# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended June 30, 2020**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from to**

**Commission File Number: 001-38052**

# FORTE BIOSCIENCES, INC.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware**<br>**(State or other jurisdiction of incorporation or organization)** | **26-1243872**<br>**(I.R.S. Employer Identification No.)** |
|---|---|
| **1124 W Carson Street**<br>**MRL Building 3-320**<br>**Torrance, California**<br>**(Address of principal executive offices)** | **90502**<br>**(Zip Code)** |

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

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 | FBRX | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☒ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☒ |
| 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. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 4, 2020, the registrant had 11,204,844 shares of common stock, $0.001 par value per share, outstanding.

**Table of Contents**

## PART I – FINANCIAL INFORMATION

## Item 1: Financial Statements

**FORTE BIOSCIENCES, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(in thousands, except share and par value data)**

| | June 30, 2020 (unaudited) | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ 27,749 | $ 6,939 |
| Prepaid expenses and other current assets | 395 | 567 |
| Total current assets | 28,144 | 7,506 |
| Property and equipment, net | 124 | 152 |
| Other assets | 43 | - |
| **Total assets** | $ 28,311 | $ 7,658 |
| | | |
| **Liabilities, convertible preferred stock and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,567 | $ 1,569 |
| Accrued liabilities | 866 | 343 |
| Total current liabilities | 3,433 | 1,912 |
| | | |
| **Commitments and contingencies (Note 5)** | | |
| Series A Convertible Preferred Stock, $0.001 par value; 10,000,000 shares authorized and 0 and 3,177,744 shares issued and outstanding as of June 30, 2020 (unaudited) and December 31, 2019, respectively; aggregate liquidation preference of $10,820,773 as of December 31, 2019 | - | 10,515 |
| Stockholders' equity (deficit): | | |
| Common stock, $0.001 par value: 200,000,000 shares authorized as of June 30, 2020 (unaudited) and December 31, 2019; 11,198,315 and 2,108,266 shares issued and outstanding at June 30, 2020 (unaudited) and December 31, 2019, respectively | 11 | 2 |
| Additional paid-in capital | 66,648 | 199 |
| Accumulated deficit | (41,781) | (4,970) |
| Stockholders' equity (deficit): | 24,878 | (4,769) |
| **Total liabilities, convertible preferred stock and stockholders' equity (deficit)** | $ 28,311 | $ 7,658 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

| | Three Months Ended | | Six Months Ended | |
|---|---|---|---|---|
| | June 30, 2020 | June 30, 2019 | June 30, 2020 | June 30, 2019 |
| Operating expenses: | | | | |
| Research and development | $ 1,937 | $ 310 | $ 3,291 | $ 1,173 |
| General and administrative | 760 | 319 | 1,433 | 643 |
| In process research and development assets acquired | 32,057 | - | 32,057 | - |
| Total operating expenses | 34,754 | 629 | 36,781 | 1,816 |
| Loss from operations | (34,754) | (629) | (36,781) | (1,816) |
| Other income (expenses) | (7) | (1) | (30) | 1 |
| Net loss | $ (34,761) | $ (630) | $ (36,811) | $ (1,815) |
| Per share information: | | | | |
| Net loss per share - basic and diluted | $ (9.52) | $ (0.30) | $ (12.77) | $ (0.86) |
| Weighted average shares outstanding, basic and diluted | 3,650,422 | 2,108,266 | 2,882,819 | 2,108,266 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**FORTE BIOSCIENCES, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
**(unaudited)**
**(in thousands, except share data)**

| | Series A Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | |
| **Balance — December 31, 2018** | 1,738,759 | $ 5,659 | 2,108,266 | $ 2 | $ 163 | $ (901) | $ (736) |
| Issuance of Series A convertible preferred stock, net of issuance cost of $44 | 1,438,985 | 4,856 | - | - | - | - | - |
| Stock based compensation | - | - | - | - | 2 | - | 2 |
| Net loss | - | - | - | - | - | (1,185) | (1,185) |
| **Balance — March 31, 2019** | 3,177,744 | 10,515 | 2,108,266 | 2 | 165 | (2,086) | (1,919) |
| Stock based compensation | - | - | - | - | 1 | - | 1 |
| Net loss | - | - | - | - | - | (630) | (630) |
| **Balance — June 30, 2019** | 3,177,744 | $ 10,515 | 2,108,266 | $ 2 | $ 166 | $ (2,716) | $ (2,548) |
| | | | | | | | |
| **Balance — December 31, 2019** | 3,177,744 | $ 10,515 | 2,108,266 | $ 2 | $ 199 | $ (4,970) | $ (4,769) |
| Exercise of employee stock options | - | - | 52,706 | - | 45 | - | 45 |
| Stock based compensation | - | - | - | - | 2 | - | 2 |
| Net loss | - | - | - | - | - | (2,050) | (2,050) |
| **Balance — March 31, 2020** | 3,177,744 | 10,515 | 2,160,972 | 2 | 246 | (7,020) | $ (6,772) |
| Conversion of preferred stocks into common stock | (3,177,744) | (10,515) | 3,177,744 | 3 | 10,512 | - | 10,515 |
| Sale of common stock, net of issuance costs of $43 | | | 4,215,929 | 4 | 24,012 | - | 24,016 |
| Issuance of common stock in connection with reverse merger | - | - | 1,656,076 | 2 | 31,807 | - | 31,809 |
| Restricted stock awards withholdings for taxes | - | - | (16,294) | - | - | - | - |
| Exercise of employee stock options | - | - | 3,888 | - | 47 | - | 47 |
| Stock based compensation | - | - | - | - | 24 | - | 24 |
| Net loss | - | - | - | - | - | (34,761) | (34,761) |
| **Balance — June 30, 2020** | - | $ - | 11,198,315 | $ 11 | $ 66,648 | $ (41,781) | $ 24,878 |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**FORTE BIOSCIENCES, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(unaudited)**
**(in thousands)**

| | Six Months Ended June 30, 2020 | Six Months Ended June 30, 2019 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Net loss | $ (36,811) | $ (1,815) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| In process research and development acquired | 30,885 | - |
| Depreciation expense | 27 | - |
| Stock based compensation expense | 26 | 3 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 1,385 | 20 |
| Accounts payable | 959 | 124 |
| Accrued liabilities | (3,352) | 103 |
| Net cash used in operating activities | (6,881) | (1,565) |
| **Cash flows from investing activities:** | | |
| Cash and restricted cash acquired in reverse merger | 3,583 | - |
| Net cash provided by investing activities | 3,583 | - |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of common stock, net of issuance costs | 24,016 | - |
| Proceeds from issuance of convertible preferred stock, net of issuance costs | - | 4,856 |
| Proceeds from exercise of employee stock options | 92 | - |
| Net cash provided by financing activities | 24,108 | 4,856 |
| Net increase in cash and restricted cash | 20,810 | 3,291 |
| Cash — beginning of period | 6,939 | 5,016 |
| Cash — end of period | $ 27,749 | $ 8,307 |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Conversion of preferred stock to common stock | $ 10,515 | $ - |
| Issuance of common stock to Tocagen shareholders | $ 31,809 | $ - |

The accompanying notes are an integral part of these condensed consolidated financial statements.

## 1. Organization and Description of Business

Forte Biosciences, Inc. (www.fortebiorx.com), together with its subsidiary referred to herein as the "Company", is a clinical-stage biopharmaceutical company focused on advancing its clinical program and developing a live biotherapeutic for the treatment of inflammatory skin diseases, particularly for pediatric atopic dermatitis patients for which there is currently a significant unmet need for safe and effective therapies. The Company entered into a business combination ("Merger") between Forte Subsidiary, Inc. ("Forte Subsidiary") a private entity, and Tocagen, Inc. ("Tocagen"), a publicly traded biotechnology company. The Merger closed on June 15, 2020, in which Telluride Merger Sub, Inc., a wholly-owned subsidiary of Tocagen, merged with and into Forte Subsidiary, with Forte Subsidiary surviving the Merger as a wholly-owned subsidiary of Tocagen. Immediately prior to the closing of the Merger, the shares of Tocagen common stock were adjusted with a reverse split ratio of 1-for-15. At the closing of the Merger, each share of Forte Subsidiary common stock outstanding immediately prior to the Merger was converted into the right to receive approximately 3.1624 shares of Tocagen common stock (before giving effect to the reverse split). All share and per share amounts have been retrospectively adjusted to give effect to the exchange of Forte Subsidiary common stock and the reverse split of Tocagen common stock. The par value per share of our capital stock was not adjusted as a result of the stock split. Immediately prior to the closing of the Merger, Tocagen changed its name to Forte Biosciences, Inc. The Company's common stock is traded on the Nasdaq stock exchange under the ticker symbol "FBRX." Immediately following the Merger, the former Forte Subsidiary and Tocagen security holders owned approximately 84.7% and 15.3% of the number of shares of the Company's common stock, respectively.

Prior to the Merger, Forte Subsidiary was incorporated as Forte Biosciences, Inc. under the laws of the State of Delaware on May 3, 2017 as a privately-held company. Forte Biosciences, Inc. was renamed Forte Subsidiary, Inc. in connection with the Merger.

The Merger was accounted for as a reverse asset acquisition. Forte Subsidiary is deemed to be the accounting acquirer for accounting purposes and Tocagen the accounting acquiree (Note 4). Accordingly, for accounting purposes: (i) the merger was treated as the equivalent of Forte Subsidiary issuing stock to acquire the net assets of Tocagen, (ii) the transaction price will be allocated over the acquired Tocagen net assets based upon their relative fair value at the time of closing, (iii) the reported historical operating results of the combined company prior to the merger will be those of Forte Subsidiary and not of Tocagen, and (iv) for periods prior to the transaction, shareholders' authorized capital of the combined company is presented based on the historical authorized capital of Tocagen.

### *Liquidity and Risks*

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. Since inception, the Company has incurred losses and negative cash flows from operations. As of June 30, 2020, the Company had an accumulated deficit of $41.8 million, which includes a charge of $32.1 million of acquired in-process research and development assets in connection with the Merger. The Company used $6.9 million of cash in operating activities for the six months ended June 30, 2020.

Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities. However, the Company believes that its cash of approximately $27.7 million as of June 30, 2020 will be sufficient to allow the Company to fund its operations for at least 12 months from the filing date of this Form 10-Q. Future operations will be reliant on additional equity or financing arrangements. There can be no assurances that, in the event that the Company requires additional financing, such financing will be available on terms which are favorable to the Company, or at all. If the Company is unable to raise

additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations.

Because of the numerous risks and uncertainties associated with pharmaceutical development, the Company is unable to predict the timing or amount of increased expenses or when or if it will start to generate revenues. Even if the Company is able to generate revenues, it may not be able to achieve or maintain profitability. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

The pandemic caused by an outbreak of a new strain of coronavirus, or COVID-19, has resulted, and is likely to continue to result, in significant national and global economic disruption and may adversely affect the Company's operations. The Company is actively monitoring the impact of COVID-19 and the possible effects on its financial condition, liquidity, operations, suppliers, industry, and workforce. However, the full extent, consequences, and duration of the COVID-19 pandemic and the resulting impact on the Company cannot currently be predicted. The Company will continue to evaluate the impact that these events could have on the operations, financial position, and the results of operations and cash flows during fiscal year 2020.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements of the Company should be read in conjunction with Forte Subsidiary's audited financial statements and accompanying notes thereto as of and for the year ended December 31, 2019 included in Tocagen's Registration Statement on Form S-4 (Registration No. 333-237371) as filed with the U.S. Securities and Exchange Commission (the "SEC") on March 25, 2020, as amended and declared effective by the SEC on May 13, 2020. The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim condensed consolidated financial statements. Any reference in the Notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The Merger (Note 1) was accounted for as a reverse asset acquisition. Forte Subsidiary is deemed to be the acquirer for accounting purposes(Note 4) and Tocagen is the accounting acquiree. Accordingly, for accounting purposes: (i) the merger will be treated as the equivalent of Forte Subsidiary issuing stock to acquire the net assets of Tocagen, (ii) the transaction price will be allocated over the acquired Tocagen net assets based upon their relative fair value at the time of closing, (iii) the reported historical operating results of the combined company prior to the merger will be those of Forte Subsidiary and not of Tocagen, and (iv) for periods prior to the transaction, shareholders' authorized capital of the combined company is presented based on the historical authorized capital of Tocagen.

In the opinion of management, the accompanying condensed consolidated financial statements include all adjustments that are of a normal and recurring nature and that are necessary for the fair presentation of the Company's financial position, the results of its operations and cash flows for the periods presented. Interim results are not necessarily indicative of results for the full year or any future period.

***Principles of Consolidation***

The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Forte Subsidiary, Inc. All intercompany accounts and transactions have been eliminated in the preparation of the condensed consolidated financial statements.

***Use of Estimates***

The preparation of the Company's financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the Company's financial statements and accompanying notes. Significant management estimates that affect the reported amounts of assets and liabilities include useful lives of property and equipment, stock-based compensation, accruals for clinical trials and deferred tax assets. Although these estimates are based on

the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

***Acquired In-Process Research and Development Expense***

The Company acquired in-process research and development assets in connection with its Merger with Tocagen. As the acquired in-process research and development assets were deemed to have no current or alternative future use, an expense of $32.1 million was recognized in the condensed consolidated statements of operations for the three-month period ended June 30, 2020.

***Impairment of Long-Lived Assets***

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded through June 30, 2020.

***Comprehensive Loss***

Comprehensive loss includes net loss and other comprehensive income (loss) for the period. The Company did not have other comprehensive income (loss) items such as unrealized gains and losses. For the three and six months ended June 30, 2020 and 2019, the comprehensive loss was equal to the net loss.

***Net Loss Per Share***

Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents.

Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding during the period. The following number of unexercised stock options, convertible preferred stock and warrants, which are common stock equivalents, have been excluded from the diluted net loss calculation as their effect would have been anti-dilutive for all periods presented:

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Options | 821,910 | 516,521 | 821,910 | 516,521 |
| Convertible preferred stock | - | 3,177,744 | - | 3,177,744 |
| Warrants | 2,756,980 | - | 2,756,980 | - |
| **Total** | 3,578,890 | 3,694,265 | 3,578,890 | 3,694,265 |

***Recently Adopted Accounting Standards***

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses*, which changes the accounting for recognizing impairments of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. The Company adopted this ASU as of January 1, 2020, which did not have a material impact on its financial position or results of operations.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement ("ASC 820").* The new guidance removes, modifies and adds to certain disclosure requirements on fair value measurements in ASC 820. The Company adopted this ASU as of January 1, 2020, which did not have a material impact on its financial position or results of operations.

***Recently Issued Accounting Standards***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of a specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes ("ASC 740")*, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for calendar-year public business entities in 2021 and interim periods within that year. Early adoption is permitted. The Company does not expect adoption of this new guidance will have a material impact on its financial position or results of operations.

## 3. Balance Sheet Components

***Prepaid Expenses and Other Current Assets***

Prepaid expenses and other current assets as of June 30, 2020 and December 31, 2019 consist of the following (in thousands):

| | As of June 30, 2020 (unaudited) | As of December 31, 2019 |
|---|---|---|
| Prepaid manufacturing expenses | $ 74 | $ 514 |
| Deposits for manufacturing components | 161 | - |
| Other | 160 | 53 |
| Total Prepaid Expenses and Other Current Assets | $ 395 | $ 567 |

***Accrued Liabilities***

Accrued liabilities, as of June 30, 2020 and December 31, 2019 consist of the following (in thousands):

| | As of June 30, 2020 (unaudited) | As of December 31, 2019 |
|---|---|---|
| Accrued legal and professional fees | $ 32 | $ 168 |
| Accrued manufacturing and clinical expenses | 527 | — |
| Accrued compensation | 174 | 175 |
| Other | 133 | — |
| Total Accrued Liabilities | $ 866 | $ 343 |

## 4. Merger

On June 15, 2020, the Company completed the Merger (see Note 1). The Merger was accounted for as a reverse asset acquisition as Tocagen did not meet the definition of a business pursuant to *Topic 805, Business Combinations, as* Tocagen did not have the ability to create output, and substantially all of its fair value was concentrated in cash and in-process research and development ("IPR&D") assets. Forte Subsidiary is deemed to be

the acquirer for accounting purposes because immediately following the merger: (i) Forte Subsidiary stockholders owned a substantial majority of the voting rights of the combined company; (ii) Forte Subsidiary designated a majority of the initial members of the board of directors of the combined company; and (iii) Forte Subsidiary's senior management held all key positions of the combined company and no employees were retained from Tocagen. Accordingly, for accounting purposes: (i) the merger has been treated as the equivalent of Forte Subsidiary issuing stock to acquire the net assets of Tocagen, (ii) the transaction price has been allocated over the acquired Tocagen net assets based upon their relative fair value at the time of closing, (iii) the reported historical operating results of the combined company prior to the merger are those of Forte Subsidiary, and (iv) for periods prior to the transaction, shareholders' authorized capital of the combined company is presented based on the historical authorized capital of Tocagen.

The following summarizes the estimated fair value of the assets and liabilities acquired at June 15, 2020, the date of the Merger (in thousands):

| | | |
|---|---|---|
| Cash | $ | 2,997 |
| Restricted cash | | 586 |
| Prepaid and other assets | | 1,257 |
| In-process research and development | | 32,057 |
| Accounts payable and accrued expenses assumed | | (3,916) |
| Purchase price | $ | 32,981 |

The estimated fair value of total consideration given was $33.0 million based on 1,594,670 shares of Tocagen common stock, 61,406 vested restricted stock awards and in-the-money options to purchase 26,975 shares of common stock of Tocagen outstanding immediately prior to the merger date, multiplied by the Tocagen closing stock price of $18.90 on the date of the merger, and transaction costs of approximately $1.2 million. The fair value of the IPR&D assets is expensed as a charge in the condensed consolidated statements of operations for the three and six months ended June 30, 2020 as there is no alternative use to these assets.

