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

November 9, 2020
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 2.02. Financial Statements and Exhibits

On November 9, 2020, Forte Biosciences, Inc. issued a press release reporting its financial results for the third quarter ended September 30, 2020. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished in this Current Report under Item 2.02 and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be 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 dated November 9, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: November 9, 2020

By: /s/ Paul Wagner
Paul Wagner
Chief Executive Officer

Exhibit 99.1

FORTE BIOSCIENCES, INC

FORTE BIOSCIENCES, INC. ANNOUNCES THIRD QUARTER 2020 RESULTS AND PROVIDES GENERAL BUSINESS UPDATE

TORRANCE, CA – NOVEMBER 9, 2020 – Forte Biosciences, Inc. (www.fortebiorx.com) (NASDAQ: FBRX), a clinical-stage biopharmaceutical company, today announced third quarter 2020 financial results and provided a general business update.

"This was an eventful quarter for Forte with significant progress in advancing FB-401 for the treatment of atopic dermatitis." said Paul Wagner, Ph.D., CEO of Forte Biosciences "The initiation of our randomized trial in atopic dermatitis patients, including adults and children 2 years of age and older, was a pivotal event and the achievement of this important milestone was the result of a fantastic effort by the Forte team. There is a significant need for safe and effective atopic dermatitis therapies, particularly for children, and we were pleased by the FDA's recognition of this unmet need with the granting of Fast Track designation to FB-401 for the treatment of atopic dermatitis."

Third Quarter 2020 Results

Business Highlights

In September 2020, Forte initiated a multi-center, placebo controlled clinical trial of our lead product candidate, FB-401 which is expected to enroll pediatric, adolescent and adult atopic dermatitis ("AD") subjects aged 2 years of age and older. For additional information about the trial, see ClinicalTrials.gov using the identifier NCT04504279.

In October 2020, the U.S. Food and Drug Administration ("FDA") granted Fast Track Designation to FB-401 for the treatment of atopic dermatitis.

Forte Biosciences ended the quarter with approximately $20.2 million in cash which the company believes is sufficient to fund operations for at least the next 12 months. Approximately $2.4 million of the cash utilization in the quarter was due to merger related costs. Forte had 11.2 million shares of common stock outstanding as of September 30, 2020. Following the close of the quarter, Forte raised $46.0 million in gross proceeds from a public offering on November 2nd.

Operating Results

Research and development expenses were $3.7 million and $7.0 million for the three and nine months ended September 30, 2020, respectively, compared to $0.4 million and $1.5 million for the comparable periods in 2019. The increases in 2020 were primarily due to manufacturing costs and clinical development costs as we continue to advance FB-401.

General and administrative expenses were $1.3 million and $2.8 million for the three and nine months ended September 30, 2020, respectively, compared to $0.3 million and $1.0 million for the comparable periods in 2019. The increases in 2020 were primarily due to professional fees for legal, auditing, tax and business consulting services, and personnel expenses as we transitioned to being a public company.

In 2Q 2020, we recognized a charge of $32.1 million for acquired in-process research and development related to the reverse merger with Tocagen which closed on June 15th.

FORTE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 3,688	$ 353	$ 6,979	$ 1,526
General and administrative	1,320	331	2,753	974
In process research and development assets acquired	—	—	32,057	—
Total operating expenses	5,008	684	41,789	2,500
Loss from operations	(5,008)	(684)	(41,789)	(2,500)
Other income (expenses)	(92)	(6)	(122)	(5)
Net loss	$ (5,100)	$ (690)	$ (41,911)	$ (2,505)
Per share information:				
Net loss per share - basic and diluted	$ (0.45)	$ (0.33)	$ (7.36)	$ (1.19)
Weighted average shares outstanding, basic and diluted	11,209,052	2,108,266	5,691,587	2,108,266

Additional detail on our financial results for the third quarter 2020 can be found in our Form 10-Q as filed today with the SEC. You can also find more information in the investor relations section of our website at www.fortebiorx.com.

Conference Call and Webcast Information

The Forte management will host a conference call and webcast today at 4:30 PM Eastern Time. Participants may access the call by dialing 877-705-6003 (Domestic) or 201-493-6725 (International), the conference ID number is: 13712591. The call will also be webcast and can be accessed from the investor relations section of Forte's website at https://www.fortebiorx.com/ or http://public.viavid.com/index.php?id=142246. A replay of the call will also be available through November 16th.

About Forte

Forte Biosciences, Inc. is a clinical stage, dermatology company developing a live biotherapeutic, FB-401, for the treatment of inflammatory skin diseases. FB-401 has completed Phase 1/2a testing in adult and pediatric (3 years of age and older) patients with atopic dermatitis. There is a significant unmet need for safe and effective therapies particularly for pediatric atopic dermatitis patients. In September 2020, Forte initiated a multi-center, placebo controlled clinical trial of FB-401 which is expected to enroll approximately 124 pediatric, adolescent and adult AD subjects aged 2 years of age and older. For additional information about the trial, see ClinicalTrials.gov using the identifier NCT04504279.

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 Company’s current beliefs and expectations. Forward looking statements include statements regarding Forte’s beliefs, goals, intentions and expectations regarding the potential of Fast Track designation to accelerate development and approval of FB-401and achieve potential clinical development milestones in the future. 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 September 30, 2020 filed with the Securities and Exchange Commission on November 9, 2020 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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