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 28, 2019

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)

(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))

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 7.01 Regulation FD Disclosure.

On March 28, 2019, Tricida, Inc. (the "Company"), reported results from its blinded, randomized, placebo-controlled, 40-week extension trial, TRCA-301E. A copy of the press release announcing the results from the TRCA-301E trial is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release

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.

TRICIDA, INC.

Dated: March 28, 2019

By: /s/ Geoffrey M. Parker
Name: Geoffrey M. Parker
Title: Chief Financial Officer and Senior Vice President

Exhibit 99.1

Tricida Announces Positive Results from Long-Term Clinical Trial of TRC101 in Patients with CKD and Metabolic Acidosis

Blinded, randomized, placebo-controlled, 40-week extension trial, TRCA-301E, met its primary and all secondary endpoints, supporting the long-term safety and efficacy profile of TRC101

Patients treated with TRC101 showed a significant reduction in all-cause mortality and progression of CKD (defined as the composite of all-cause mortality, renal replacement therapy or a ≥ 50% decrease from baseline in eGFR) versus placebo within just one year in a prespecified analysis.

Patients treated with TRC101 showed significant improvement from baseline in measures of physical function and physical function-related quality of life versus placebo

Webcast Today at 8:00 am ET

SOUTH SAN FRANCISCO, Calif., March 28, 2019 (Business Wire) — Tricida, Inc. (NASDAQ: TCDA), a pharmaceutical company focused on the development and commercialization of its drug candidate, TRC101 (veverimer), a non-absorbed, orally-administered polymer to treat metabolic acidosis in patients with chronic kidney disease (CKD), announced today results from its blinded, randomized, placebo-controlled, multicenter clinical trial, TRCA-301E, in 196 CKD patients with metabolic acidosis. TRC101 represents a first-in-class drug candidate for the treatment of metabolic acidosis, a chronic condition commonly caused by CKD that is believed to accelerate the progression of CKD, increase the risk of muscle wasting and cause the loss of bone density. The TRCA-301E trial was a 40-week extension of the 12-week TRCA-301 trial, which randomized 217 patients with non-dialysis dependent CKD and metabolic acidosis to treatment with TRC101 (N=124) or placebo (N=93). Two hundred eight (208; 95.9%) subjects completed the 12-week treatment period in the TRCA-301 trial and had the option to continue into the extension trial and receive the same blinded treatment (TRC101 or placebo) to which they were assigned in the parent trial. One hundred ninety-six subjects (196; 94.2%), (114 in the TRC101 group and 82 in the placebo group) elected and were qualified to continue in the extension trial. One hundred eleven (111; 97.4%) subjects in the TRC101 group and 74 (90.2%) subjects in placebo group completed one year of treatment. Results from the TRCA-301 and TRCA-301E trials will support the TRC101 New Drug Application (NDA) submission planned for the second half of 2019.

Based on the initial topline data analyses, the TRCA-301E trial met its primary and all secondary endpoints. The primary endpoint of the TRCA-301E trial was the assessment of the long-term safety profile of TRC101 versus placebo. The results demonstrated that fewer subjects on TRC101 than on placebo discontinued the 40-week treatment period prematurely (2.6% versus 9.8%, respectively). The incidence of serious adverse events was 1.8% for subjects in the TRC101 group and 4.9% for subjects in the placebo group, and none were assessed to be related to study drug by the trial investigator, Medical Monitor or Drug Safety and Pharmacovigilance Team. The only adverse event with a between-group frequency difference of >5% was headache, which was more common in the placebo group.

Gastrointestinal adverse events occurred in 21.4% of subjects in the TRC101 group and in 25.9% of subjects in the placebo group.

The statistical analysis plan for the TRCA-301E trial also specified a comparison of the TRC101 and placebo groups for the time to the composite clinical endpoint of death (all-cause mortality), dialysis/kidney transplant (renal replacement therapy) or a ≥50% decline in estimated glomerular filtration rate (eGFR) (taken together, DD50) over the combined (TRCA-301 and TRCA-301E) 52-week treatment period. Of the 124 subjects randomized to the TRC101 group, 5 (4.0%) subjects had a DD50 event. There were no deaths in the TRC101 group and one TRC101-treated subject initiated dialysis during the 52-week treatment period. Of the 93 subjects randomized to the placebo group, 10 (10.8%) subjects had a DD50 event, including four subjects who died and one who initiated dialysis during the 52-week treatment period. The time to DD50 was prolonged in the TRC101 group compared to the placebo group, with an annualized DD50 incidence rate, calculated as 100 times the number of events divided by the total person-years, of 4.2% in the TRC101 group vs 12.0% in the placebo group ($p = 0.0224$).

The secondary endpoints of the TRCA-301E trial assessed the durability of effect of TRC101, both on blood bicarbonate levels and on measures of physical function, over the 52-week treatment period for those subjects who participated in the TRCA-301E trial. All were met with high statistical significance.