**5. Commitments and Contingencies**

***Concentrations of Credit Risk***

Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation (FDIC) up to $250,000. The Company's primary operating cash accounts significantly exceed FDIC limits.

***Indemnifications***

As permitted under Delaware law, the Company indemnifies its officers, directors, and employees for certain events and occurrences while the officer, or director is, or was, serving at the Company's request in such capacity.

***License to Patented Technology***

In December 2017, the Company entered into an exclusive license agreement with the Department of Health and Human Services ("DHHS"). Under the agreement, the DHHS granted the Company an exclusive, sublicensable, worldwide license to certain patent rights under which the Company may develop and commercialize pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and conditions (the "DHHS License"). Under the DHHS License, the Company is obligated to meet certain development benchmarks within certain time periods. If the Company is unable to meet any of these development benchmarks, the DHHS could terminate the license. In addition, the DHHS may terminate or modify the DHHS License in the event of a material breach or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such material breach or insolvency event. The DHHS also has the right to require the Company to grant mandatory sublicenses to patent rights licensed from the DHHS to product candidates covered by other DHHS licenses under certain specified circumstances, including if it is necessary to

meet health and safety needs that the Company is not reasonably satisfying or if necessary to meet requirements for public use specified by federal regulations, which the Company is not reasonably satisfying.

Under the DHHS License, the Company is obligated to pay the DHHS a minimum annual payment of $20,000 and is required to reimburse the DHHS for certain patent-related expenses. In addition, the Company may also be obligated to make milestone payments to the DHHS aggregating up to $105.5 million based on achieving specified development, regulatory and commercial milestones for the first licensed product. Such development milestone payments are the completion of patient enrollment in a phase 3 clinical trial and the completion of a phase 3 clinical trial demonstrating statistically significant efficacy benefit. The regulatory milestones are the receipt of the first FDA approval and the first non-USA regulatory agency approval. The commercial milestones are the first $100.0 million of annual net sales, the first $500.0 million of annual net sales, and the first $1,000.0 million of annual net sales. In addition, to the extent licensed products are approved for commercial sale, the Company is also obligated to pay the DHHS royalties within the range of 10% to 15% based on net sales of licensed products sold by the Company and if applicable, its sublicensees.

In May 2020, the Company and DHHS entered into a second amendment to the DHHS License agreement, where the Company agreed to pay a minimum annual royalty of $100,000 beginning January 1, 2021. The second amendment reduced total milestone payments to the DHHS from $105.5 million to $40.5 million, based on achieving specified development and regulatory milestones for the first licensed product. In addition, DHHS royalties were reduced to a new range of 5% to 10% based on net sales of licensed products sold by the Company and if applicable, its sublicensees. No milestones have been achieved as of June 30, 2020.

No milestones have been achieved as of June 30, 2020. The Company incurred $15,000 and $5,000 in minimum royalty expenses for the three months ended June 30, 2020 and 2019, respectively. The Company incurred $20,000 and $10,000 in minimum royalty expenses for the six months ended June 30, 2020 and 2019, respectively.

***Lease Agreement***

In April 2019, the Company entered into a lease agreement for certain office and laboratory space in Torrance, California. The lease agreement is cancellable by the Company at any time with 30-day notice. The Company recorded total rent expenses of $8,000 and $4,000 for the three months ended June 30, 2020 and 2019, and $14,000 and $4,000 for the six months ended June 30, 2020 and 2019, respectively.

**6. Equity**

***Series A Convertible Preferred Stock***

On November 27, 2018, the Company entered into a preferred stock purchase agreement with certain investors and issued 1,738,758 shares of Series A convertible preferred stock for net proceeds of $5.7 million, including $0.7 million from conversion of convertible notes and accrued interest. In addition, on January 2, 2019, the Company completed a second round of the Series A preferred stock financing and issued 1,438,985 shares at $3.41 per share for net proceeds of $4.9 million. All outstanding Series A convertible preferred stocks were converted into common stock at a one for one ratio in connection with closing of the Merger on June 15, 2020.

***Common Stock***

In connection with the Merger, the Company issued 3,804,817 shares of its common stock, and warrants to purchase 2,752,546 shares of the Company’s common stock at an exercise price of $10.56 per share, for net proceeds of $19.4 million. In addition, on June 16, 2020, the Company issued an additional 411,112 shares of common stock for net proceeds of $4.6 million.

Warrants to purchase 4,434 shares of the Company’s common stock at an exercise price of $140.25 per share which were previously issued by Tocagen, survived the Merger and remained outstanding as of June 30, 2020.

**7. Stock-Based Compensation**

***Equity Plans***

In December 2018, Forte Subsidiary adopted the 2018 Equity Incentive Plan (the "2018 Incentive Plan"). The terms and conditions of stock-based awards are defined at the sole discretion of the Forte Subsidiary's Board of Directors. Forte Subsidairy issues service-based awards, vesting over a defined period of service, and performance-based awards that vest upon the achievement of defined conditions. Service-based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service and the remaining awards vesting monthly in equal installments over the following thirty-six months. Stock options granted under the 2018 Incentive Plan expire ten years from the date of grant and the exercise price must be at least equal to the fair market value of common stock on the grant date. In connection with the Merger, all outstanding options under the 2018 Plan was exchanged into options to purchase common stock of Tocagen, which changed its name to Forte Biosciences Inc. after the Merger. Subsequent to the Merger, the 2018 Incentive Plan were frozen and no more stock-based awards will be granted.

In connection with the Merger, the Company assumed Tocagen's 2017 Equity Incentive Plan, which was effective on April 12, 2017 and was subsequently amended September 30, 2018 and further amended February 12, 2019 (the "2017 Plan"). The 2017 Plan provides for the grant of incentive stock options (ISOs), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, other forms of equity compensation and performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of the Company and its affiliates. Subsequent to the Merger, service-based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service and the remaining awards vesting monthly in equal installments over the following thirty-six months. For certain service-based awards to the board of directors, vesting occurs in thirty-six equal monthly installments over a three-year period.

Immediately upon closing of the Merger, 61,406 restricted stock awards and stock options to purchase 26,968 shares of common stock granted under the 2017 Plan prior to the Merger became fully vested in consideration for pre-merger services provided to Tocagen.

On July 26, 2020, the Company adopted the 2020 Inducement Equity Incentive Plan (the "2020 Inducement Plan") and reserved 500,000 shares for future grant under the 2020 Inducement Plan.

***Options***

The risk-free interest rate assumption for options is based on the U.S. Treasury yield curve rate at the date of grant with a maturity approximating the expected term of the option.

The expected term assumption for options granted to employees is determined using the simplified method that represents the average of the contractual term of the option and the weighted average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term.

Due to the Company's limited trading of its common stock and lack of company-specific historical or implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies in the life sciences industry whose shares are publicly traded. The Company selects the peer group based on comparable characteristics, including development stage, product pipeline, and enterprise value. The Company computes historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until sufficient amount of historical information regarding the volatility of its own stock price become available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption.

The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The fair value per share is determined by the Company's Board of Directors, as of the date of each grant based on independent third-party valuations, taking into consideration various objective and subjective factors.

The weighted average grant-date fair value of stock options granted to employees and non-employees in the three and six months ended June 30, 2020 was $10.08 and $8.17, respectively. The weighted-average assumptions used to value these stock options using the Black-Scholes option-pricing were as follows.

| | Three months ended June 30, 2020 | Six months ended June 30, 2020 |
|---|---|---|
| Fair value of common stock | $ 16.53 | $ 13.39 |
| Risk-free interest rate | 0.40% | 0.59% |
| Dividend yield | 0.00% | 0.00% |
| Expected term of options (years) | 5.94 | 5.97 |
| Volatility | 70.0% | 70.0% |

There were no stock options granted during the six months ended June 30, 2019.

***Stock-Based Compensation Expense***

Stock-based compensation expenses included in the Company's condensed consolidated statements of operations for the three and six months ended June 30, 2020 and 2019 were (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Research and development | $ 4 | $ 1 | $ 6 | $ 3 |
| General and administrative | 20 | - | 20 | - |
| **Total** | $ 24 | $ 1 | $ 26 | $ 3 |

As of June 30, 2020, there was unrecognized stock-based compensation expense related to stock options with service conditions of $2.7 million, which is expected to be recognized over a weighted-average period of 3.37 years. Total unrecognized stock-based compensation related to stock options with performance conditions was approximately $232,000, which is expected to be recognized if and when performance conditions become probable. The table below summarizes the stock option activity during the six months ended June 30, 2020:

| | Number of Shares Outstanding | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balances at December 31, 2019 | 516,521 | $ 0.85 | 9.00 | |
| Granted | 335,015 | 13.39 | | |
| Assumed from reverse merger | 26,968 | 9.59 | | |
| Exercised | (56,594) | 1.46 | | |
| Cancelled/Forfeited | — | — | | |
| Balances at June 30, 2020 | 821,910 | $ 6.21 | 8.83 | 7,340 |
| Vested and expected to vest at June 30, 2020 | 821,910 | $ 6.21 | 8.83 | 7,340 |
| Exercisable at June 30, 2020 | 38,889 | $ 5.98 | 3.80 | 334 |

The aggregate intrinsic value of options at June 30, 2020 is based on the Company's fair value of the stock price on that date of $14.58 per share.

**8. Related party transactions**

Two members of the Company's board of directors received $2,000 and $24,000 of cash payments during the three and six months ended June 30, 2020 for scientific consulting services provided to the Company, respectively. As of June 30, 2020, the Company had $1,000 in accounts payable to one of these directors.

**Item 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements of Forte Biosciences, Inc. ("Forte", "we", "our") and the accompanying notes appearing in Tocagen's Registration Statement on Form S-4 as (Registration No. 333-237371), initially filed on March 25, 2020, as amended, and declared effective by the Securities and Exchange Commission, or SEC, on May 13, 2020. This discussion of the financial condition and results of operations regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Act of 1995 and, known as the PSLRA. These include statements regarding management's intention, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as "anticipates," "believes," "plans," "expects," "projects," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA.*

*Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to the sufficiency of the Company's cash balance to fund the Company's activities, and the expectations with respect thereto; the business and prospects of the Company; Forte's plans to develop and potentially commercialize its product candidates, including FB-401; the timing of initiation of Forte's planned clinical trials; the timing of the availability of data from Forte's clinical trials; the timing of any planned investigational new drug application or new drug application; Forte's plans to research, develop and commercialize its current and future product candidates; Forte's ability to successfully enter into collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Forte's product candidates; Forte's commercialization, marketing and manufacturing capabilities and strategy; Forte's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Forte's competitors and its industry; the impact of government laws and regulations; Forte's ability to protect its intellectual property position; Forte's estimates regarding future revenue, expenses, capital requirements and need for additional financing following the proposed transaction; and the impact of COVID-19 on the Company, the Company's industry or the economy generally.*

*The known risks and uncertainties are described in detail under the caption "Risk Factors" and elsewhere in this Form 10-Q and our Registration Statement filed on Form S-4 (Registration No. 333-237371), initially filed on March 25, 2020, as amended, and declared effective by the SEC, on May 13, 2020. Forward-looking statements included in this Form 10-Q are based on information available to Forte as of the date of this Form 10-Q. Accordingly, our actual results may materially differ from our current expectations, estimates and projections. Forte undertakes no obligation to update such forward-looking statements to reflect events or circumstances after the date of this presentation.*

**Overview**

Forte Biosciences Inc. (www.fortebiorx.com) ("Forte", "we", "our") is a clinical-stage biopharmaceutical company focused on advancing through clinical trials our lead product candidate, FB-401, which is a live biotherapeutic for the treatment of inflammatory skin disease, including pediatric and adult patients with atopic dermatitis. There is currently a significant unmet need for safe and effective therapies for pediatric atopic dermatitis patients. FB401 was developed in collaboration with the National Institutes of Health ("NIH"), and the National Institute of Allergy and Infectious Diseases ("NIAID").

Forte entered into a business combination ("Merger") between Forte Subsidiary, Inc. ("Forte Subsidiary") and Tocagen, Inc. ("Tocagen"), a publicly traded biotechnology company. The merger closed on June 15, 2020, in which Telluride Merger Sub, Inc. a wholly-owned subsidiary of Tocagen, merged with and into Forte Subsidiary, with Forte Subsidiary surviving that Merger as a wholly-owned subsidiary of Tocagen. Immediately prior to the closing of the Merger, then outstanding Tocagen common stocks were adjusted with a reverse split ratio of 1-for-15. At the closing of the Merger, each share of Forte Subsidiary's common stock was converted into the right to receive approximately 3.1624 shares of Tocagen common stock (before giving effect of the reverse split). Immediately prior to closing of the Merger, Tocagen changed its name to Forte Biosciences, Inc. Our common stock is publicly traded on the Nasdaq Capital Market under the ticker symbol FRBX. Prior to the Merger, Forte Subsidiary was a privately held company incorporated in Delaware on May 3, 2017.

**FB-401**

We are developing a new approach to treating inflammatory skin disease using a topical live biotherapeutic, FB-401, which consists of three therapeutic strains of a commensal gram-negative bacteria, *Roseomonas mucosa* that were specifically selected for their impact on key parameters of inflammatory skin disease. Genetic-based microbiome identification revealed significant differences in the Gram-negative skin biome between atopic dermatitis ("AD") patients and healthy volunteers ("HV"). Over 50% of AD patients did not have any culturable Gram-negative flora. Our extensive preclinical and mechanism of action data demonstrate that FB-401 improves atopic dermatitis disease parameters by driving tissue repair and anti-inflammation as well as suppressing potentially harmful bacteria like *S. aureus*. Specifically, Forte believes that FB-401:

- drives immune pathways that are defective;
- suppresses *Staphylococcus aureus* growth; and
- improves skin barrier function.

To date, a Phase 1/2a study has been completed with pediatric and adult patients, demonstrating significant reduction in atopic dermatitis disease and pruritus, as well as control of *S. aureus* while tapering/eliminating steroid use. Forte is currently planning to initiate a double-blinded randomized Phase 2 clinical trial for mild to moderate AD in the third quarter of 2020.

**Intellectual Property**

On June 18, 2020, we announced the issuance of our seventh U.S. patent (10,682,379), broadening protection to include methods for culturing gram negative bacteria from the skin. Together with the six U.S. patents previously issued, we now have extensive patent protection covering the composition and method of use of our technology focused on inflammatory skin conditions. We also have two pending foreign patent applications, both of which are international patent applications filed under the Patent Cooperation Treaty.

In December 2017, Forte Subsidiary entered into an exclusive license agreement with DHHS, as amended in May 2020. Under the agreement, the DHHS granted Forte Subsidiary an exclusive, sublicensable, worldwide license to certain patent rights under which we may develop and commercialize pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and conditions.

**Revenue**

We have no products approved for commercial sale and have not generated any revenue from product sales. In the future, we may generate revenue from product sales, royalties on product sales, or license fees, milestones, or other upfront payments if we enter into any collaborations or license agreements. We expect that our future revenue will fluctuate from quarter to quarter for many reasons, including the uncertain timing and amount of any such payments and sales.

**Research and Development Expenses**

Research and development expenses consist primarily of costs incurred to advance our product candidate, FB-401. Our research and development expenses include external research and development expenses incurred under arrangements with third parties, such as contract research and manufacturing organizations, consultants, and our scientific advisors.

We expense research and development costs as incurred. Nonrefundable advance payments for goods and services that will be used in future research and development activities are capitalized as an asset and expensed when the service has been performed or when the goods have been received.

We expect our research and development expenses to increase for the foreseeable future as we continue to conduct our ongoing regulatory and commercialization activities, initiate new clinical trials and build our pipeline. The process of commercialization and conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for any of our product candidates. Due to the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration, costs and timing of our clinical trials, and, as a result, the actual costs to complete our planned clinical trials may exceed the expected costs.

**General and Administrative Expenses**

General and administrative expenses consist primarily of professional fees for legal, auditing, tax and business consulting services, personnel expenses and travel costs. We expect that general and administrative expenses will increase in the future as we expand our operating activities. In addition, we expect to incur significant additional costs associated with being a SEC registrant. These increases will likely include legal fees, costs associated with Sarbanes-Oxley compliance, accounting fees, directors' and officers' liability insurance premiums, and other expenses.

**Critical Accounting Policies and Estimates**

Critical accounting policies are those that, in management's view, are most important in the portrayal of our financial condition and results of operations. Aside from the changes disclosed in Note 2 to the Notes to Condensed Consolidated Financial Statements included in Item 1, Part I of this Quarterly Report on Form 10-Q, management believes there have been no material changes during the three months ended June 30, 2020 to the critical accounting policies discussed in Forte Subsidiary's Management's Discussion and Analysis of Financial Condition and Results of Operations section of Tocagen's Registration Statement on Form S-4 as filed with the U.S. Securities and Exchange Commission (the "SEC") on March 25, 2020, as amended and declared effective by the SEC on May 13, 2020.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments. We based our estimates on historical experience and on various assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially from these estimates.

*COVID-19*

The pandemic caused by an outbreak of a new strain of coronavirus, or COVID-19, has resulted, and is likely to continue to result, in significant national and global economic disruption and may adversely affect our operations. We are actively monitoring the impact of COVID-19 and the possible effects on its financial condition, liquidity, operations, suppliers, industry, and workforce. However, the full extent, consequences, and duration of the COVID-19 pandemic and the resulting impact on us cannot currently be predicted. We will continue to evaluate the impact that these events could have on our operations, financial position, and the results of operations and cash flows during fiscal year 2020 and beyond.

