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): August 11, 2021

Summit Therapeutics Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	001-36866	37-1979717
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One Broadway, 14th Floor, Cambridge, MA	02142
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: 617-514-7149

Not Applicable
(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 (*see* General Instruction A.2. below):

☐ 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 Each Exchange on Which Registered
Common stock, $0.01 par value per share	SMMT	The Nasdaq Stock Market LLC

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 August 11, 2021, Summit Therapeutics Inc. (the "Company") issued a press release announcing that, based on a thorough review of the design and enrollment status of its two ongoing blinded Phase III Ri-CoDIFy trials, it will combine its two blinded pivotal Phase III clinical trials evaluating ridinilazole versus vancomycin into a single study.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 11, 2021.

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, thereunto duly authorized.

SUMMIT THERAPEUTICS INC.

Date: August 11, 2021

By: /s/ Robert W. Duggan
Robert W. Duggan
Chief Executive Officer

Summit Therapeutics Provides Update on Ri-CoDIFy Trials

Cambridge, Massachusetts – Based on a thorough review of the design and enrollment status of two ongoing blinded Phase III Ri-CoDIFy trials, Summit Therapeutics Inc. (NASDAQ: SMMT) today announced that it will combine its two blinded pivotal Phase III clinical trials evaluating ridinilazole versus vancomycin into a single study.

Ridinilazole, a novel first-in-class drug, is currently under investigation for use as first-line therapy for the treatment of initial and recurrent *Clostridioides difficile* infection. The trial's primary endpoint seeks to prove ridinilazole's superiority in sustained clinical response as compared to vancomycin. Ridinilazole is not currently approved for use by any regulatory authority.

Current enrollment in the two Ri-CoDIFy Phase III trials is 753 patients, split approximately evenly between each of the two trials. This enrollment level offers a unique opportunity to combine the studies, as the two ongoing trials have enrolled just over 50% of their targeted goal, are still blinded, and allow for a prospectively planned analysis.

"In spite of a worldwide healthcare, COVID-19 pandemic-driven crisis and an unprecedented challenge in enrolling patients in clinical trials in the current setting, we are proud of the enrollment achieved within these two clinical trials," said Dr. Maky Zanganeh, Summit's Chief Operating Officer and a Director of the company. "In the best interest of all Summit and Ri-CoDIFy study stakeholders, including patients, physicians, hospitals, and other facilities providing care for patients with infectious diseases, the correct and appropriate action to take at this time is to prospectively plan to combine the two Ri-CoDIFy trials and to analyze the data. A positive result from the combined study could form the basis of a presentation of the trial results to the regulatory authorities and inform further decisions on next steps."

The ridinilazole clinical program commenced with the Phase I trial beginning in 2012, a 100-patient Phase II clinical trial began in 2014, and the current Ri-CoDIFy Phase III clinical trials enrolled the first patient in February 2019.

The company recently released breakthrough Phase II clinical study data, including the relative sparing of ridinilazole on the gut microbiome as compared to vancomycin, ridinilazole's minimal impact on the gut resistome, and its novel mechanism of action[1].

"On behalf of Team Summit, we would like to express our thanks to each of our investigators, healthcare providers, patients, and the associated facilities, as well as BARDA for their collaboration and support of our clinical trials," stated Robert W. Duggan, Summit's Chairman and Chief Executive Officer. "We look forward to concluding these studies and assessing the trial data in the coming months."

This effort is funded in whole or in part with federal funds from the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, under contract number HHSO100201700014C.

[1] E. Duperchy et al. ECCMID 2021, abstract P02515; E. Duperchy et al. ECCMID 2021, abstract P03486; T. Avis et al. ECCMID 2021, abstract P03404.

About Summit Therapeutics
The overriding objective of Summit Therapeutics is to create value for patients, hospital caregivers, and community-based healthcare providers, as well as healthcare payers around the world. We seek to create value by developing drugs with high therapeutic efficacy - curing the cause of the patient's condition with minimal or zero disease recurrence or antimicrobial resistance, for the longest extent possible - and minimizing the trauma caused to the patient and healthcare ecosystem by minimizing serious side effects, disease recurrence, and inaccessibility to our treatments as a result of financial or other barriers. Summit Therapeutics, empowered by its Discuva Platform, the Company's innovative antibiotic discovery engine, and supported by BARDA and CARB-X funding, intends to be the leader in patient-friendly and paradigm-shifting treatments for infectious diseases and other significant unmet medical needs while being an ally to physicians. Our new mechanism pipeline product candidates are designed with the goal to become the patient-friendly, new-era standard of care, by working in harmony with the human microbiome to treat prospective patients suffering from infectious diseases, initially focusing on *Clostridioides difficile* infection (CDI). Currently, Summit's lead product candidate, ridinilazole, is a novel, first-in-class drug engaged in a global Phase III trial program versus vancomycin, for use as first-line therapy for the treatment of initial and recurrent *Clostridioides difficile* infection, and to show superiority in sustained clinical response. Commercialization of ridinilazole is subject to regulatory approvals. SMT-738, the second candidate within Summit's portfolio, is currently in the IND-enabling phase for the treatment of multidrug resistant infections, specifically those caused by carbapenem-resistant Enterobacteriaceae (CRE).

For more information, please visit https://www.summittxinc.com and follow us on Twitter @summitplc. For more information on the Company's Discuva Platform, please visit https://www.summittxinc.com/our-science/discuva-platform.

About *C. difficile* Infection
Clostridioides difficile, or *C. difficile,* infection (CDI) is a bacterial infection of the colon that produces toxins causing inflammation of the colon, severe watery diarrhea, painful abdominal cramping, nausea, fever, and dehydration. CDI can also result in more serious disease complications, including bowel perforation, sepsis, and death. CDI is a contagious infectious disease that represents a serious healthcare issue in hospitals, long-term care facilities, and the wider community. Summit estimates that there are approximately 500,000 cases of CDI each year across the United States with acute care costs exceeding $5.4 billion in the US based on a meta-analysis published in the *Journal of Global Health*, June 2019.

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Summit Forward-looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including but not limited to, statements about the clinical and preclinical development of the Company's product candidates, the therapeutic potential of the Company's product candidates, the potential commercialization of the Company's product candidates, the timing of initiation, completion and availability of data from clinical trials, the potential submission of applications for marketing approvals, the impact of the COVID-19 pandemic on the Company's operations and clinical trials and other statements containing the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation of future clinical trials, availability and timing of data from ongoing and future clinical trials and the results of such trials, global public health crises, including the coronavirus COVID-19 outbreak, that may affect timing and status of our clinical trials and operations, whether preliminary results from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials or preclinical studies will be indicative of the results of later clinical trials, expectations for regulatory approvals, laws and regulations affecting government contracts and funding awards, availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements and other factors discussed in the "Risk Factors" section of filings that the Company makes with the Securities and Exchange Commission. Any change to our ongoing trials could cause delays, affect our future expenses, and add uncertainty to our commercialization efforts, as well as to affect the likelihood of the successful completion of clinical development of ridinilazole. Accordingly, readers should not place undue reliance on forward-looking statements or information. In addition, any forward-looking statements included in this press release represent the Company's views only as of the date of this release and should not be relied upon as representing the Company's views as of any subsequent date. The Company specifically disclaims any obligation to update any forward-looking statements included in this press release.