The durability of effect of TRC101 was assessed by comparing the changes in blood bicarbonate from baseline to Week 52 between TRC101 versus placebo subjects who completed the 52-week treatment period. Sixty-three percent of the 111 TRC101 subjects treated for 52 weeks exhibited an increase in blood bicarbonate level of at least 4 milliequivalents per liter (mEq/L) or achieved a blood bicarbonate level in the normal range of 22 to 29 mEq/L, compared with 38% of the 74 placebo subjects who completed 52 weeks of treatment ($p=0.0015$). The least squares (LS) mean change in blood bicarbonate from baseline to end of treatment in the TRC101 group was 4.7 mEq/L, compared with 2.7 mEq/L in the placebo group ($p=0.0002$). We believe these results support the long-term durability of blood bicarbonate effect of the TRC101-treated group compared to placebo.

Measures of physical function were assessed through the self-reported responses to the physical functioning subpart of the Kidney Disease and Quality of Life Short Form survey (KDQOL Physical Functioning Survey) and a repeated chair stand test. Improvement from baseline to end of treatment in the self-reported responses to the KDQOL Physical Functioning Survey was significantly greater in the TRC101 group (+11.4 points) compared to the placebo group (-0.7 points), with a between-group difference of 12.1 points in favor of TRC101 ($p<0.0001$). Improvement from baseline to end of treatment in physical function using a repeated chair stand test, which involved a timed measurement of five repetitions of moving from a seated to standing position, was also significantly greater in the TRC101 group (4.3 seconds faster) compared to the placebo group (1.4 seconds faster), with a between-group difference of 2.9 seconds in favor of TRC101 ($p<0.0001$). The placebo-adjusted improvements in favor of TRC101-treated subjects in the two measures of physical function at Week 52 approximately doubled compared to the results at Week 12 observed in the parent trial, TRCA-301. We believe the results from the KDQOL Physical Functioning Survey and the repeated chair stand test provide consistent evidence of a clinically meaningful improvement in physical function and related aspects of quality of life for TRC101-treated subjects.

“This trial provides evidence of long-term safety and tolerability of TRC101 and that the sustained increase in blood bicarbonate led to improvements in multiple clinical outcomes that matter to both patients and physicians,” said Donald E. Wesson, M.D., M.B.A., Professor of Medicine at Texas A&M Health Sciences Center College of Medicine in Dallas, TX, and the lead investigator for the trial. “Furthermore, the outcomes observed in the placebo arm of this well-controlled, multi-center trial reiterate the importance to diagnose and treat metabolic acidosis in patients with CKD.”

The TRCA-301/TRCA-301E clinical trials were not designed or powered to assess all-cause mortality and/or the progression of CKD outcomes; they enrolled only 217 subjects and followed them over a one-

year treatment period to support the long-term safety and efficacy profile of TRC101. Nevertheless, we observed a 65% reduction in the annualized event rate of the composite endpoint of all-cause mortality and/or the progression of CKD (DD50) in TRC101-treated subjects versus subjects in the placebo group.

“The 52-week TRCA-301/301E results far exceeded our expectations,” said Gerrit Klaerner, Chief Executive Officer and President of Tricida. “We did not anticipate that we would observe evidence of clinical benefit beyond the increase in blood bicarbonate in patients treated with TRC101 until the read out of the results of our postmarketing trial, VALOR-CKD, in the 2022 to 2023 timeframe. We remain committed to submitting our NDA under the Accelerated Approval Program in the second half of 2019 and look forward to the results of our VALOR-CKD confirmatory postmarketing trial.”

Today’s Conference Call and Webcast

Tricida will host a conference call and webcast at 8:00 am Eastern Time to discuss its TRCA-301E results, fourth quarter and full year 2018 financial results and other business progress. The call or webcast may be accessed as follows:

Tricida TRCA-301E Clinical Trial Results and Financial Results Conference Call

Thursday, March 28, 2019

8:00 am Eastern Time

Website: IR.Tricida.com
Dial-in: (877) 377-5478
International: (629) 228-0740
Conference ID: 1756243

A replay of the webcast will be available on Tricida’s website approximately two hours following the completion of the call and will be available for up to 90 days.

About Tricida

Tricida, Inc. is a pharmaceutical company focused on the development and commercialization of its drug candidate, 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 has successfully completed all of the clinical trials that it planned to complete prior to submission of an NDA to the U.S. Food and Drug Administration (FDA). Tricida plans to submit an NDA, in the second half of 2019, seeking approval of TRC101 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, statements about our ability to submit an NDA for TRC101 under the FDA’s Accelerated Approval Program. 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 timing of Tricida's NDA submission; 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 find that our clinical trials have provided evidence of clinical benefit; there can be no assurance that the FDA would approve an NDA under the Accelerated Approval Program, or at all, and even if approval for a drug 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 to manufacture TRC101. 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.

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