**Results of Operations**

***Comparison of Three and Six Months Ended June 30, 2020 and 2019***

The following tables summarize our results of operations for the three and six months ended June 30, 2020 and 2019 (in thousands):

| | Three Months Ended June 30, 2020 | Three Months Ended June 30, 2019 | Change in $ | Change in % |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | $ 1,937 | $ 310 | $ 1,627 | 525% |
| General and administrative | 760 | 319 | 441 | 138% |
| In process research and development assets acquired | 32,057 | - | 32,057 | 100% |
| | $ 34,754 | $ 629 | | |

| | Six Months Ended June 30, 2020 | Six Months Ended June 30, 2019 | | |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | $ 3,291 | $ 1,173 | $ 2,118 | 181% |
| General and administrative | 1,433 | 643 | 790 | 123% |
| In process research and development assets acquired | 32,057 | - | 32,057 | 100% |
| | $ 36,781 | $ 1,816 | | |

*Research and Development Expenses*

Research and development expenses were $1.9 million for the three months ended June 30, 2020, compared to $0.3 million during the same period in 2019. The increase of $1.6 million was primarily due to increased manufacturing and clinical expenses related to advancement of our FB-401 program.

Research and development expenses were $3.3 million for the six months ended June 30, 2020, compared to $1.2 million during the same period in 2019. The increase of $2.1 million was primarily due to increased manufacturing and clinical expenses related to advancement of our FB-401 program.

*General and Administrative Expenses*

General and administrative expenses were $0.8 million for the three months ended June 30, 2020 compared to $0.3 million for the same period in 2019. This increase of $0.5 million was primarily due to a $0.2 million increase in legal costs, a $0.2 million increase in compensation related expenses and a $0.1 million increase in other expenses.

General and administrative expenses were $1.4 million for the six months ended June 30, 2020 compared to $0.6 million for the same period of 2019. This increase of $0.8 million was primarily due to a $0.4 million increase in legal expenses, a $0.2 million increase in compensation expense, and a $0.2 million increase in other expenses.

*In-process research and development assets acquired*

In connection with the Merger, we recognized a charge of $32.1 million of acquired in-process research and development expenses for assets with no alternative use for the three and six months ended June 30, 2020.

*Other Expense*

Other expense consists primarily of foreign exchange income or loss partially offset by income earned from our cash.

**Liquidity and Capital Resources**

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since inception. Our net losses were approximately $36.8 million for the six months ended June 30, 2020, which includes a $32.1 million charge for in-process research and development expenses. As of June 30, 2020, we had an accumulated deficit of approximately $41.8 million. Substantially all of our operating losses, excluding the charge of in-process research and development expenses, resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the clinical development of FB-401. In addition, operating as a SEC registrant will involve the hiring of additional financial and other personnel, upgrading financial information systems, and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of clinical development programs.

Prior to the closing of the Merger, we had raised net cash proceeds of approximately $9.9 million in a Series A financing round from private placements of preferred stock. In connection with the Merger, we issued 3,804,817 shares of our common stock (after giving effect to the exchange ratio and reverse split), and warrants to purchase 2,752,546 shares of our common stock (after giving effect to the exchange ratio and reverse split) for gross proceeds of $19.4 million. In addition, on June 16, 2020, we issued an additional 411,112 shares of common stock for gross proceeds of $4.6 million.

As of June 30, 2020, we had cash of approximately $27.7 million. While we expect our existing cash will enable us to fund operations and capital expenditure requirements for at least the next 12 months from the date of this Form 10-Q, we may not have sufficient funds to reach commercialization. We expect to require substantial additional capital to continue and complete our clinical development activities and fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development, regulatory and commercialization efforts. Failure to raise capital as and when needed, on favorable terms, if at all, would have a negative impact on our financial condition and our ability to develop and commercialize our product candidates.

The following table shows a summary of our cash flows for the six months ended June 30, 2020 and 2019 (in thousands):

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (6,881) | $ (1,565) |
| Investing activities | 3,583 | - |
| Financing activities | 24,108 | 4,856 |
| Net increase in cash | $ 20,810 | $ 3,291 |

*Operating Activities*

Cash used in operating activities was $6.9 million for the six months ended June 30, 2020 compared to $1.6 million for the same period of 2019. The increase of $5.3 million was principally due to increases in manufacturing activity related to the development of FB-401, our product candidate, and Merger related expenses.

*Investing activities*

Cash provided from investing activities of $3.6 million consisted of cash acquired from the reverse merger with Tocagen, Inc. that closed on June 15, 2020.

*Financing Activities*

Net cash provided by financing activities was $24.1 million for the six months ended June 30, 2020 was primarily from net proceeds received from the sale of the company's common stock. Net cash provided by financing activities for the six months ended June 30, 2019 of $4.9 million was from net proceeds received from the sale of our preferred stock.

**Future Capital Requirements**

We have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval and commercialize our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacture and clinical trials of, and seek regulatory approval for FB-401. Immediately prior to the closing of the Merger, we received gross proceeds of $19.4 million from the issuance of our common stock. Immediately after the closing the Merger, we raised gross proceeds of $4.6 million from the issuance of our common stock. We expect to incur additional costs associated with operating as a SEC registrant. We anticipate that we will need substantial additional funding in connection with our continuing operations.

As of June 30, 2020, we had approximately $27.7 million in cash. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we continue to advance FB-401 in the clinic.

Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

- the terms and timing of any strategic alliance, licensing and other arrangements that Forte may establish;
- the initiation and progress of Forte's ongoing clinical trials for its product candidates;
- the number of programs Forte pursues;
- the outcome, timing and cost of regulatory approvals;
- the cost and timing of hiring new employees to support Forte's continued growth;
- the costs involved in patent filing, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of Forte's product candidates manufactured.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any equity or debt financing may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other parties rights to develop or commercialize our drug candidates that we would prefer to retain.

**Off-Balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

**Contractual Obligations**

See Note 5 to the Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

**Recent Accounting Standards**

See Note 2 to the Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

**Qualitative and Quantitative Disclosures About Market Risk**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

## ITEM 4. CONTROLS AND PROCEDURES

**Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this quarterly report on Form 10-Q. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

***Changes in Internal Control over Financial Reporting***

On June 15, 2020, we completed the Merger as described above. Otherwise, there has been no change in our internal control over financial reporting during the quarter ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that some of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

## Part II. OTHER INFORMATION

**Item 1: Legal Proceedings**

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material pending litigation or other material legal proceeding.

**Item 1A: Risk Factors**

*You should consider carefully the following information about the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q and in our other public filings, in evaluating our business. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline.*

**Risks related to Forte Biosciences Inc. ("Forte")'s business, technology and industry**

***Forte has incurred net losses in every year since its inception and anticipates that it will continue to incur net losses in the future.***

Forte is a clinical stage healthcare company with a limited operating history. Investment in product development in the healthcare industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Forte's lead product candidate, FB-401, is currently in clinical development. Forte has no products approved for commercial sale and has not generated any revenue from product sales to date, and Forte continues to incur significant research and development and other expenses related to its ongoing operations. As a result, Forte is not profitable and has incurred losses in each period since its inception in 2017. For the years ended December 31, 2019 and 2018, Forte reported net losses of $4.1 million and $0.9 million, respectively. As of December 31, 2019, Forte had an accumulated deficit of $5.0 million. Forte expects to continue to incur significant losses for the foreseeable future, and Forte expects these losses to increase as Forte continues its research and development of, and seeks regulatory approvals for, its product candidate, FB-401. Forte anticipates that its expenses will increase substantially if, and as, it:

- conducts clinical trials for its product candidate, FB-401;
- continues to discover and develop additional applications for FB-401;
- maintains, expands and protects its intellectual property portfolio;
- hires or contracts additional clinical, scientific, manufacturing and commercial personnel to support its product development and commercialization efforts;
- validates a manufacturing process and specifications for FB-401;
- establishes in-house manufacturing capabilities;
- establishes a commercial manufacturing source and secures supply chain capacity sufficient to provide clinical trial material and commercial quantities of any product candidate for which Forte may obtain regulatory approval;
- acquires or in-licenses other product candidate and technologies;
- seeks various regulatory approvals;
- establishes a sales, marketing and distribution infrastructure to commercialize any product candidate for which Forte may obtain regulatory approval; and
- adds operational, compliance, financial and management information systems and personnel to support being a public company.

To become and remain profitable, Forte or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require Forte to be successful in a range of challenging activities, including completing clinical trials, obtaining marketing approval for FB-401, manufacturing, marketing and selling products for which Forte may obtain marketing approval and satisfying any post-marketing requirements. Forte may never succeed in any or all of these activities and, even if Forte does, Forte may never generate revenue that is significant enough to achieve profitability. If Forte does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Forte's failure to become and remain profitable would decrease the value of the company and could impair its ability to raise capital, maintain its research and development efforts, expand its business or continue its operations.

Even if Forte succeeds in obtaining regulatory approval and commercializing its current product candidate, FB-401, Forte may continue to incur substantial research and development and other expenditures to develop and market additional applications for its current product candidate or any future product candidates. Forte may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may

adversely affect its business. The size of its future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenue. Forte's prior losses and expected future losses have had and will continue to have an adverse effect on its stockholders' equity and working capital.

***Forte will require additional capital to fund its operations and if Forte fails to obtain necessary financing, Forte will not be able to complete the development and commercialization of its product candidate, FB-401.***

Forte's operations have consumed substantial amounts of cash since inception. Forte expects to continue to spend substantial amounts to conduct clinical trials of its current and future programs, to validate the manufacturing process and specifications for its product candidate, to seek regulatory approvals for its product candidate and to launch and commercialize any products for which Forte receives regulatory approval, including potentially building its own commercial organization. As of June 30, 2020, Forte had $27.7 million of cash on hand. Based on its current operating plan, Forte believes that its current cash available will enable it to fund its operating expenses, capital expenditure requirements through at least twelve months from the issuance date of this Form 10-Q. However, its future capital requirements and the period for which its existing resources will support its operations may vary significantly from what Forte currently expects, and Forte will in any event require additional capital in order to complete clinical development of FB-401. Forte's monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of FB-401 is highly uncertain, Forte is unable to estimate the actual funds it will require for development and any approved marketing and commercialization activities. Forte's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of clinical trials for FB-401 and any need to conduct additional such studies as may be required by a regulator;
- the clinical development plans Forte establishes for FB-401;
- the terms of any collaboration agreements Forte may choose to initiate or conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration ("FDA"), and other comparable foreign regulatory authorities;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards ("IRBs") in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- failure of third-party contractors, such as contract research organizations ("CROs"), or investigators to comply with regulatory requirements, including GCPs;
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of its product candidate by the FDA or other comparable foreign regulatory authorities;
- undertaking and completing additional pre-clinical studies to generate data required to support the continued clinical development of a product candidate;
- inability to enroll sufficient patients to complete a protocol;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- problems with biopharmaceutical product candidate storage, stability and distribution;
- its inability to add new or additional clinical trial sites;
- varying interpretations of the data generated from its preclinical or clinical trials;
- Forte's inability to manufacture, or obtain from third parties, adequate supply of biopharmaceutical product candidate sufficient to complete its preclinical studies and clinical trials;

- the costs of establishing, maintaining, and overseeing a quality system compliant with current good manufacturing practice requirements ("cGMPs") and a supply chain for the development and manufacture of its product candidate;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against Forte or FB-401;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which Forte may receive regulatory approval in regions where Forte chooses to commercialize its products on its own; and
- potential unforeseen business disruptions or market fluctuations that delay its product development or clinical trials and increase its costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises, such as the current COVID-19 outbreak.

Forte does not have any committed external source of funds or other support for its development efforts, and Forte cannot be certain that additional funding will be available on acceptable terms, or at all. Until Forte can generate sufficient product or royalty revenue to finance its cash requirements, which Forte may never do, Forte expects to finance its future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If Forte raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. Further, to the extent that Forte raises additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, each existing investors' ownership interest will be diluted. If Forte raises additional capital through debt financing, Forte would be subject to fixed payment obligations and may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights. If Forte raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, Forte may have to relinquish certain valuable rights to its product candidate, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Forte also could be required to seek collaborators for one or more of its current or future product candidates at an earlier stage than otherwise would be desirable or relinquish its rights to product candidates or technologies that Forte otherwise would seek to develop or commercialize itself. If Forte is unable to raise additional capital in sufficient amounts or on terms acceptable to it, Forte may have to significantly delay, scale back or discontinue the development or commercialization of its current product candidate, FB-401, or one or more of its other research and development initiatives. Any of the above events could significantly harm its business, prospects, financial condition and results of operations and cause the price of its common stock to decline.

***Forte has a limited operating history, which may make it difficult to evaluate its technology and product development capabilities and predict its future performance.***

Forte is early in its development efforts. Prior to the closing of the reverse merger ("Merger") with Tocagen Inc. on June 15, 2020, Forte's predecessor company was formed in 2017 as a privately-held company. Forte has no products approved for commercial sale and has not generated any revenue from product sales. Forte's ability to generate product revenue or profits, which Forte does not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of FB-401, which may never occur. Forte may never be able to develop or commercialize a marketable product.

Forte's current and future programs and product candidates will require additional discovery research, preclinical development, clinical development, regulatory approval to commercialize the product, manufacturing validation, obtaining manufacturing supply, capacity and expertise, building of a commercial and distribution organization, substantial investment and significant marketing efforts before Forte generates any revenue from product sales. In addition, its drug product candidate must be approved for marketing by the FDA or certain other health regulatory agencies before Forte may commercialize any product in the respective jurisdictions.

Forte's limited operating history may make it difficult to evaluate its technology and industry and predict its future performance. Forte's short history as an operating company makes any assessment of its future success or viability subject to significant uncertainty. Forte will encounter risks and difficulties frequently experienced by early-stage companies in evolving fields. If Forte does not address these risks successfully, its business will suffer. Similarly, Forte expects that its financial condition and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond its control. As a result, its stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, as an early-stage company, Forte may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As Forte advances FB-401, Forte will need to transition from a company with a research focus to a company capable of supporting clinical development and if successful, commercial activities. Forte may not be successful in such a transition.

***If Forte fails to comply with its obligations under the license agreement with the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases ("DHHS") or otherwise experience disruptions to its business relationship with DHHS, Forte could lose license rights that are important to its business.***

Forte's DHHS license agreement imposes various diligence, milestone payment, royalty and other obligations on Forte. If Forte fails to comply with its obligations under these agreements, or Forte is subject to a bankruptcy, the licensor may have the right to terminate the license, in which event Forte would not be able to market products covered by the license.

***Forte's near-term prospects are highly dependent on future revenues from a single product candidate, FB-401, and Forte may be unable to achieve regulatory approval for FB-401 and its commercialization.***

Forte's long-term prospects are highly dependent on future acceptance and revenues from a single product, FB-401, and Forte has no other product candidates or products in active development at this time. Forte's success depends on its ability to eventually commercialize FB-401. Acceptance of its product in the marketplace by health care providers is uncertain, and its failure to achieve sufficient market acceptance will significantly limit its ability to generate revenue and be profitable. Market acceptance will require substantial marketing efforts and the expenditure of significant funds by it to inform health care providers of the benefits of using FB-401 and to provide further training on its use. Forte may not be able to build key relationships with health care providers to increase sales in the United States or sell FB-401 outside the United States. Product orders may be cancelled, patients or customers currently using its products may cease to do so and patients or customers expected to begin using its products may not. In addition, market acceptance of FB-401 may require that Forte make enhancements to it. Forte cannot be sure that it will be able to successfully develop such enhancements, or that if developed they will be viewed favorable by the market. Forte's ability to achieve acceptance of FB-401 depends on its ability to demonstrate the safety, efficacy, ease-of-use and cost-effectiveness.

***Topical live biotherapeutic is a novel approach and negative perception of any product candidate that Forte develops could adversely affect its ability to conduct its business or obtain regulatory approvals for FB-401.***

Microbiome therapies and therapy candidates in general are a relatively new and novel approach. In the United States and the European Union, no products to date have been approved specifically demonstrating an impact on the microbiome as part of their therapeutic effect. Microbiome therapies in general may not be successfully developed or commercialized or gain the acceptance of the public or the medical community. Forte's success will depend upon physicians who specialize in the treatment of diseases targeted by its product candidate that Forte pursue as drugs, prescribing potential treatments that involve the use of its product candidate in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Forte's access will also depend on consumer acceptance and adoption of its products that
Forte commercializes. Adverse events in clinical trials of its product candidate or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of the microbiome, could result in delay in regulatory approval for its product candidate or a decrease in demand for any product that Forte may develop. In addition, responses by the U.S., state or foreign governments to negative public

perception or ethical concerns may result in new legislation or regulations that could limit its ability to develop or commercialize any product candidate, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on Forte's business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of FB-401 or demand for any products Forte may develop.

***Forte's initial product candidate targeting atopic dermatitis ("AD") in adults will require significant additional clinical development before it can seek regulatory approval for and launch a therapeutic product commercially.***

Forte's business and future success depends on its ability to submit a Biologics License Application ("BLA") and obtain regulatory approval of and then successfully launch and commercialize FB-401. Forte is the sponsor of an active Investigational New Drug Application ("IND") for its initial product candidate, which allows it to commence a Phase 2 clinical trial.

