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

September 2, 2021
Date of Report (Date of earliest event reported)

Forte Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38052**	**26-1243872**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1124 W Carson Street **MRL Building 3-320** **Torrance, California**	**90502**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (310) 618-6994

(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 obligations 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 each exchange on which registered
Common Stock, par value $0.001 per share	**FBRX**	**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 September 2, 2021, Forte Biosciences, Inc. (the "Company") issued a press release announcing its Phase 2 clinical trial of FB-401 for the treatment of atopic dermatitis failed to meet statistical significance for the primary endpoint of EASI-50 (the proportion of patients with at least a 50% improvement in atopic dermatitis disease severity as measure by EASI). The full text 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 No.	Description
99.1	Press Release dated September 2, 2021

SIGNATURES

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 hereunto duly authorized.

FORTE BIOSCIENCES, INC.

Date: September 2, 2021

By: /s/ Antony Riley
Antony Riley
Chief Financial Officer

Exhibit 99.1

FORTE BIOSCIENCES, INC

CLINICAL TRIAL OF FB-401 FOR THE TREATMENT OF ATOPIC DERMATITIS FAILS TO MEET STATISTICAL SIGNIFICANCE

TORRANCE, CA – SEPTEMBER 2, 2021 – Forte Biosciences, Inc. (www.fortebiorx.com) (NASDAQ: FBRX), a clinical-stage biopharmaceutical company, today announced that topline data from its Phase 2 clinical trial of FB-401 for the treatment of atopic dermatitis failed to meet statistical significance for the primary endpoint of EASI-50 (the proportion of patients with at least a 50% improvement in atopic dermatitis disease severity as measure by EASI).

Positive trends were observed in key secondary endpoints including EASI-90 with 27.6% of subjects in the active arm achieving the EASI-90 endpoint compared to 20.5% in the control arm (p=0.3075) and in IGA success (2 point reduction and clear or almost clear) with 38.2% of active subjects achieving success compared to 29.5% in the placebo arm (p=0.2599). The primary endpoint of EASI-50 was achieved by 58% of subjects on FB-401 compared to 60% of subjects on placebo (p=0.7567).

“We are appreciative of the clinical trial sites and the patients for participating in this trial and we are grateful to our investors for taking the risk to support the advancement of a new therapeutic modality for atopic dermatitis.” said Paul Wagner, Ph.D., CEO of Forte Biosciences. “The topline data is disappointing and we will continue to analyze the data; however, given this readout we will not continue to advance FB-401. We expect to provide investors with an update on the future plans for the company over the next several months.”

Forte Biosciences previously reported that it had cash and cash equivalents of $50.8 million as of June 30, 2021.

Given the release of the topline data today, Forte Biosciences will no longer be hosting a conference call on September 7, 2021 as previously announced.

About Forte

Forte Biosciences, Inc. is a clinical-stage, biopharmaceutical company developing a live biotherapeutic, FB-401, for the treatment of inflammatory skin diseases. For more information, please visit www.fortebiorx.com.

Forward Looking Statements

Forte cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negatives of these terms or other similar expressions. These statements are based on the Forte’s current beliefs and expectations. Forward looking statements include statements regarding Forte’s beliefs, goals, intentions and expectations regarding FB-401. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which

include, without limitation: risks related to Forte's ability to obtain sufficient additional capital to continue to advance Forte's product candidates and preclinical programs; uncertainties associated with the clinical development and regulatory approval of Forte's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; the risk that interim results of clinical trials do not necessarily predict final results and that one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, and as more patient data become available; the risk that unforeseen adverse reactions or side effects may occur in the course of developing and testing product candidates; risks associated with the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; and risks related to the impact of the COVID-19 outbreak on Forte's operations, the biotechnology industry and the economy generally. Information on these and additional risks, uncertainties, and other information affecting Forte's business and operating results is contained in Forte's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on August 16, 2021 and in its other filings with the Securities and Exchange Commission. All forward-looking statements in this press release are current only as of the date hereof and, except as required by applicable law, Forte undertakes no obligation to revise or update any forward-looking statement, or to make any other forward-looking statements, whether as a result of new information, future events or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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