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): May 19, 2022

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.

On May 19, 2022, Tricida, Inc. issued a press release announcing that it is stopping its VALOR-CKD renal outcomes trial early for administrative reasons pursuant to the existing study protocol to allow for six months of financial runway following the reporting of top-line results, currently anticipated to occur in the fourth quarter of 2022. The press release is attached as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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

Dated: May 19, 2022

TRICIDA, INC.

By: /s/ Geoffrey M. Parker

Name: Geoffrey M. Parker

Title: Chief Operating Officer, Chief Financial Officer and Executive Vice Presic

Exhibit 99.1

FOR IMMEDIATE RELEASE

Tricida Announces Administrative Stop of the VALOR-CKD Trial

Expects to Announce Top-Line Results Early in the Fourth Quarter of 2022

SOUTH SAN FRANCISCO, Calif., May 19, 2022 — Tricida, Inc. (Nasdaq: TCDA) announced today that as anticipated it is stopping its VALOR-CKD renal outcomes trial early for administrative reasons pursuant to the existing study protocol to allow for six months of financial runway following the reporting of top-line results, currently anticipated to occur early in the fourth quarter of 2022.

As of May 18, 2022, the average treatment duration of the 1480 subjects randomized in the trial was approximately 25 months, and the trial had accrued 237 subjects with positively adjudicated primary endpoint events, defined as renal death, end-stage renal disease (ESRD), or greater than or equal to 40% reduction in estimated glomerular filtration rate (eGFR). The trial will continue to accrue primary endpoint events as clinical trial subjects complete their participation in the study which, for the last subject, is currently projected to occur in the third quarter of 2022.

“We have previously received feedback from the FDA on the administrative stop and believe that stopping the VALOR-CKD trial early will allow us to obtain interpretable data from the trial. We expect this data will allow us to evaluate how treatment with veverimer impacts slowing of CKD progression in patients with metabolic acidosis and CKD,” said Gerrit Klaerner, Ph.D., Tricida’s Chief Executive Officer and President.

About the VALOR-CKD Renal Outcomes Trial

The VALOR-CKD trial was initiated in the fourth quarter of 2018. It is a multi-center, randomized, placebo-controlled trial designed to evaluate veverimer’s ability to slow CKD progression in patients with metabolic acidosis and CKD. It is being conducted in over 200 clinical trial sites in 34 countries.

Tricida announced in November 2021 that there was a substantial likelihood that it would not have adequate resources or be able to obtain such resources on reasonable terms in the necessary timeframe to continue the VALOR-CKD trial to reach the protocol-specified target of 511 subjects with positively adjudicated primary endpoint events, which Tricida anticipated would not be reached until 2024. Tricida corresponded with the U.S. Food and Drug Administration (FDA) regarding approaches to stop the

VALOR-CKD trial early based on its financial resources and the procedures for study close-out. Consistent with feedback provided by the FDA, Tricida concluded that stopping the VALOR-CKD trial early for administrative reasons pursuant to the existing protocol would likely provide the most complete and interpretable data, reduce the risk of missing data required for key efficacy analyses, and maintain the integrity of the trial. The exact timing of the administrative stop has been determined by the company's financial runway. Tricida's goal with respect to the timing of the administrative stop has been to have approximately six months of financial runway upon receipt of the VALOR-CKD data.

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer, a non-absorbed, orally-administered polymer designed to slow CKD progression in patients with metabolic acidosis and CKD. Tricida is currently conducting a renal outcomes clinical trial, VALOR-CKD, to determine if veverimer slows CKD progression in patients with metabolic acidosis associated 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 4.3 million patients with CKD in the United States. There are currently no therapies approved by the FDA to slow progression of kidney disease by correcting chronic metabolic acidosis in patients with CKD.

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

Cautionary Note on Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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. These forward-looking statements include, but are not limited to, all of the statements about the Company's plans and expectations for the VALOR-CKD trial, including event accrual rates for the trial and the estimated timing for receipt of top-line data and its evaluability, and the Company's expectations regarding financial runway. Forward-looking statements 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, the Company's plans and expectations with regard to its interactions with the FDA, including the potential resubmission of an NDA for veverimer; the timing of the FDA's approval of veverimer, if at all; the Company's plans and expectations for its VALOR-CKD trial and future clinical and product development milestones; the Company's contractual and financial obligations to our key suppliers and vendors; the Company's financial projections and cost estimates; the Company's ability to raise additional funds; risks associated with the ongoing conflict in Ukraine; and risks associated with the Company's business prospects, financial results and business operations.

These and other factors that may affect the Company's future business prospects, results and operations are identified and described in more detail in the Company's filings with the Securities and Exchange Commission (the "SEC"), including the Company's most recent Annual Report filed on Form 10-K and the 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 press release. 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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Contact:
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