Additionally, its planned Phase 2 clinical trial is intended to allow it to evaluate the efficacy and safety of FB-401 in reducing AD in adults and pediatrics. It may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Forte's inability to enroll a sufficient number of pediatric patients in a clinical trial could result in significant delays, could require it to abandon one or more clinical trials altogether, could impact its ability to raise additional capital and could delay or prevent its ability to obtain regulatory approvals for FB-401 in pediatric patients. In addition, if Forte is unable to obtain regulatory approval for FB-401 for an indication in pediatric patients, the commercial prospects or viability could be materially harmed, even if Forte obtains regulatory approval for an indication in adult patients.

FB-401 is in the early stages of development and will require significant additional clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient validated and cGMP-compliant commercial manufacturing capacity and significant marketing efforts before Forte can generate any revenue from product sales. In addition, because FB-401 is its most advanced product candidate, if FB-401 encounters safety, efficacy, supply or manufacturing problems, developmental delays, regulatory or commercialization issues or other problems, its development plans, including for other product candidate, and business would be significantly harmed.

***The successful development of Forte's product candidate is highly uncertain.***

Successful development of FB-401 is highly uncertain and is dependent on numerous factors, many of which are beyond Forte's control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical study results may show the product candidate to be less effective than desired or to have harmful or problematic side effects or toxicities;
- clinical trial results may show the product candidate to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to execute the clinical trials caused by slow enrollment in clinical trials, patients dropping out of clinical trials, length of time to achieve clinical trial endpoints, additional time requirements for data analysis, inability to validate the manufacturing process or to achieve cGMP compliance for the product candidate or inability to identify a suitable bioanalytical assay method agreeable to applicable regulators;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals for, including but not limited to, a BLA, delays in BLA preparation responding to an FDA request for additional clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, manufacturing deficiencies or other factors that make FB-401 uneconomical; and
- proprietary rights of others and their competing products and technologies that may prevent FB-401 from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval of a drug product candidate for a final decision by a regulatory authority may be difficult to predict for FB-401, in large part because of its limited regulatory history.

The full impact of the COVID-19 pandemic on Forte's clinical trial plans, product development, and how the FDA reviews study data that has been significantly impacted by the pandemic is difficult to predict, but may have a material adverse impact on Forte's business operations, clinical trial plans, and product development, including delays in IRB approval, delays in clinical trial and study participant recruitment, delay in FDA approval of our product candidates, and additional costs and resources. The pandemic's impact on the economy and drug product manufacturing and supply chain may also adversely affect Forte's clinical trial plans and drug development. Additionally, depending on the duration of shelter-in-place, social distancing, and similar measures, as well as business closures and stresses on our healthcare systems and clinical trial sites, Forte's ability to recruit participants for its clinical trials may be significantly impacted. Forte may not be able to commence or complete its clinical trials as currently planned. Forte may be required to significantly modify its study protocol, policies and procedures in order to address or accommodate patients and study site needs during the pandemic. Such changes can include modification to protocol inclusion and exclusion criteria, extending the time for patient follow up visits, using telemedicine, phone interviews and other technology to monitor patient safety, all of which will need to be approved by study site IRBs. Forte will also need to timely document how the pandemic impacted study and study patients, and submit that information to the FDA for evaluation. Forte cannot provide any assurance that the pandemic will not significantly impact how the FDA reviews any protocol deviations that occur during the pandemic, or that FDA will not require it to repeat a clinical study.

Even if Forte is successful in obtaining market approval for a drug product, commercial success of any approved products will also depend in large part on marketing acceptance, the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require Forte to conduct additional studies, including post-marketing studies related to the cost-effectiveness of the product, to qualify for reimbursement, which could be costly and divert its resources. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for any of its drug products once approved, market acceptance and commercial success would be reduced.

In addition, if any of Forte's drug product candidates, including FB-401, are approved for marketing, Forte will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration. If approved, any of its drug products would be subject to restrictions on its products' labels and other conditions of regulatory approval that may limit its ability to market its products. Forte will also need to comply (and ensure that its third-party contractors comply) with cGMPs, and Good Clinical Practice ("GCP"), as Forte (and its third-party contractors) will be required to comply with these requirements for the products or product candidates used in its clinical trials or post-approval studies. In addition, Forte will need to comply with GCPs for any clinical trial conducted for any therapeutic indications Forte may develop for approval, including any additional therapeutic indications Forte develop after approval of its first drug candidate for treatment in AD. In addition, there is always the risk that Forte or a regulatory authority might identify previously unknown problems with a drug product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements and other regulatory requirements is costly and any failure to comply or other issues with its product post-approval could have a material adverse effect on its business, financial condition and results of operations.

***Clinical development is a lengthy and expensive process, with an uncertain outcome. Forte may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidate.***

To obtain the requisite regulatory approvals to commercialize any product candidate, Forte must demonstrate through extensive clinical trials that its product candidate is safe and effective in humans for its intended use. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Forte may be unable to establish clinical endpoints, dose levels and regimens or bioanalytical assay methods that applicable regulatory authorities would consider clinically meaningful, and a

clinical trial can fail at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of these studies or trials do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidate performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidate.

Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, and similar marketing applications to comparable foreign regulatory authorities, for each product candidate, and, consequently, the ultimate approval and commercial marketing of any product candidate. Forte does not know whether any of its clinical trials will begin or be completed on schedule, if at all.

Forte may experience delays in completing its clinical trials. Forte also may experience numerous unforeseen events during, or as a result of, any future clinical trials that Forte could conduct that could delay or prevent its ability to receive marketing approval or commercialize its product candidate, including:

- regulators or IRBs, or ethics committees may not authorize Forte or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- Forte may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or produce negative or inconclusive results and Forte may decide, or regulators may require it, to conduct additional preclinical studies or clinical trials or Forte may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidate may be larger than Forte anticipates, enrollment in these clinical trials may be slower than Forte anticipates, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than Forte anticipates;
- clinical trials of its product candidates may produce negative or inconclusive results, and Forte may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- regulators may require Forte to perform additional or unanticipated clinical trials to obtain approval or Forte may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving its product candidates, or such requirements may not be as Forte anticipate;
- Forte’s third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to it in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that Forte add new clinical trial sites or investigators;
- the cost of clinical trials of its product candidate may be more than Forte anticipates or more than its available financial resources, and Forte may need to delay or suspend one or more trials until Forte completes additional financing transactions or otherwise receives adequate funding;
- the supply or quality of Forte’s product candidate or other materials necessary to conduct clinical trials of its product candidate may be insufficient or inadequate and may not achieve compliance with applicable cGMPs;
- Forte’s product candidate may have undesirable side effects or other unexpected characteristics, causing it or its investigators, regulators or IRBs or ethics committees to suspend or terminate clinical trials, or reports may arise from clinical testing of its product candidate that raise safety or efficacy concerns about its product candidate;

- clinical trials of Forte's product candidate may produce negative or inconclusive results, which may result in it deciding, or regulators requiring it, to conduct additional clinical trials or suspend or terminate its clinical trials;
- the FDA or other regulatory authorities may disagree with the design, implementation or results of its clinical trials, or require Forte to submit additional data such as long-term toxicology studies or impose other requirements before permitting it to initiate a clinical trial;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- Forte's limited experience in filing and pursuing a BLA necessary to gain regulatory approval;
- any failure to develop substantial evidence of clinical efficacy and safety, and to develop quality standards and manufacturing processes to demonstrate consistent safety, purity, identity, and/or potency standards;
- a decision by Forte, IRBs, or regulators to suspend or terminate its clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulatory inspections of its clinical trials, clinical trial sites or manufacturing facilities, which may, among other things, require Forte to undertake corrective action or suspend or terminate its clinical trials if regulators find it not to be in compliance with applicable regulatory requirements;
- Forte's ability to produce sufficient quantities of the product candidate to complete its clinical trials;
- varying interpretations of the data generated from its clinical trials; and
- changes in governmental regulations or administrative action.

Forte could also encounter delays if a clinical trial is suspended or terminated for any reason. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or its clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of its product candidate. Further, the FDA or other regulatory authorities may disagree with its clinical trial design and its interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for its clinical trials.

Forte's product development costs will increase if it experiences delays in clinical testing or marketing approvals. Forte does not know whether any of its clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which Forte may have the exclusive right to commercialize its product candidate and may allow its competitors to bring products to market before Forte does, potentially impairing its ability to successfully commercialize its product candidate upon approval and harming its business and results of operations. Any delays in its future clinical development programs may harm its business, financial condition and prospects significantly.

***Forte's planned clinical trials or those of its future collaborators may reveal significant adverse events not seen in its preclinical studies or other clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidate.***

Before obtaining regulatory approvals for the commercial sale of any products, Forte must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that FB-401 is both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process.

The results of preclinical studies as well as early clinical trials of its product candidate may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such clinical trials are completed. There is typically an extremely high rate of attrition from the failure of product candidate proceeding through clinical trials. Forte believes that its product candidate will be well tolerated by participants in its clinical trials, but there is no certainty that it will be able to dose trial participants at a high enough dose that will demonstrate efficacy without unacceptable safety risk, such as an unanticipated immune response in clinical trial participants.

Forte's FB-401 may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the healthcare industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy and/or unacceptable safety issues, notwithstanding promising results in earlier preclinical studies or clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of its current or future clinical trials will ultimately be successful or support further clinical development of any of its product candidates.

If significant adverse events or other side effects are observed in any of its current or future clinical trials, Forte may have difficulty recruiting patients to its clinical trials, patients may drop out of its clinical trials or Forte may be required to significantly redesign or terminate trials or its development efforts of one or more product candidates altogether. Forte, the FDA, or other applicable regulatory authorities or an IRB may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the healthcare industry that initially showed therapeutic promise in early-stage clinical trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm Forte's business, financial condition and prospects.

***Positive results from early preclinical studies and clinical trials of FB-401 are not necessarily predictive of the results of any future clinical trials of its product candidate. If Forte cannot replicate the positive results from its earlier preclinical studies and clinical trials of its product candidate in its future clinical trials, Forte may be unable to successfully develop, obtain regulatory approval for and commercialize its product candidate.***

Any positive results from its preclinical studies and clinical trials of its product candidate may not necessarily be predictive of the results from required later clinical trials. Similarly, even if Forte is able to complete its planned preclinical studies or any future clinical trials of FB-401 according to its current development timeline, the positive results from such preclinical studies and clinical trials of FB-401 may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and Forte cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidate performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or similar regulatory approval.

***If Forte encounters difficulties enrolling patients in its clinical trials, its clinical development activities could be delayed or otherwise adversely affected.***

Forte may experience difficulties in patient enrollment in its clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on its ability to enroll a sufficient number of patients who remain in the clinical trial until its conclusion. The enrollment of patients depends on many factors, including:

- the severity of the disease or condition under investigation;

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the study patient population required for analysis of the primary endpoint(s) of the clinical trial;
- the proximity of patients to trial sites;
- the design of the clinical study or trial;
- Forte's ability to recruit investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications Forte is investigating;
- the efforts to facilitate timely enrollment in clinical studies or trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- Forte's ability or the ability of its CRO to ensure regulatory compliance and to obtain and maintain patient consents for its clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion.

In addition, Forte's clinical studies or trials will compete with other clinical studies or trials for product candidates that are in the same therapeutic areas as its product candidate, and this competition will reduce the number and types of patients available for its clinical trial, because some patients who might have opted to enroll in its clinical studies or trials may instead opt to enroll in a study or trial being conducted by one of its competitors. Since the number of qualified clinical investigators is limited, Forte expects to conduct some of its clinical studies or trials at the same clinical trial sites that some of its competitors may use, which will reduce the number of patients who are available for its clinical trials in such clinical trial site. Moreover, because its product candidate represents a departure from more commonly used methods for its targeted therapeutic areas, potential patients and their doctors may be inclined to use conventional therapies, rather than enroll patients in any future clinical study or trial related to Forte's product candidate.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical studies or trials, which could prevent completion of these clinical studies or trials and adversely affect Forte's ability to advance the development of its product candidate.

***Interim top-line and preliminary data from its clinical trials that Forte announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, once Forte commences future clinical trials, Forte may publish interim top-line or preliminary data from its clinical trials. Interim data from these clinical trials that Forte may complete are subject to the risk that one or more of the outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data Forte previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm its business prospects.

***If Forte fails to comply with environmental, health and safety laws and regulations, Forte could become subject to significant fines or penalties or incur costs that could have a material adverse effect on the success of its business.***

Forte is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. Forte generally contracts with third parties for the disposal of these materials and wastes. Forte cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of its commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although Forte believes that the safety procedures utilized by its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, Forte cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Forte may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail its use of certain materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. Forte cannot predict the impact of such changes and cannot be certain of its future compliance. In addition, Forte may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair its research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although Forte maintain workers' compensation insurance to cover it for costs and expenses, Forte may incur due to injuries to its employees resulting from the use of biological waste or hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. Forte does not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

***If product liability lawsuits are brought against it, Forte may incur substantial liabilities and may be required to limit commercialization of FB-401 upon approval.***

Forte faces an inherent risk of product liability as a result of testing its product candidate in clinical trials and will face an even greater risk if it commercializes any products. For example, Forte may be sued if its product candidates, upon regulatory approval, are perceived to cause injury or are found to be otherwise unsuitable or defective. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If Forte cannot successfully defend itself against product liability claims, Forte may incur substantial liabilities or be required to limit commercialization of its product candidate. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring a product candidate to the market;
- decreased demand for its products;
- damage to its reputation;
- withdrawal of clinical trial participants and patients and inability to enroll future participants or continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and its resources;
- substantial monetary awards to participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;

- loss of revenue;
- exhaustion of any available insurance and its capital resources;
- the inability to commercialize any product candidate via any regulatory pathway; and
- decline in its share price.

While Forte maintains clinical trial insurance, it cannot anticipate all the risks associated with its clinical trials or risks after regulatory approval and commercial launch of its product. Forte reviews its clinical trial insurance policy annually, and Forte believes that its coverage is currently adequate to cover any claims that may arise in connection with its clinical trials. There is no guarantee that Forte will be able to obtain additional clinical trial insurance at an acceptable cost in the future, which could prevent or inhibit the ongoing development of its products.

Since Forte has not yet commenced marketing of any products Forte does not yet hold product liability insurance for commercialization of its products. Its inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products Forte develops, alone or with collaborators. If and when coverage is secured, its insurance policies may also have various exclusions, and Forte may be subject to a product liability claim for which Forte has no coverage. Forte may have to pay any amounts awarded by a court or negotiated in a settlement that exceed its coverage limitations or that are not covered by its insurance, and Forte may not have, or be able to obtain, sufficient capital to pay such amounts. Even if its agreements with any future corporate collaborators entitle Forte to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

***The market opportunities for FB-401 may be limited and its estimates of the incidence and prevalence of its target patient populations may be inaccurate.***

Forte's projections of both the number of people who have the diseases Forte is targeting, as well as the subset of people with these diseases in a position to receive its therapies, if approved, are based on its beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations or secondary market research databases, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases or regulatory approvals may include limitations for use or contraindications that decrease the addressable patient population. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for its product candidate may be limited or may not be amenable to treatment with its product candidate. Even if Forte obtains significant market share for its product candidate, because certain of the potential target populations are small, Forte may never achieve profitability without obtaining regulatory approval for additional indications.

***Forte faces significant competition from other healthcare companies, and its operating results will suffer if Forte fails to compete effectively.***

The healthcare industry is characterized by intense competition and rapid innovation. Forte's competitors may be able to develop other compounds or products that are able to achieve similar or better results. Forte's potential competitors include major multinational pharmaceutical, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of its competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidate that Forte develop obsolete. Mergers and acquisitions in the healthcare industry may result in even more resources being concentrated amongst its competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Forte's competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis microbiome therapies that are more effective, safer, more easily commercialized or less costly than FB-401 or may develop proprietary technologies or secure patent protection that Forte may need for the

development of its technologies and products. Forte believes the key competitive factors that will affect the development and commercial success of its product candidate are efficacy, safety, tolerability, reliability, convenience of use, compliance with regulatory requirements, acceptance by patients or prescribers, competitive pricing and reimbursement.

Forte anticipates competing with the largest healthcare companies in the world, many of which have greater financial, human, and manufacturing resources than Forte currently has. In addition to these fully integrated healthcare companies, Forte also competes with those companies whose products target the same indications as FB-401. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by its competitors could be superior to its product candidate. It is possible that these competitors will succeed in developing technologies that are more effective than Forte's products or that would render its product candidate obsolete or noncompetitive. Forte anticipates that it will face increased competition in the future as additional companies enter its market and scientific developments surrounding competing therapies continue to accelerate.

Even if Forte obtains regulatory approval to market FB-401, the availability and price of its competitors' products could limit the demand and the price Forte is able to charge for FB-401. Forte may not be able to implement its business plan if the acceptance of its product candidate is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to its product candidate, or if physicians switch to other new drug or biologic products or choose to reserve its product candidate for use in limited circumstances.

