health risk to approximately three million patients with CKD in the United States and currently there are no FDA-approved chronic therapies for treating metabolic acidosis. Metabolic acidosis is a serious condition in which the body has accumulated too much acid and occurs when a patient's kidneys can no longer excrete sufficient acid or produce enough bicarbonate to balance acid production. The prevalence and severity of metabolic acidosis in people with CKD progressively rises as kidney function declines. As a chronic condition, metabolic acidosis is associated with an increased risk of CKD progression and death. It is also associated with an increased risk of muscle wasting and loss of bone density.

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. Tricida is currently conducting its confirmatory postmarketing trial, VALOR-CKD, of veverimer. As announced today, Tricida has submitted an NDA seeking approval of veverimer through the FDA's Accelerated Approval Program.

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

Cautionary Note on Forward-Looking Statements

This press release includes forward-looking statements, including for example, the approval of our NDA submission for veverimer under the FDA's Accelerated Approval Program and the potential timing of the approval and commercial launch of veverimer. Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, among others, the cost, timing and results of clinical trials and other studies; that many drug candidates that have completed Phase 3 trials do not become approved drugs on a timely or cost effective basis, or at all; there can be no assurance that the FDA will approve our NDA for veverimer under the Accelerated Approval Program, or at all, and even if approval for veverimer is obtained, there can be no assurance that it will be adopted in the market or accepted as a benefit to patients and healthcare providers; possible safety and efficacy concerns; and that we completely rely on third-party suppliers and manufactures. These and other factors that may affect our future results of operations are identified and described in more detail in our filings with the Securities and Exchange Commission (the "SEC"), including our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2019, filed with the SEC on August 8, 2019. You should not place undue reliance on these forward-looking statements. The forward-looking statements contained in this press release reflect Tricida's current views with respect to future events, and Tricida does not undertake and specifically disclaims any obligation to update any forward-looking statements.

Contact:

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Source: Tricida, Inc.