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): March 2, 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 March 2, 2022, Tricida, Inc. issued a press release providing an update on the timing of top-line VALOR-CKD data based on conflict in Ukraine.

The press release is attached as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Supplemental Risk Factor

Our clinical trial sites, including in Ukraine, may be impacted by local and regional economic, political and social conditions, including war, as well as government policies and actions, any of which could have a material adverse effect on our ability to operate clinical trials in such jurisdictions.

Recent actions taken by the Russian Federation in Ukraine and surrounding areas have destabilized the region and may have a material adverse effect on our ability to adequately conduct VALOR-CKD clinical trial procedures and maintain compliance with the trial protocol in Ukraine, due to the prioritization of hospital resources away from clinical trials, reallocation or evacuation of site staff and subjects, or as a result of government-imposed curfews, warfare, violence or other governmental action or events that restrict movement. Some patients may not be able to comply with clinical trial protocols if the conflict impedes patient movement or interrupts healthcare services. We may not be able to access sites for monitoring in regions affected by economic, political or social disruptions due to the Russian invasion of Ukraine and we may not be able to obtain data from affected sites going forward. We could also experience disruptions in our supply chain or limits to our ability to obtain sufficient investigational materials in regions affected by these actions. If our access to VALOR-CKD trial sites and data were to experience significant disruption due to these risks or for other reasons, it could have a material adverse effect on the timing of our termination of VALOR-CKD and our financial runway. The ability of the Food and Drug Administration to conduct pre-approval inspections in Ukraine or other disrupted areas could also be adversely affected. In addition, the Russian invasion of Ukraine has caused the adoption of comprehensive sanctions by, among others, the E.U., the U.S., and the U.K., which restrict a wide range of trade and financial dealings with Russia and Russian persons, as well as certain regions in Ukraine, including by imposing stricter export controls, prohibiting dealings with major Russian banks and credit institutions, and prohibiting trade with the Donetsk and Luhansk regions of Ukraine. These sanctions could also extend to Russian allies, such as Belarus, that also contain sites for VALOR-CKD. If we are unable to overcome the challenges we encounter with respect to these risks and other factors affecting companies operating in the affected region, our business operations and future prospects could be materially adversely affected.

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: March 2, 2022

TRICIDA, INC.

By: /s/ Geoffrey M. Parker

Name: Geoffrey M. Parker

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

Exhibit 99.1

FOR IMMEDIATE RELEASE

Tricida Provides Update on Timing of Top-Line Data for the VALOR-CKD Trial Based on Conflict in Ukraine

SOUTH SAN FRANCISCO, Calif., March 2, 2022 — Tricida, Inc. (Nasdaq: TCDA), a pharmaceutical company focused on the development and commercialization of its investigational drug candidate, veverimer, a non-absorbed, orally-administered polymer designed to slow chronic kidney disease (CKD) progression in patients with metabolic acidosis and CKD, announced today an update on the anticipated date for top-line data from the VALOR-CKD trial based on the ongoing events in Ukraine. Approximately fifteen percent (15%) of the patients randomized in VALOR-CKD are from Ukraine. Given the uncertainty around future participation of Ukrainian subjects in the trial and the potential challenges to collecting and monitoring data from Ukrainian sites, top-line data from the VALOR-CKD trial is now anticipated early in the fourth quarter of 2022, versus Tricida's previous guidance of the third quarter of 2022. The revised guidance is based on Tricida's evaluation of the current situation in Ukraine which is dynamic. Its estimates may change as events in Ukraine evolve. Tricida believes it will need this incremental time to deal with anticipated disruptions and/or delays in data collection. Tricida does not expect the utility of the data already collected from Ukrainian subjects to be affected. Based upon the latest review of its forecast, Tricida believes that its financial resources will extend for approximately six months following the anticipated announcement of top-line results from the VALOR-CKD trial.

As of March 1, 2022, the VALOR-CKD trial had accrued 197 subjects with positively adjudicated primary endpoint events, defined as renal death, end-stage renal disease (ESRD), or greater than or equal to a 40% decline in estimated glomerular filtration rate (eGFR), with an average treatment duration of approximately 23 months.

"We are deeply concerned for the people of Ukraine, including the VALOR-CKD patients, investigators, site staff and our CRO colleagues who we have worked with for many years. We are horrified by what they and all of the Ukrainian people are having to endure defending their homeland against a brutal Russian invasion," said Gerrit Klaerner, Ph.D., Tricida's Chief Executive Officer and President. "We believe that an incremental delay of the administrative stop is prudent to obtain interpretable data from the VALOR-CKD trial with approximately the same number of events and six-months cash runway as outlined in our prior communications."

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. There are currently no therapies approved by the FDA to slow progression of kidney disease through the treatment of chronic metabolic acidosis in patients with CKD. It is estimated to pose a health risk to approximately three million patients with CKD in the United States.

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, statements regarding the Company’s plans and expectations for the VALOR-CKD trial, including early termination of the trial, and the rate of accrual of primary endpoint events, and its expectations regarding the potential timing of the announcement of top-line date from the VALOR-CKD trial and its financial runway. These 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, developments in Ukraine and the region, the Company’s plans and expectations for its VALOR-CKD trial, including the estimated number of subjects with primary endpoints in the final analysis and the estimated timing for receipt of top-line data from that trial, 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.

#####

Contact:
Jackie Cossmon, IRC
Tricida, Inc.
Senior Vice President of
Investor Relations and Communications
IR@Tricida.com