***Even if FB-401 or any other product candidate that Forte develops receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, consumers and others in the medical or healthcare community necessary for commercial success.***

If any product candidate Forte develops receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, consumers and others in the medical community. If any such product candidate Forte develops does not achieve an adequate level of acceptance, Forte may not generate significant product revenues and Forte may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including:

- efficacy, safety and potential advantages compared to alternative treatments;
- the labeled uses or limitations for use, including age limitations or contraindications, for its product candidate compared to alternative treatments
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- public perception of new therapies;
- the strength of marketing and distribution support;
- the ability to offer its products, if approved, for sale at competitive prices;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

***Forte's operations and financial results could be adversely impacted by the 2019 Novel Coronavirus (COVID-19) outbreak in China and the rest of the world including the United States.***

COVID-19, the infectious disease caused by the most recently discovered coronavirus, has spread to most countries across the world, including all 50 states within the United States, resulting in the World Health Organization characterizing COVID-19 as a pandemic. While the extent of the impact of the current COVID-19 coronavirus outbreak on Forte's business and financial results is uncertain, a continued and prolonged public

health crisis such as the COVID-19 coronavirus outbreak could have a negative impact on its business, financial condition and operating results. Due to the global pandemic impacting the United States, its clinical trial recruiting and participants could also be slowed or delayed, or in a more severe scenario, its business, financial condition and operating results could be more severely affected. Given the dynamic nature of these circumstances, the duration of any business disruption or potential impact to its business of the COVID-19 coronavirus is difficult to predict, which may increase its costs or expenses.

***Forte will need to grow the size of its organization, and Forte may experience difficulties in managing this growth.***

As of June 30, 2020, Forte had 5 full-time employees. As its research, development, manufacturing and commercialization plans and strategies develop, and as Forte continues to transition into operating as a public company following the Merger, Forte expects to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- managing its internal research and development efforts effectively, including identification of clinical candidates, scaling its manufacturing process and navigating the clinical and FDA review process for its product candidate; and
- improving its operational, financial and management controls, reporting systems and procedures.

Forte's future financial performance and its ability to commercialize FB-401 will depend, in part, on its ability to effectively manage any future growth, and its management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

Forte currently relies, and for the foreseeable future will continue to rely, in substantial part on certain organizations, advisors and consultants to provide certain services, including many aspects of regulatory affairs, clinical management and manufacturing. There can be no assurance that the services of these organizations, advisors and consultants will continue to be available to Forte on a timely basis when needed or that Forte can find qualified replacements. In addition, if Forte is unable to effectively manage its outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, its clinical trials may be extended, delayed or terminated, and Forte may not be able to obtain regulatory approval ofFB-401 or otherwise advance its business. There can be no assurance that Forte will be able to manage its existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If Forte is not able to effectively expand its organization by hiring new employees and expanding its groups of consultants and contractors, Forte may not be able to successfully implement the tasks necessary to further develop and commercialize its product candidate and, accordingly, may not achieve its research, development and commercialization goals.

***Forte's current operations are located in California, and Forte or the third parties upon whom Forte depends, may be adversely affected by natural disasters or the COVID-19 outbreak, and its business continuity and disaster recovery plans may not adequately protect Forte from a serious disaster.***

Forte's current operations are located in California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 outbreak, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in it being unable to fully utilize its facilities, or the manufacturing facilities of its third-party contract manufacturers, may have a material and adverse effect on its ability to operate its business, particularly on a daily basis, and have significant negative consequences on its financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of its product candidate or interruption of its business operations. Earthquakes or other natural disasters could further disrupt its operations and have a material and adverse effect on its business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred

that prevented it from using all or a significant portion of its headquarters, that damaged critical infrastructure, such as its research facilities or the manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for Forte to continue its business for a substantial period of time. The disaster recovery and business continuity plans Forte has in place may prove inadequate in the event of a serious disaster or similar event. Forte may incur substantial expenses as a result of the limited nature of its disaster recovery and business continuity plans, which, could have a material adverse effect on its business. As part of its risk management policy, Forte maintains insurance coverage at levels that Forte believes are appropriate for its business. However, in the event of an accident or incident at these facilities, Forte cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If its facilities, or the manufacturing facilities of its third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of its research and development programs may be harmed. Any business interruption may have a material and adverse effect on its business, financial condition, results of operations and prospects.

***If Forte loses key management personnel, or if Forte fails to recruit additional highly skilled personnel, its ability to identify and develop new or next generation product candidate will be impaired, could result in loss of markets or market share and could make Forte less competitive.***

Forte's ability to compete in the highly competitive healthcare industry depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel. Forte is highly dependent on its management, scientific and medical personnel, including Paul Wagner, Ph.D. The loss of the services of any of its executive officers, other key employees, and other scientific and medical advisors, and its inability to find suitable replacements could result in delays in product development and harm its business.

Forte conducts its operations in California. Competition for skilled personnel in its market is intense and may limit its ability to hire and retain highly qualified personnel on acceptable terms or at all.

To retain valuable employees at its company in a competitive market, in addition to salary and cash incentives, Forte has provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in its stock price that are beyond its control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite its efforts to retain valuable employees, members of its management, scientific and development teams may terminate their employment with Forte on short notice. Employment of its key employees is at-will, which means that any of its employees could leave its employment at any time, with or without notice. Forte does not maintain "key man" insurance policies on the lives of these individuals or the lives of any of its other employees. Forte's success also depends on its ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

***Business disruptions could seriously harm Forte's future revenue and financial condition and increase its costs and expenses.***

Forte's operations, and those of its CROs, contract manufacturing organizations ("CMOs"), and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which Forte is predominantly self-insured. The occurrence of any of these business disruptions could seriously harm its operations and financial condition and increase its costs and expenses. For materials to be used in its clinical trials, Forte plans to rely on an external contract manufacturing organization for the entire manufacturing supply chain. Forte's ability to obtain clinical supplies of its product candidate could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

***Forte's internal computer systems, or those used by its CROs, CMOs or other contractors or consultants, may fail or suffer security breaches.***

Despite the implementation of security measures, Forte's internal computer systems and those of its future CROs, CMOs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While Forte has not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of its development programs and its business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in its regulatory approval efforts and significantly increase its costs to recover or reproduce the data. Likewise, Forte currently relies on third parties for the manufacture of its product candidate and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on its business. To the extent that any disruption or security breach were to result in a loss of, or damage to, its data or applications, or inappropriate disclosure of confidential or proprietary information, Forte could incur liability and the further development and commercialization of its product candidate could be delayed.

Regulators globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the European Union adopted the GDPR, which became effective on May 25, 2018. The GDPR applies to any company that collects and uses personal data in connection with offering goods or services to individuals in the European Union or the monitoring of their behavior. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase the cost of providing its product candidate, if approved, or even prevent Forte from offering its product candidate, if approved, in certain jurisdictions.

***Forte's employees, independent contractors, consultants, commercial partners and vendors acting on its behalf may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

Forte is exposed to the risks of employee fraud or other illegal activity by its employees, independent contractors, consultants, commercial partners and vendors acting on its behalf. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards Forte has established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If Forte obtains FDA approval of any of its product candidate and begin commercializing those products in the United States, its potential exposure under such laws will increase significantly, and its costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, its current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Manufacturers of biopharmaceutical products and their facilities, vendors and suppliers are subject to continual review and periodic unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, which include requirements relating to quality control and quality assurance as well as to the corresponding maintenance of records and documentation. Furthermore, its manufacturing facilities must be approved by regulatory agencies before these facilities can be used to manufacture its products or product candidates, and they will also be subject to additional regulatory inspections. Any material changes Forte may make to its manufacturing process or to the components used in its products may require additional prior approval by the FDA and state or foreign regulatory authorities. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

***A variety of risks associated with testing and developing its product candidate internationally could materially adversely affect Forte's business.***

Forte may seek regulatory approval of its product candidate outside of the United States and, if so, Forte expects that it will be subject to additional risks related to operating in foreign countries if Forte obtains the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, import or export controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act ("FCPA"), or comparable foreign regulations;
- challenges enforcing its contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, terrorism and public health crises, such as COVID-19.

These and other risks associated with its international operations may materially adversely affect its ability to attain or maintain profitable operations.

Obtaining and maintaining regulatory approval of its product candidates in one jurisdiction does not guarantee that Forte will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the product, manufacturing, and in many cases reimbursement of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In some cases, the price that Forte intends to charge for its products is also subject to approval by regulatory authorities. If Forte fails to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, its target market will be reduced and its ability to realize the full market potential of its product candidates will be harmed.

***Forte currently has no marketing and sales organization and has no experience in marketing products. If Forte is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell its product candidate, Forte may not be able to generate product revenue.***

Forte currently has no sales, marketing or distribution capabilities and has no experience in marketing products. Forte intends to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. Forte will have to compete with other healthcare companies to recruit, hire, train and retain marketing and sales personnel.

In addition to establishing internal sales, marketing and distribution capabilities, Forte intends to optimistically pursue collaborative arrangements regarding the sales and marketing of its products, however, there can be no assurance that Forte will be able to establish or maintain such collaborative arrangements, or if Forte is able to do so, that it will have effective sales forces. Any revenue Forte receives will depend upon the efforts of such third parties, which may not be successful. Forte may have little or no control over the marketing and sales efforts of such third parties and its revenue from product sales may be lower than if Forte had commercialized its product candidate ourselves. Forte also faces competition in its search for third parties to assist it with the sales and marketing efforts of its product candidate, FB-401.

There can be no assurance that Forte will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

***The FDA and other regulatory authorities may implement additional regulations or restrictions on the development and commercialization of biopharmaceutical products that contain live bacteria, which may be difficult to predict.***

The FDA and regulatory authorities in other countries have each expressed interest in further regulating biotechnology products and product candidates. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of Forte's current and future product candidates. Adverse developments in clinical trials of products containing live bacteria conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of its product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require Forte to perform additional studies or trials, increase its development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of its product candidate or lead to significant post-approval limitations or restrictions. As Forte advances its product candidate, Forte will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If Forte fails to do so, Forte may be required to delay or discontinue development of such product candidate. These additional processes may result in a review and approval process that is longer than Forte otherwise would have expected, delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of its product candidate can be costly and could negatively impact its ability to complete clinical trials and commercialize its current and future product candidate in a timely manner, if at all.

***Comprehensive tax reform legislation could adversely affect its business and financial condition.***

Recent changes to U.S. tax laws, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of its business and financial condition. For example, on December 22, 2017, President Trump signed into law the Tax Act, that significantly reforms the Code. The Tax Act, among other things, contains significant changes to corporate taxation, including changes to U.S. federal tax rates, limitation of the tax deduction for interest expense, and the modification and repeal of many business deductions and credits (including the reduction of the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs").

***Forte's ability to use net operating losses and research and development credits to offset future taxable income or tax liability may be subject to certain limitations.***

As of December 31, 2019, Forte had U.S. federal NOL carryforwards and state NOL carryforwards of approximately $2 million and $2 million, respectively. Forte's U.S. federal NOL carryforwards arising in tax years ending on or before December 31, 2017 will begin expiring in varying amounts in 2038 and 2039, respectively, unless utilized. Its U.S. federal NOL carryforwards arising in taxable years ending after December 31, 2017 will be carried forward indefinitely. Additionally, the deductibility of its U.S. federal NOL carryforwards arising in tax years beginning after December 31, 2017 is limited to 80% of current year taxable income in tax years beginning after December 31, 2020. These NOL carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Sections 382, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable

income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Forte's existing NOL carryforwards may be subject to limitations arising from previous ownership changes, and if Forte undergo an ownership change in connection with or after the Merger, its ability to utilize NOL carryforwards could be further limited by Section 382. In addition, future changes in its stock ownership, many of which are outside of its control, could result in an ownership change under Sections 382. Forte's NOL carryforwards may also be impaired under state law. Accordingly, Forte may not be able to utilize a material portion of its NOL carryforwards. Furthermore, its ability to utilize its NOL carryforwards is conditioned upon its attaining profitability and generating U.S. federal and state taxable income. As described above, Forte has incurred significant net losses since its inception and anticipate that Forte will continue to incur significant losses for the foreseeable future; and therefore, Forte does not know whether or when Forte will generate the U.S. federal or state taxable income necessary to utilize its NOL carryforwards that are subject to limitation by Sections 382.

***Unstable market and economic conditions may have serious adverse consequences on Forte's business, financial condition and stock price.***

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Forte's general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on its growth strategy, financial performance and stock price and could require Forte to delay or abandon clinical development plans. In addition, there is a risk that one or more of its current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect its ability to attain its operating goals on schedule and on budget. Furthermore, its stock price may decline due in part to the volatility of the stock market and the general economic downturn.

**Risks related to government regulation**

***Forte is very early in its development efforts. FB-401 will require significant additional clinical development before Forte seeks regulatory approval of its product candidate and launch a product commercially. If Forte is unable to advance its product candidate, FB-401, to clinical development, obtain regulatory approval and ultimately commercialize its product candidate or experiences significant delays in doing so, its business will be materially harmed.***

Forte is very early in its development efforts and has invested substantially all of its efforts and financial resources in the development of FB-401. Its ability to generate product revenues, which Forte does not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of its product candidate, which may never occur. Forte currently generates no revenue from sales of any products, and Forte may never be able to develop or commercialize a marketable product. The success of FB-401 will depend on several factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for FB-401 or any other product candidate;
- establishing cGMP-compliant clinical supply and commercial manufacturing operations or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for FB-401;
- launching commercial sales of FB-401, if and when approved or allowed for marketing, whether alone or in collaboration with others;

- acceptance of FB-401, if and when approved, by patients, the medical community and third-party payors; Effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims;
- the marketing of FB-401; and
- maintaining a continued acceptable safety profile of FB-401 following approval or commercialization.

If Forte does not achieve one or more of these factors in a timely manner or at all, Forte could experience significant delays or an inability to successfully commercialize FB-401, which would materially harm its business. If Forte does not receive regulatory approvals for FB-401, it may not be able to continue its operations.

***Changes in the legal and regulatory environment could limit Forte's future business activities, increase its operating or regulatory costs, reduce demand for its product candidate or result in litigation.***

The conduct of Forte's business, including the development, testing, production, storage, distribution, sale, display, advertising, marketing, labeling, health and safety practices are subject to various laws and regulations administered by federal, state and local governmental agencies in the United States, as well as to laws and regulations administered by government entities and agencies outside the United States in markets in which its products candidates and components thereof (such as packaging) may be manufactured or sold.

These laws and regulations and interpretations thereof may change, sometimes dramatically, as a result of a variety of factors, including political, economic or social events. Such changes may include changes in:

- FDA regulations;
- laws related to product candidate labeling;
- advertising and marketing laws and practices;
- laws and programs restricting the sale and advertising of certain products;
- increased regulatory scrutiny of, and increased litigation involving, product claims and concerns regarding the actual or possible effects or side effects of its product candidate; and
- state and federal consumer protection and disclosure laws.

New laws, regulations or governmental policy and their related interpretations, or changes in any of the foregoing, may alter the environment in which Forte does business and, therefore, may impact its operating results or increase its costs or liabilities

***Inadequate funding for the FDA, the SEC and other government agencies, or disruptions in their staffing levels related to the COVID-19 global pandemic, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the approval of Forte's product candidates rely, which would negatively impact its business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which its operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect its business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process its regulatory submissions, which could have a material adverse effect on its business, including its ability to access the public markets and obtain necessary capital in order to properly capitalize and continue its operations.

***Forte's relationships with healthcare providers, including physicians and clinical investigators, CROs, and third-party payors in connection with its current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose Forte to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, reputational harm, exclusion from federal health care programs, administrative burdens, and diminished profits and future earnings.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Arrangements with third-party payors and customers can expose pharmaceutical manufactures to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. In particular, the research, promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect Forte's ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute can constitute a false or fraudulent claim under the False Claims Act ("FCA"). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and a referral source on the other, including prescribers, purchasers, and formulary managers. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;
- federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations, which require applicable manufacturers of certain drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- GDPR and other ex-U.S. protections.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations or inquiries by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible

exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of its operations, as well as additional reporting obligations and oversight if Forte becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Forte maintains a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions Forte takes to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting Forte from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that its business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that its business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and Forte is not successful in defending ourselves or asserting its rights, those actions could have a significant impact on its business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of its operations, any of which could adversely affect its ability to operate its business and its results of operations. In addition, the approval and commercialization of any of its product candidates outside the United States will also likely subject Forte to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

***Obtaining and maintaining regulatory approval of any of its product candidates in one jurisdiction does not mean that Forte will be successful in obtaining regulatory approval for its product candidate in other jurisdictions.***

Obtaining and maintaining regulatory approval does not guarantee that Forte will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies and clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that Forte intends to charge for its products may also be subject to approval.

Forte may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of a product candidate with which Forte must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for Forte and could delay or prevent the introduction of its products in certain countries. If Forte fails to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, its target market will be reduced and its ability to realize the full market potential of its product candidate will be harmed.

***Clinical development is uncertain. Forte's clinical trials may experience delays or may never advance to the next stage of development, which would adversely affect its ability to obtain regulatory approvals to commercialize these programs on a timely basis or at all, which would have an adverse effect on its business.***

To proceed with its development plans and ultimately commercialization of FB-401, Forte will be required to conduct additional clinical trials. The FDA may require additional extensive preclinical studies. Forte cannot be certain of the timely completion or outcome of its preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept its proposed clinical programs, including the design, dose level, and dose regimen, or if the outcome of its preclinical testing and studies will ultimately support the further development of its clinical programs.

***If Forte is not able to obtain, or if there are delays in obtaining, required regulatory approvals for its product candidate, Forte will not be able to commercialize, or will be delayed in commercializing, its product candidate, and its ability to generate revenue will be materially impaired.***

Forte's product candidate and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before Forte can commercialize its product candidate, Forte must obtain marketing approval. Forte has not received approval to market any of its current and future product candidates from regulatory authorities in any jurisdiction and it is possible that none of its current and future product candidates will ever obtain regulatory approval. Forte, as a company, has no experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist it in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety, efficacy, purity, and potency.

Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Forte's product candidate may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude it from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND/BLA, or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that its data are insufficient for approval and require additional preclinical, clinical or other studies. Forte's product candidate could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, including study population, dose level, dose regimen, endpoint measure of efficacy, and bioanalytical assay methods, or implementation of its clinical trials;
- Forte may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that its product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- Forte may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with its interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of its product candidate may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which Forte contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering its clinical data insufficient for approval.

Of the large number of biopharmaceutical products in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in Forte failing to obtain regulatory approval to market its product candidate, which would significantly harm its business, results of operations and prospects.

Forte expects the novel nature of its product candidate to create further challenges in obtaining regulatory approval. As a result, its ability to develop product candidate and obtain regulatory approval may be significantly impacted.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on its ability to obtain approval of any product candidate that Forte develops based on the completed clinical trials.

In addition, even if Forte were to obtain approval, regulatory authorities may approve its product candidate for fewer or more limited indications than Forte requests, may include limitations for use or contraindications that limit the suitable patient population, may not approve the price Forte intends to charge for its products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for Forte's product candidate.

If Forte experiences delays in obtaining approval or if Forte fails to obtain approval of its product candidate, the commercial prospects for its product candidate may be harmed, and its ability to generate revenues will be materially impaired.

***Forte's product candidate, FB-401, may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.***

Undesirable side effects caused by its product candidate could cause Forte to interrupt, delay or halt preclinical studies or could cause Forte or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive clinical label or the delay or denial of regulatory approval by the FDA or other regulatory authorities for its product candidate. Results of its clinical studies or trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, its clinical studies or trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order Forte to cease further development of or deny approval of its product candidate for any or all targeted indications. Additionally, its regulators could require significant modifications or amendments to ongoing clinical studies or trials that limit the available study population or lead to withdrawal of participation by already enrolled subjects. Any treatment-related side effects could affect patient recruitment or the ability of enrolled patients to complete the study or trial or result in potential product liability claims. Any of these occurrences may harm Forte's business, financial condition and prospects significantly.

Further, clinical studies or trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of its product candidate may only be uncovered with a significantly larger number of patients exposed to the product candidate. If its product candidate receives marketing approval and Forte or others identify undesirable side effects caused by such product candidate (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidate;
- regulatory authorities may require the addition of labeling statements, such as a "boxed" warning or a contraindication;
- Forte may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

- Forte may be required to change the way such product candidate is distributed or administered, conduct additional clinical trials or change the labeling of the product candidate;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy ("REMS"), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- Forte may be subject to regulatory investigations and government enforcement actions;
- Forte may decide to remove such product candidate from the marketplace;
- Forte could be sued and held liable for injury caused to individuals exposed to or using its product candidate; and
- Forte's reputation may suffer.

Forte believes that any of these events could prevent it from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing its product candidate, if approved, and significantly impact its ability to successfully commercialize its product candidate and generate revenues.

***Even if Forte receives regulatory approval of any product candidate, Forte will be subject to ongoing regulatory compliance obligations and continued regulatory review, which may result in significant additional expense. Additionally, if Forte fails to comply with regulatory requirements or experiences unanticipated problems with its product candidate, if approved, Forte could be subject to labeling and other restrictions, market withdrawal, and penalties.***

If FB-401 is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, Forte will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that Forte conducts post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, Forte and its contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to inspection observations. Accordingly, Forte and others with whom Forte works must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

The FDA has significant post-marketing authority, including, for example, the authority to require labeling changes based on new safety information and to require post-marketing studies or clinical trials to evaluate serious safety risks related to the use of a drug. Any regulatory approvals that Forte receives for its product candidate may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of its product candidate, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves its product candidate, Forte will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously

unknown problems with its product candidate, including adverse events of unanticipated severity or frequency, or with its third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of its products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled enforcement letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by Forte or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of its product candidate; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label or other regulatory marketing pathway. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and a company that is found to have improperly promoted off-label uses may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. In addition, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of its product candidate. If Forte is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Forte is not able to maintain regulatory compliance, Forte may lose any marketing approval that Forte may have obtained which would adversely affect its business, prospects and ability to achieve or sustain profitability.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of its product candidate. Forte also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current administration may impact its business and industry. Namely, the current administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities, such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these executive actions, including any executive orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, its business may be negatively impacted. In addition, if Forte is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Forte is not able to maintain regulatory compliance, Forte may lose any marketing approval that Forte may have obtained, and Forte may not achieve or sustain profitability.

Non-compliance by Forte or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance requirements, can also result in significant financial penalties.

***Healthcare insurance coverage and reimbursement may be limited or unavailable in certain market segments for its product candidate, if approved, which could make it difficult for Forte to sell any product candidate or therapies profitably.***

The success of its product candidate depends on the availability of adequate coverage and reimbursement from third-party payors. In addition, because its product candidate, FB-401, represents a new approach to the treatment of the disease it targets, Forte cannot be sure that coverage and reimbursement will be available for, or accurately

estimate the potential revenue from, its product candidate or assure that coverage and reimbursement will be available for any product that Forte may develop.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require Forte to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of its products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if Forte obtains coverage for a given product, the resulting reimbursement payment rates might not be adequate for Forte to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidate. Patients are unlikely to use its product candidate unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of its product candidate. Because its product candidate may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for Forte to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for its product candidate.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain pharmaceutical products or additional pricing pressures.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for its product candidate. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. Congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Forte expects to experience pricing pressures in connection with the sale of any of its product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

***Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on Forte's business and results of operations.***

Changes in regulations, statutes or the interpretation of existing regulations could impact Forte's business in the future by requiring, for example: (i) changes to its manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of its products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of its business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and Forte's business. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Legislative and regulatory measures have been enacted and proposed that may expand post-approval requirements and restrict sales and promotional activities for biotechnology products. Forte cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of its product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject Forte to more stringent product labeling and post-marketing testing and other requirements.

Forte expects that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that Forte receives for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent Forte from being able to generate revenue, attain profitability or commercialize its current and future product candidates.

***Forte's business activities may be subject to the FCPA and similar anti-bribery and anti-corruption laws of other countries in which Forte operates, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit its ability to compete in foreign markets and subject it to liability if Forte violates them.***

If Forte expand its operations outside of the United States, Forte must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which Forte plans to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the

corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If Forte expands its presence outside of the United States, it will require Forte to dedicate additional resources to comply with these laws, and these laws may preclude Forte from developing, manufacturing, or selling certain current and future product candidates, if approved, outside of the United States, which could limit its growth potential and increase its development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Additionally, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Forte has direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. Forte also expects its non-U.S. activities to increase in time. Forte plans to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and Forte can be held liable for the corrupt or other illegal activities of its personnel, agents, or partners, even if Forte do not explicitly authorize or have prior knowledge of such activities.

Compliance with applicable regulatory requirements regarding the export of any of Forte's current and future approved products may create delays in the introduction of its products in international markets or, in some cases, prevent the export of its products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. sanctions. If Forte fails to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of its products by, or in its decreased ability to export its approved products to, existing or potential customers with international operations. Any decreased use of its approved products or limitation on its ability to export or sell its products would likely adversely affect Forte's business.

**Risks related to Forte's intellectual property**

***If Forte is unable to obtain and maintain patent protection for any product candidate Forte develops, its competitors could develop and commercialize products or technology similar or identical to Forte's, and its ability to successfully commercialize any product candidate Forte may develop, and its technology, may be adversely affected.***

Forte's success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to its product candidate and other technologies Forte may develop. Forte seeks to protect its proprietary position by filing patent applications in the United States and abroad relating to FB-401, as

well as other technologies that are important to its business. Given that the development of its technology and product candidate is at an early stage, its intellectual property portfolio with respect to certain aspects of its technology and product candidate is also at an early stage. Forte has filed or intends to file patent applications on these aspects of its technology and its product candidate; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, Forte has only filed provisional patent applications on certain aspects of its technology and product candidate and each of these provisional patent applications is not eligible to become an issued patent until, among other things, Forte files a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause Forte to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. Forte cannot be certain, however, that the claims in its pending patent applications covering the composition of matter of its product candidate, FB-401, will be considered patentable by the United States Patent and Trademark Office ("USPTO"), or by patent offices in foreign countries, or that the claims in any of its issued patents will be considered valid and enforceable by courts in the United States or foreign countries. In particular, Forte cannot be certain that composition claims relating to microorganisms, including species of gram negative bacteria such as *Roseomonas mucosa*, will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of its issued patents will be considered valid and enforceable by courts in the United States or foreign countries.

Furthermore, in some cases, Forte may not be able to obtain issued claims covering compositions of matter relating to its product candidate, as well as other technologies that are important to its business, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to Forte's product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for its targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by its method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as Forte's competitors, from utilizing its technology. Any failure to obtain or maintain patent protection with respect to its product candidate could have a material adverse effect on Forte's business, financial condition, results of operations, and prospects.

***If any of its owned patent applications do not issue as patents in any jurisdiction, Forte may not be able to compete effectively.***

Changes in either the patent laws or their interpretation in the United States and other countries may diminish its ability to protect its inventions, obtain, maintain, and enforce its intellectual property rights and, more generally, could affect the value of its intellectual property or narrow the scope of its owned or licensed patents. With respect to owned intellectual property, Forte cannot predict whether the patent applications Forte is currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and Forte may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that Forte will fail to identify patentable aspects of its research and development output in time to obtain patent protection. Although Forte enters into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of its research and development output, such as its employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing its ability to seek patent protection. In addition, Forte's ability to obtain and maintain valid and enforceable patents depends on whether the differences between its inventions and the prior art allow its inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications

in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, Forte cannot be certain that it was the first to make the inventions claimed in any of its owned or pending patent applications, or that Forte was the first to file for patent protection of such inventions.

***If the scope of any patent protection Forte obtains is not sufficiently broad, or if Forte loses any of its patent protection, its ability to prevent its competitors from commercializing similar or identical technology and product candidate would be adversely affected.***

The patent position of healthcare companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of Forte's patent rights are highly uncertain. Forte's owned pending and future patent applications may not result in patents being issued which protect its product candidate, or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish Forte's ability to protect its inventions and enforce its intellectual property rights, and more generally could affect the value of its intellectual property. In particular, its ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe its intellectual property will depend in part on its success in obtaining and enforcing patent claims that cover its technology, inventions and improvements. With respect to company-owned intellectual property, Forte cannot be sure that patents will be granted with respect to any of its pending patent applications or with respect to any patent applications filed by it in the future, nor can Forte be sure that any of its existing patents or any patents that may be granted to Forte in the future will be commercially useful in protecting its products and the methods used to manufacture those products. Moreover, even its issued patents do not guarantee Forte the right to practice its technology in relation to the commercialization of its products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent Forte from commercializing its patented product candidate and practicing its proprietary technology. Forte's issued patents and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit its ability to stop competitors from marketing related products or limit the length of the term of patent protection that Forte may have for its product candidate. In addition, the rights granted under any issued patents may not provide Forte with protection or competitive advantages against competitors with similar technology. Furthermore, its competitors may independently develop similar technologies. For these reasons, Forte may have competition for its product candidate. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications Forte own issue as patents, they may not issue in a form that will provide Forte with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide Forte with any competitive advantage. Any patents that Forte own may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, Forte do not know whether its product candidate or other technologies will be protectable or remain protected by valid and enforceable patents. Forte's competitors or other third parties may be able to circumvent its patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect its business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and patents that Forte own may be challenged in the courts or patent offices in the United States and abroad. Forte may be subject to a third party preissuance submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging its owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, Forte's owned patent rights, allow third parties to commercialize Forte's product candidate or other technologies, and compete directly with Forte, without payment to Forte, or result in Forte's inability to manufacture or commercialize products

without infringing third-party patent rights. Moreover, Forte may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge its priority of invention or other features of patentability with respect to its owned patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit its ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its product candidate and other technologies. Such proceedings also may result in substantial cost and require significant time from its scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidate, patents protecting such product candidate might expire before or shortly after such product candidate are commercialized. As a result, its intellectual property may not provide Forte with sufficient rights to exclude others from commercializing products similar or identical to ours.

Forte may in the future co-own patent rights relating to future product candidates with third parties. Forte may need the cooperation of any such co-owners of its patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on its competitive position, business, financial conditions, results of operations, and prospects.

***Forte's rights to develop and commercialize its product candidate may be subject, in part, to the terms and conditions of future licenses granted to it by others.***

Forte may rely upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of its product candidate. Patent rights that Forte in-license in the future may be subject to a reservation of rights by one or more third parties. As a result, any such third parties may have certain rights to such intellectual property.

In addition, subject to the terms of any such license agreements, Forte may not have the right to control the preparation, filing, prosecution and maintenance, and Forte may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that Forte licenses from third parties. Forte cannot be certain that its in-licensed patent applications (and any patents issuing therefrom) that are controlled by its licensors will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of its business. If its licensors fail to prosecute, maintain, enforce, and defend such patents rights, or lose rights to those patent applications (or any patents issuing therefrom), the rights Forte has licensed may be reduced or eliminated, its right to develop and commercialize any of its product candidates that are subject of such licensed rights could be adversely affected, and Forte may not be able to prevent competitors from making, using and selling competing products. Moreover, Forte cannot be certain that such activities by its potential future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, even where Forte may have the right to control patent prosecution of patents and patent applications that Forte may license to and from third parties, Forte may still be adversely affected or prejudiced by actions or inactions of its potential future licensees, licensors and their counsel that took place prior to the date of assumption of control over patent prosecution.

***Forte may not be able to protect its intellectual property and proprietary rights throughout the world.***

Filing, prosecuting and defending patents on Forte's product candidate and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect its rights to the same extent as the laws of the United States. Consequently, Forte may not be able to prevent third parties from practicing its inventions in all countries outside the United States, or from selling or importing products made using its inventions in and into the United States or other jurisdictions. Competitors may use its technologies in jurisdictions where Forte has not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where Forte has patent protection but enforcement is not as strong as that in the United States. These products may compete with Forte's products, and Forte's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for Forte to stop the infringement of its patents or marketing of competing products in violation of its intellectual property and proprietary rights generally. Proceedings to enforce its intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert its efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly, could put its patent applications at risk of not issuing, and could provoke third parties to assert claims against us. Forte may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, its efforts to enforce its intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that Forte develops or licenses.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If Forte is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired, and its business, financial condition, results of operations, and prospects may be adversely affected.

***Obtaining and maintaining Forte's patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and its patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of its owned patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on Forte's business, financial condition, results of operations, and prospects.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing Forte's ability to protect its products.***

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before Forte could therefore be awarded a patent covering an invention of ours even if Forte had made the invention before it was made by such third party. This will require Forte to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, Forte cannot be certain that it was the first to file any patent application related to its product candidates or other technologies.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to

the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate Forte's patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of Forte's owned patent applications and the enforcement or defense of its owned issued patents, all of which could have a material adverse effect on Forte's business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on Forte's existing patent portfolio and its ability to protect and enforce its intellectual property in the future.

***Issued patents covering Forte's product candidate could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.***

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of Forte's owned patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to Forte's patents in such a way that they no longer cover its product candidate or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, Forte cannot be certain that there is no invalidating prior art, of which Forte and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, Forte would lose at least part, and perhaps all, of the patent protection on its product candidate or other technologies. Such a loss of patent protection would have a material adverse impact on Forte's business, financial condition, results of operations, and prospects.

***If Forte does not obtain patent term extension and/or data exclusivity for any product candidate that Forte may develop, its business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidate Forte may develop, one or more of its owned U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, Forte may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than Forte requests. If Forte is unable to obtain patent term extension or the term of

any such extension is shorter than what Forte requests, its competitors may obtain approval of competing products following its patent expiration, and its business, financial condition, results of operations and prospects could be materially harmed.

***Forte may be subject to claims challenging the inventorship of its patents and other intellectual property.***

Forte may be subject to claims that former employees, collaborators or other third parties have an interest in its owned patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, Forte may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing its product candidate or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or its ownership of its owned patent rights, trade secrets or other intellectual property. If Forte fails in defending any such claims, in addition to paying monetary damages, Forte may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to its product candidate and other technologies. Even if Forte is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on Forte's business, financial condition, results of operations and prospects.

***If Forte is unable to protect the confidentiality of its trade secrets, its business and competitive position would be harmed.***

In addition to seeking patents for its product candidate and other technologies, Forte also relies on trade secrets and confidentiality agreements to protect its unpatented know-how, technology, and other proprietary information and to maintain its competitive position. Trade secrets and know-how can be difficult to protect. Forte expects its trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions.

Forte currently, and may continue in the future continue to, relies on third parties to assist it in developing and manufacturing its product candidate. Accordingly, Forte must, at times, share know-how and trade secrets with them. Forte may in the future also enter into research and development collaborations with third parties that may require it to share know-how and trade secrets under the terms of its research and development partnerships or similar agreements. Forte seeks to protect its know-how, trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements, and including in its vendor and service agreements terms protecting its confidential information, know-how and trade secrets, with parties who have access to such information, such as its employees, scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. Forte also enters into confidentiality and invention or patent assignment agreements with its employees and consultants as well as trains its employees not to bring or use proprietary information or technology from former employers to Forte or in their work, and Forte reminds former employees when they leave their employment of their confidentiality obligations. However, Forte cannot guarantee that Forte has entered into such agreements with each party that may have or have had access to its trade secrets or proprietary technology and processes. Forte also seeks to preserve the integrity and confidentiality of its data and other confidential information by maintaining physical security of its premises and physical and electronic security of its information technology systems.

Despite Forte's efforts, any of the aforementioned parties may breach the agreements and disclose Forte's proprietary information, including its trade secrets, or there may be a lapses or failures in its physical and electronic security systems which lead to its proprietary information being disclosed, and Forte may not be able to obtain adequate remedies in the event of any such breaches. Monitoring unauthorized uses and disclosures is difficult, and Forte does not know whether the steps it has taken to protect its proprietary technologies will be effective. If any of its scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, Forte may not have adequate remedies for any such breach or violation, and Forte could lose its trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to Forte by its partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, Forte may be exposed to liability to the owner of that confidential information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of its trade secrets were to be lawfully obtained or independently developed by a

competitor or other third party, Forte would have no right to prevent them from using that technology or information to compete with us. If any of its trade secrets were to be disclosed to or independently developed by a competitor or other third party, Forte's competitive position would be materially and adversely harmed.

***Forte may not be successful in obtaining, through acquisitions, in-licenses or otherwise, necessary rights to its product candidate or other technologies.***

Forte currently have rights to certain intellectual property, through licenses from third parties, to develop its product candidate. Some healthcare companies and academic institutions are competing with Forte in the field of microbiome therapies and may have patents and have filed and are likely filing patent applications potentially relevant to Forte's business. In order to avoid infringing these third-party patents, Forte may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. Forte may also require licenses from third parties for certain technologies that Forte may evaluating for use with its current or future product candidate. However, Forte may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that Forte identifies as necessary for its current or any future product candidate at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that Forte may consider attractive or necessary. These established companies may have a competitive advantage over Forte due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Forte to be a competitor may be unwilling to assign or license rights to us. Forte also may be unable to license or acquire third party intellectual property rights on terms that would allow Forte to make an appropriate return on its investment or at all.

In the event that Forte tries to obtain rights to required third party intellectual property rights, and are ultimately unsuccessful, Forte may be required to expend significant time and resources to redesign its technology, product candidate, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If Forte is unable to do so, Forte may be unable to develop or commercialize the affected product candidate which could harm its business, financial condition, results of operations, and prospects significantly.

***Forte may be subject to claims that its employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what Forte regards as its own intellectual property.***

Many of Forte's employees, consultants, and advisors are currently or were previously employed at universities or other healthcare companies, including its competitors and potential competitors. Although Forte tries to ensure that its employees, consultants, and advisors do not use the proprietary information or know-how of others in their work for Forte, Forte may be subject to claims that Forte or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If Forte fails in defending any such claims, in addition to paying monetary damages, Forte may lose valuable intellectual property rights or personnel. Even if Forte is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is Forte's policy to require its employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to Forte, Forte may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that Forte regards as its own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and Forte may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what Forte regards as its intellectual property. Such claims could have a material adverse effect on Forte's business, financial condition, results of operations, and prospects.

***Third-party claims of intellectual property infringement, misappropriation or other violation against Forte or its collaborators may prevent or delay the development and commercialization of Forte's product candidate and other technologies.***

The field of developing therapeutics that target the microbiome is competitive and dynamic. Due to the focused research and development that is taking place by several companies, including Forte and its competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to Forte's owned, and other third party, intellectual property and proprietary rights in the future.

Forte's commercial success depends in part on its and its collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to Forte's patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to microbiome technologies and in the fields in which Forte is developing its product candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that its product candidate and other technologies may give rise to claims of infringement of the patent rights of others. Forte cannot assure you that its product candidate and other technologies that Forte has developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. Forte may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which Forte is developing its product candidate and other technologies might assert are infringed by its current or future product candidate or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover its product candidate or other technologies. It is also possible that patents owned by third parties of which Forte is aware, but which Forte does not believe are relevant to its product candidate or other technologies, could be found to be infringed by its product candidate or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that its product candidate or other technologies may infringe. Forte cannot provide any assurances that third-party patents do not exist which might be enforced against its current technology, manufacturing methods, product candidate, or future methods or products resulting in either an injunction prohibiting its manufacture or future sales, or, with respect to its future sales, an obligation on its part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of Forte's product candidate or other technologies infringes upon these patents. In the event that any third-party claims that Forte infringes their patents or that Forte is otherwise employing their proprietary technology without authorization and initiates litigation against us, even if Forte believes such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by Forte's product candidate or other technologies. In this case, the holders of such patents may be able to block Forte's ability to commercialize the applicable product candidate or technology unless Forte obtains a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if Forte is able to obtain a license, the license would likely obligate Forte to pay license fees or royalties or both, and the rights granted to Forte might be non-exclusive, which could result in its competitors gaining access to the same intellectual property. If Forte is unable to obtain a necessary license to a third-party patent on commercially reasonable terms, Forte may be unable to commercialize its product candidate or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm Forte's business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from Forte's business, and may impact its reputation. In the event of a successful claim of infringement against Forte, Forte may be enjoined from further developing or commercializing its infringing product candidate or other technologies. In addition, Forte may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign its infringing product candidate or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, Forte would be unable to further develop and commercialize its product candidate, FB-401, or other technologies, which could harm its business significantly.

Engaging in litigation to defend against third parties alleging that Forte has infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of its size, and time-consuming. Some of its competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than Forte can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against Forte could impair its ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on Forte's business, financial condition or results of operations.

***Forte may become involved in lawsuits to protect or enforce its patents and other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.***

Competitors may infringe Forte's patents, or Forte may be required to defend against claims of infringement. In addition, its patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned by Forte is invalid or unenforceable, the other party's use of its patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1), or may refuse to stop the other party from using the technology at issue on the grounds that its owned patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of its owned patents at risk of being invalidated or interpreted narrowly. Even if Forte establishes infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of Forte's confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in Forte's favor, litigation or other legal proceedings relating to intellectual property claims may cause Forte to incur significant expenses and could distract its personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of Forte's common stock. Such litigation or proceedings could substantially increase its operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Forte may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of its competitors may be able to sustain the costs of such litigation or proceedings more effectively than Forte can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Forte's ability to compete in the marketplace.

***If Forte's trademarks and trade names are not adequately protected, then Forte may not be able to build name recognition in its markets of interest and its business may be adversely affected.***

Forte's registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Forte may not be able to protect its rights to these trademarks and trade names, which Forte needs to build name recognition among potential partners or customers in its markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to Forte's, thereby impeding Forte's ability to build brand identity and possibly leading to market confusion. If Forte asserts trademark infringement claims, a court may determine that the marks Forte has asserted are invalid or

unenforceable, or that the party against whom Forte has asserted trademark infringement has superior rights to the marks in question. In this case, Forte could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of Forte's registered or unregistered trademarks or trade names. Over the long term, if Forte is unable to establish name recognition based on its trademarks and trade names, then Forte may not be able to compete effectively, and its business may be adversely affected. Forte's efforts to enforce or protect its proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect its business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats.***

The degree of future protection afforded by Forte's intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect its business or permit Forte to maintain its competitive advantage. For example:

- others may be able to make products that are similar to Forte's product candidate or utilize similar technology but that are not covered by the claims of the patents that Forte may own;
- Forte, or its current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that Forte own now or in the future;
- Forte, or its current or future licensors or collaborators, might not have been the first to file patent applications covering certain of its or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of Forte's technologies without infringing Forte's owned intellectual property rights;
- it is possible that Forte's current or future pending owned patent applications will not lead to issued patents;
- issued patents that Forte hold rights to may be held invalid or unenforceable, including as a result of legal challenges by its competitors or other third parties;
- Forte's competitors or other third parties might conduct research and development activities in countries where Forte do not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- Forte may not develop additional proprietary technologies that are patentable;
- the patents of others may harm Forte's business; and
- Forte may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on Forte's business, financial condition, results of operations and prospects.

**Risks related to Forte's reliance on third parties**

***Forte will rely on third parties to conduct its clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, Forte may not be able to obtain regulatory approval of or commercialize any potential product candidate.***

Forte will depend upon third parties, including independent investigators, to conduct its clinical trials under agreements with universities, medicinal institutions, CROs, strategic partners and others. Forte expects to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to its development timelines and increased costs.

Forte will rely heavily on third parties over the course of its clinical trials, and, as a result, will have limited control over the clinical investigators and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, Forte is responsible for ensuring that each of its clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and its reliance on third parties does not relieve Forte of its regulatory responsibilities. Forte and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidate in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If Forte or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in its clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Forte to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving its marketing applications. Forte cannot be certain that, upon inspection, such regulatory authorities will determine that any of its clinical trials comply with the GCP requirements. In addition, its clinical trials must be conducted with drug product produced under cGMP requirements and may require a large number of patients.

Forte's failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require Forte to repeat clinical trials, which would delay the regulatory approval or commercialization process. Moreover, its business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting Forte's future clinical trials will not be its employees and, except for remedies that may be available to Forte under its agreements with such third parties, Forte cannot control whether or not they devote sufficient time and resources to its ongoing clinical programs. These third parties may also have relationships with other commercial entities, including Forte's competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on Forte's behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to Forte's clinical protocols or regulatory requirements or for other reasons, Forte's clinical trials may be extended, delayed or terminated and Forte may not be able to complete development of, obtain regulatory approval of or successfully commercialize its product candidate. As a result, its financial results and the commercial prospects for its product candidate would be harmed, its costs could increase and its ability to generate revenue could be delayed.

If any of its relationships with these third-party CROs or others terminate, Forte may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact Forte's ability to meet its desired clinical development timelines. Though Forte carefully manages its relationships with its CROs, there can be no assurance that Forte will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on its business, financial condition and prospects.

***Forte expects to rely on third parties to manufacture its clinical supply of product candidate, and Forte intends to rely on third parties to produce and process its products, if approved.***

Forte currently relies on outside vendors to supply raw materials and other important components. Forte has not yet caused any product candidate to be manufactured or processed on a commercial scale and may not be able to do so for any of its product candidates. Forte will make changes as Forte works to optimize the manufacturing process for its product candidates, and Forte cannot be sure that even minor changes in the process will result in therapies that are safe and effective.

The facilities used to manufacture Forte's product candidate must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after Forte submits a marketing application to the FDA or other foreign regulatory agencies. Forte does not currently control all aspects of the manufacturing process of, and are currently largely dependent on, its contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for manufacture of its product candidate. If and when its

manufacturing facility becomes operational, Forte will be responsible for compliance with cGMP requirements. If Forte or its contract manufacturers cannot successfully manufacture in conformance with its specifications and the strict regulatory requirements of the FDA or other regulatory authorities, Forte and they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to the manufacture of its product candidate. In addition, Forte has no control over the ability of its contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of its product candidate or if it withdraws any such approval in the future, Forte may need to find alternative manufacturing facilities, which would significantly impact its ability to develop, obtain regulatory approval for or market its product candidate, if approved.

For more information, see "Risk Factors—Risks Related to Manufacturing and Supply" below.

***If Forte's contract manufacturing organization for materials to be used in its clinical trials fails to supply Forte with the necessary materials, Forte may be unable to complete its clinical trials on a timely basis, if at all.***

Forte has entered into a services agreement with a third party to handle the manufacturing supply chain for drug substance synthesis for its planned clinical trials. If this manufacturer is unable or unwilling to provide Forte with sufficient quantities of its microbiome candidate to meet its demands or fails to meet its standards of quality or other specification or to achieve drug cGMP compliance, Forte may not be able to locate any alternative suppliers or enter into commercially reasonable agreements with substitute suppliers in a timely manner or at all.

***A coronavirus pandemic is ongoing in many parts of the world and can result in significant disruptions to Forte's supply of the investigational product for its clinical trials which could have a material adverse effect on its business.***

As the COVID-19 pandemic is still evolving as of this time, much of its impact remains unknown, and it is impossible to predict the impact it may have on the development of Forte's product candidates and the impact on its business. The severity of the coronavirus pandemic could also make access to Forte's existing supply chain difficult or impossible by delaying the delivery of key raw materials used in its product candidates and therefore delay the delivery of such products for use in its clinical trials. Any of these results could materially impact Forte's business and have an adverse effect on its business.

***Third-party relationships are important to Forte's business. If Forte is unable to maintain its collaborations, enter into new relationships or if these relationships are not successful, its business could be adversely affected.***

Forte has limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, Forte enters into relationships with other companies to provide it with important technologies, and Forte may receive additional technologies and funding under these and other collaborations in the future. Relationships Forte enter into, may pose a number of risks, including the following:

- third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- current and future third parties may not perform their obligations as expected;
- current and future third parties may not pursue development and commercialization of any product candidate that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic merger that may divert resources or create competing priorities;
- third parties may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- current and future third parties could independently develop, or develop with third parties, products that compete directly or indirectly with Forte's products and product candidate if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with Forte may be viewed by its current or future third parties as competitive with their own product candidate or products, which may cause such third parties to cease to devote resources to the commercialization of its product candidate;
- current and future third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- current and future third parties with marketing and distribution rights to one or more of Forte's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with current or future third parties, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidate, might lead to additional responsibilities for Forte with respect to product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- current and future third parties may not properly maintain or defend its intellectual property rights or may use its proprietary information in such a way as to invite litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose Forte to potential litigation;
- current and future third parties may infringe the intellectual property rights of third parties, which may expose Forte to litigation and potential liability;
- if a current or future third parties of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by Forte; and
- current and future relationships may be terminated by the collaborator, and, if terminated, Forte could be required to raise additional capital to pursue further development or commercialization of the applicable product candidate.

If Forte's relationships do not result in the successful discovery, development and commercialization of products or if one of its third parties terminates its agreement with Forte, Forte may not receive any future research funding or milestone or royalty payments under the collaboration. If Forte does not receive the funding Forte expects under these agreements, its development of its technology and product candidates could be delayed, and Forte may need additional resources to develop product candidate and its technology. All of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of its collaborators.

Additionally, if any of Forte's current or future third parties terminate their agreement with Forte, Forte may find it more difficult to attract new collaborators and its perception in the business and financial communities could be adversely affected.

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Forte faces significant competition in seeking appropriate collaborators. Forte's ability to reach a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If Forte is unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, Forte may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own

expense. If Forte elects to increase its expenditures to fund development or commercialization activities on its own, Forte may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms, or at all. If Forte fails to enter into relationships or does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, Forte may not be able to further develop its product candidates, bring them to market and generate revenue from sales of drugs or continue to develop its technology, and its business may be materially and adversely affected.

**Risks related to manufacturing and supply**

***Forte's product candidate relies on the availability of specialty raw materials, which may not be available to Forte on acceptable terms or at all.***

Forte's product candidate requires certain specialty raw materials, some of which Forte obtain from small companies with limited resources and experience to support a commercial product. The suppliers may be ill-equipped to support Forte's needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. Forte does not currently have contracts in place with all of the suppliers that Forte may need at any point in time, and if needed, may not be able to contract with them on acceptable terms or at all. Accordingly, Forte may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

***Forte's product candidate requires specialized manufacturing capabilities. If Forte or any of its third-party manufacturers encounter difficulties in manufacturing its product candidate, its ability to provide supply of its product candidate for clinical trials or its products for patients, if approved, could be delayed or stopped, or Forte may be unable to maintain a commercially viable cost structure.***

The manufacturing process used to produce Forte's product candidate is complex and novel, and it has not yet been validated for investigational and commercial production. As a result of these complexities, the cost to manufacture Forte's product candidate is higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and is more difficult to reproduce. Furthermore, its cGMP manufacturing process development and scale-up is at an early stage. The actual cost to manufacture and process its product candidate could be greater than Forte expects and could materially and adversely affect the commercial viability of its product candidate.

Forte's manufacturing process may be susceptible to manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other contaminations are discovered in Forte's product candidate or in the manufacturing facilities in which its product candidate are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidate are developed through preclinical to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause its product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials. Further, changes made to its manufacturing process will require prior approval by FDA, which can delay Forte's clinical trials and regulatory approval of its product candidate.

Although Forte continues to optimize its manufacturing process for its product candidate, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents and/or raw materials. Forte ultimately may not be successful in transferring its production system from its contract manufacturer to any manufacturing facilities Forte establishes itself, or its contract manufacturer may not have the necessary capabilities to complete the implementation and development process. If Forte is unable to adequately validate or scale-up the manufacturing process for its product candidate with its current manufacturer, Forte will need to transfer to

another manufacturer and complete the manufacturing validation process, which can be lengthy. If Forte is able to adequately validate and scale-up the manufacturing process for its product candidate with a contract manufacturer, Forte will still need to negotiate with such contract manufacturer an agreement for commercial supply, and it is not certain Forte will be able to come to agreement on terms acceptable to it. As a result, Forte may ultimately be unable to reduce the cost of goods for its product candidate to levels that will allow for an attractive return on investment if and when that product candidate is commercialized upon approval.

The manufacturing process for any products that Forte may develop is subject to the FDA and foreign regulatory authority approval process, and Forte will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If Forte or its CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, Forte may not obtain or maintain the approvals Forte needs to commercialize such products. Even if Forte obtains regulatory approval for any of its product candidates, there is no assurance that either Forte or its CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of its product candidate, impair commercialization efforts, increase Forte's cost of goods, and have an adverse effect on its business, financial condition, results of operations and growth prospects. Forte's future success depends on its ability to manufacture its products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on its business, financial condition, and results of operations. In addition, Forte could incur higher manufacturing costs if manufacturing processes or standards change, and Forte could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because its product candidate may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for Forte to achieve profitability may be greater.

***Forte may depend on third parties for clinical and commercial supplies, including, in some instances, a single supplier.***

Forte may depend on third-party suppliers for clinical and commercial supplies, including the active ingredients which are used in its product candidate. These supplies may not always be available to Forte at the standards Forte require or on terms acceptable to it, or at all, and Forte may not be able to locate alternative suppliers in a timely manner, or at all. If Forte is unable to obtain necessary clinical or commercial supplies, its manufacturing operations and clinical trials and the clinical trials of its collaborators may be delayed or disrupted, and its business and prospects may be materially and adversely affected as a result.

Forte may rely on a single supplier for certain of its supplies. If this supplier is unable to supply to Forte in the quantities it requires, or at all, or otherwise defaults on its supply obligations to Forte, Forte may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all.

***Forte has limited experience manufacturing its drug product candidate for purposes of clinical trials and at commercial scale, and if Forte decides to establish its own manufacturing facility for its drug product candidate, Forte cannot assure you that it can manufacture its drug product candidate in compliance with regulations at a cost or in quantities necessary to make them commercially viable.***

Forte may establish a manufacturing facility for its product candidate for production as investigational new drugs for purposes of clinical trials. Forte has limited experience in cGMP compliant manufacturing of its drug product candidate for purposes of clinical trials or at a commercial scale. In the future, Forte may develop its manufacturing capacity in part by expanding its current facility or building additional facilities. This activity will require substantial additional funds, and Forte would need to hire and train a significant number of qualified employees to staff these facilities. Forte may not be able to develop cGMP-compliant manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use. The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. Forte may be subject to lengthy delays and expense in conducting validation studies, if Forte can meet the requirements at all.

**Risks Related to Ownership of Forte's Common Stock** ***The market price of Forte's common stock is expected to be volatile.***

The market price of Forte's common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of Forte's common stock to fluctuate include:

- Forte's ability to obtain regulatory approvals for its product candidates, and delays or failures to obtain such approvals;
- failure of any of Forte's product candidates, if approved, to achieve commercial success;
- Forte's failure to maintain its existing third-party license and supply agreements;
- failure by Forte or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to Forte's product candidates;
- any inability to obtain adequate supply of Forte's product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by Forte's competitors;
- failure to meet or exceed financial and development projections Forte may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by Forte or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and Forte's ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about Forte's business, or if they issue an adverse or misleading opinion regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of Forte's common stock Forte or its stockholders in the future;
- trading volume of Forte's common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of Forte;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in Forte's financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company's common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company's profitability and reputation. In addition, such securities litigation often has ensued after a reverse merger or other merger and acquisition activity. Such litigation if brought could negatively impact our business.

Additionally, a decrease in the stock price of the combined company may cause the combined company's common stock to no longer satisfy the continued listing standards of Nasdaq. If the combined company is not able to maintain the requirements for listing on Nasdaq, it could be delisted, which could have a materially adverse effect on its ability to raise additional funds as well as the price and liquidity of its common stock.

***Forte will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies.***

Following the recently completed Merger, Forte will incur significant legal, accounting and other expenses that the predecessor company of Forte did not incur as a private company, including costs associated with public company reporting requirements. Forte will also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as new implemented by the SEC and Nasdaq. These rules and regulations are expected to increase Forte's legal and financial compliance costs and to make some activities more time consuming and costly. For example, Forte's management team consists of the executive officers of the operating company that survived the Merger prior to the Merger, some of whom have not previously managed and operated a public company. These executive officers and other personnel need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations also may make it difficult and expensive for Forte to obtain and maintain directors' and officers' liability insurance. As a result, it may be more difficult for Forte to attract and retain qualified individuals to serve on its board of directors or as executive officers, which may adversely affect investor confidence in and could cause Forte's business or stock price to suffer.

***Anti-takeover provisions in Forte's charter documents and under Delaware law could make an acquisition of Forte more difficult and may prevent attempts by Forte's stockholders to replace or remove the combined company management.***

Provisions in Forte's certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because Forte is incorporated in Delaware, it is governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15% of the outstanding combined company voting stock from merging or combining with Forte. Although Forte believes these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with Forte's board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by Forte's stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

***Forte's certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between Forte and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with Forte or its directors, officers or other employees.***

Forte's certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on Forte's behalf, any action asserting a breach of fiduciary duty owed by any of its directors, officers or other employees to Forte or its stockholders, any action asserting a claim against it arising pursuant to any provisions of the DGCL, its certificate of incorporation or its bylaws, or any action asserting a claim against it that is governed by the internal affairs doctrine; *provided*, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act,

the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with Forte or its directors, officers or other employees, which may discourage such lawsuits against Forte and its directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, Forte may incur additional costs associated with resolving such action in other jurisdictions.

***Forte does not anticipate paying any cash dividends in the foreseeable future.***

The current expectation is that Forte will retain its future earnings, if any, to fund the development and growth of its business. As a result, capital appreciation, if any, of Forte's common stock will be its stockholders' sole source of gain, if any, for the foreseeable future.

***Future sales of shares by existing stockholders could cause Forte's stock price to decline.***

If existing stockholders of Forte sell, or indicate an intention to sell, substantial amounts of the Forte's common stock in the public market after legal restrictions on resale from the Merger lapse, the trading price of Forte's common stock could decline. Forte is not able to predict the effect that sales may have on the prevailing market price of Forte's common stock.

***If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about Forte, its business or its market, its stock price and trading volume could decline.***

The trading market for Forte's common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of Forte's common stock, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, Forte will not have any control over the analysts, or the content and opinions included in their reports. The price of Forte's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of Forte or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

***The combined company will have broad discretion in the use of proceeds from any capital raising efforts, including recent private placement financings, and may invest or spend the proceeds in ways with which its stockholders do not agree and in ways that may not increase the value of their investments.***

Forte has and will continue to have broad discretion over the use of proceeds from any capital raising efforts, including recent private placement financings. Its stockholders may not agree with Forte's decisions, and its use of the proceeds may not yield any return on its stockholders' investments. Forte's failure to apply the net proceeds of such financings effectively could compromise its ability to pursue its growth strategy and Forte might not be able to yield a significant return, if any, on its investment of these net proceeds. Forte's stockholders will not have the opportunity to influence its decisions on how to use the net proceeds from such financings.

***If Forte fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.***

Forte is subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that Forte maintain effective disclosure controls and procedures and internal control over financial reporting. Forte must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. As a private company, the operating entity that survived the Merger has never been required to test its internal controls within a specified period. This will require that Forte incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. Forte may experience difficulty in meeting these reporting requirements in a timely manner.

Forte may discover weaknesses in its system of internal financial and accounting controls and procedures that could result in a material misstatement of its financial statements. Forte's internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If Forte is not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, or if it is unable to maintain proper and effective internal controls, Forte may not be able to produce timely and accurate financial statements. If that were to happen, the market price of its common stock could decline and it could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

***If Forte fails to attract and retain management and other key personnel, it may be unable to continue to successfully develop or commercialize its product candidates or otherwise implement its business plan.***

Forte's ability to compete in the highly competitive pharmaceuticals industry depends on its ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. Forte is highly dependent on its management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of Forte's product pipeline, completion of its planned clinical trials, commercialization of its product candidates or in-licensing or acquisition of new assets and could impact negatively its ability to implement successfully its business plan. If Forte loses the services of any of these individuals, it might not be able to find suitable replacements on a timely basis or at all, and its business could be harmed as a result. Forte might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

***Forte is able to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies, which could result in its common stock being less attractive to investors.***

Forte currently qualifies as a smaller reporting company under the rules of the SEC. As a smaller reporting company, Forte is able to take advantage of reduced disclosure requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in its SEC filings. Decreased disclosures in Forte's SEC filings due to its status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects. Forte cannot predict if investors will find its common stock less attractive if it relies on these exemptions. If some investors find its common stock less attractive as a result, there may be a less active trading market for its common stock and its stock price may be more volatile. Forte may take advantage of the reporting exemptions applicable to a smaller reporting company until it is no longer a smaller reporting company, which status would end once it has a public float greater than $250 million. In that event, Forte could still be a smaller reporting company if its annual revenues were below $100 million and it has a public float of less than $700 million.

***Forte's principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of June 30, 2020, Forte's executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of its outstanding voting stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of Forte's organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for Forte's common stock that you may feel are in your best interest as one of Forte's stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for Forte's common stock.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

On June 16, 2020, we completed a private placement transaction in which we sold to certain investors a total of 411,112 newly issued shares of the Company's common stock at price per share of $11.25. No underwriters were involved in the issuance. The shares were issued in a private placement in reliance on Section 4(a)(2) of the Securities Act, for transactions by an issuer not involving any public offering. We relied upon this exemption from registration based in part on representations made by the investors in a stock purchase agreement entered into between us and the investors dated June 16, 2020.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

| Exhibit Number | Description |
|---|---|
| 2.1^ | Agreement and Plan of Merger and Reorganization, dated February 19, 2020, by and among the Registrant, Telluride Merger Sub, Inc. and Forte Subsidiary, Inc., incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed on February 20, 2020. |
| 2.2 | Form of Forte Subsidiary, Inc. Support Agreement, dated February 19, 2020, by and between Forte Subsidiary, Inc. and each of the parties named in each agreement therein, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 20, 2020. |
| 2.3 | Form of Registrant's Support Agreement, dated February 19, 2020, by and between the Registrant and each of the parties named in each agreement therein, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on February 20, 2020. |
| 2.4 | Form of Lock-Up Agreement, dated February 19, 2020, by each of the parties named in each agreement therein, and incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on February 20, 2020. |
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on April 19, 2017. |
| 3.2 | Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on June 15, 2020. |
| 3.3 | Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on April 19, 2017. |
| 4.1 | Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1, as amended (File No. 333-216574), originally filed on March 9, 2017. |
| 4.2* | Form of Warrant to Purchase Common Stock of the Registrant issued on June 15, 2020. |
| 10.1† | License Agreement, dated December 10, 2017, by and between Forte Subsidiary, Inc. and the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases, incorporated by reference to Exhibit 10.18 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020. |
| 10.2+ | Forte Subsidiary, Inc. 2018 Equity Incentive Plan, as amended, and Forms of Stock Option Agreement, Exercise Notice and Investment Representation Statement thereunder, incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020. |
| 10.3+ | Offer Letter, dated December 14, 2018, by and between Forte Subsidiary, Inc. and Paul A. Wagner, Ph.D., incorporated by reference to Exhibit 10.20 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020 |
| 10.4+ | Offer Letter, dated March 16, 2020, by and between Forte Subsidiary, Inc. and Antony Riley, incorporated by reference to Exhibit 10.21 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020 |
| 10.5†^ | Asset Purchase Agreement, dated April 9, 2020, by and between the Registrant and Abintus Bio, Inc., as amended on April 10, 2020, incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020. |

| | |
|---|---|
| 10.6†^ | Asset Purchase Agreement, dated April 17, 2020, by and between the Registrant and Denovo Biopharma LLC, incorporated by reference to Exhibit 10.23 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020. |
| 10.7*† | Amendment No. 2 to License Agreement by and between Forte Subsidiary, Inc. and the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases, dated May 26, 2020. |
| 31.1* | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1* | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2* | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101.INS | Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover page Interactive Data File (embedded with the Inline XBRL document) |

* Filed herewith.

\+ Indicates management contract or compensatory plan.

† Certain portions of this exhibit have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed. The Company agrees to furnish to the Securities and Exchange Commission a copy of any omitted portions of the exhibit upon request.

^ Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.

± The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Forte Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

**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 thereunto duly authorized.

Forte Biosciences, Inc.

Date: August 10, 2020

By: /s/ Paul Wagner

Paul Wagner, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: August 10, 2020

By: /s/ Antony Riley

Antony Riley
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 4.2**

**FORTE BIOSCIENCES, INC.**

**WARRANT TO PURCHASE COMMON STOCK**

Number of Shares: [ ]
(subject to adjustment)

CS Warrant No. CSW-[ ] Original Issue Date: June 12, 2020

Forte Biosciences, Inc., a Delaware corporation (the "*Company*"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [ ], or its permitted registered assigns (the "*Holder*"), is entitled, subject to the terms set forth below, to purchase from the Company up to a total of [ ] shares of common stock, $0.0001 par value per share (the "*Common Stock*"), of the Company (each such share, a "*Warrant Share*" and all such shares, the "*Warrant Shares*") at the Exercise Price (as adjusted from time to time as provided in Section 9 herein), upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "*Warrant*") at any time and from time to time on or after the Effective Time (as defined in the Merger Agreement) (the "*Original Issue Date*") and through and including 5:30 P.M., New York City time, on Expiration Date (as defined herein), and subject to the following terms and conditions. This Warrant is one of a series of similar warrants issued pursuant to that certain Securities Purchase Agreement, dated February 19, 2020, by and among the Company and the Purchaser identified therein. Capitalized terms not otherwise defined herein have the meanings given to such terms in the Purchase Agreement.

1. Definitions. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "*Affiliate*" means any Person directly or indirectly controlled by, controlling or under common control with, a Holder, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by," "controlling" and "under common control with") means, with respect to a Person, possession, direct or indirect, of (a) the power to direct or cause direction of the management and policies of such Person (whether through ownership of securities or partnership or other ownership interests, by contract or otherwise), or (b) at least 50% of the voting securities (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests.

(b) "*Commission*" means the United States Securities and Exchange Commission.

(c) "*Closing Sale Price*" means, for any security as of any date, the last trade price for such security on the Principal Trading Market for such security, as reported by Bloomberg Financial Markets, or, if such Principal Trading Market begins to operate on an extended hours basis and does not designate the last trade price, then the last trade price of such security prior to 4:00 P.M., New York City time, as reported by Bloomberg Financial Markets, or if the foregoing do not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg Financial Markets, or, if no last trade price is reported for such security by Bloomberg Financial Markets, the average of the bid and ask prices, of any market makers for such security as reported in the "pink sheets" by Pink Sheets LLC. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing

bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then the Board of Directors of the Company shall use its good faith judgment to determine the fair market value. The Board of Directors' determination shall be binding upon all parties absent demonstrable error. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(d) "*Exercise Price*" means an exercise price per share equal to the per share price calculated by dividing (i) $120,000,000 *by* (ii) the Parent Outstanding Shares (as defined in the Merger Agreement) as of immediately following the Effective Time of the Merger (which for purposes of clarity shall exclude any Warrant Shares issuable pursuant to the Warrants).

(e) "*Merger Agreement*" means that certain Agreement and Plan of Merger and Reorganization by and among Tocagen, Inc., Telluride Merger Sub, Inc., and the Company, dated as of February 19, 2020.

(f) "*Principal Trading Market*" means the national securities exchange or other trading market on which the Common Stock is primarily listed on and quoted for trading, which, as of the Original Issue Date, shall be The Nasdaq Capital Market.

(g) "*Securities Act*" means the Securities Act of 1933, as amended.

(h) "*Trading Day*" means any weekday on which the Principal Trading Market is open for trading.

(i) "*Transfer Agent*" means Computershare Trust Company, N.A., the Company's transfer agent and registrar for the Common Stock, and any successor appointed in such capacity.

2. Registration of Warrants. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "*Warrant Register*"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. Registration of Transfers. Subject to compliance with all applicable securities laws, the Company shall, or will cause its Transfer Agent to, register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, and payment for all applicable transfer taxes (if any). Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a "*New Warrant*") evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall, or will cause its Transfer Agent to, prepare, issue and deliver at the Company's own expense any New Warrant under this Section 3. Until due presentment for registration of transfer, the Company may treat the registered Holder hereof as the owner and holder for all purposes, and the Company shall not be affected by any notice to the contrary.

4. Exercise and Duration of Warrants.

(a) This Warrant shall expire 30 calendar days following the Company's certification to the Holder that the Company has publicly released data from the Company's FB-401 clinical trial for treatment of atopic dermatitis (the "*Expiration Date*"). All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Original Issue Date and through and including 5:30 P.M. New York City time, on the Expiration Date. At 5:30 P.M., New York City time, on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value and this Warrant shall be terminated and no longer outstanding.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the "*Exercise Notice*"), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice pursuant to Section 10 below), and the date on which the last of such items is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "*Exercise Date*." The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares.

5. Delivery of Warrant Shares.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than two Trading Days after the Exercise Date), upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with The Depository Trust Company ("*DTC*") through its Deposit Withdrawal Agent Commission system, or if the Transfer Agent is not participating in the Fast Automated Securities Transfer Program (the "*FAST Program*") or if the certificates are required to bear a legend regarding restriction on transferability, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. The Holder, or any natural person or legal entity (each, a "*Person*") permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares, as the case may be.

(b) If by the close of the second Trading Day after the Exercise Date, the Company fails to deliver to the Holder a certificate representing the required number of Warrant Shares in the manner required pursuant to Section 5(a) or fails to credit the Holder's balance account with DTC for such number of Warrant Shares to which the Holder is entitled, and if after such second Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "*Buy-In*"), then the Company shall, within two Trading Days after the Holder's request and in the Holder's sole discretion, either (1) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "*Buy-In Price*"), at which point the Company's obligation to deliver such certificate (and to issue such Warrant Shares) shall terminate or (2) promptly honor its obligation to deliver to the Holder a certificate or

certificates representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased in the Buy-In over the product of (A) the number of shares of Common Stock purchased in the Buy-In, times (B) the Closing Sale Price of a share of Common Stock on the Exercise Date.

(c) To the extent permitted by law and subject to 5(b), the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 11 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Subject to Section 5(b), nothing herein shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense (excluding any applicable stamp duties) in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided*, *however*, that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any certificates for Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times while this Warrant is outstanding reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are initially issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such action as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or

regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

9. Certain Adjustments. The number of Warrant Shares issuable upon exercise of this Warrant is subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock issued and outstanding on the Original Issue Date and in accordance with the terms of such stock on the Original Issue Date or as amended, that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares of Common Stock, (iii) combines its outstanding shares of Common Stock into a smaller number of shares of Common Stock or (iv) issues by reclassification of shares of capital stock any additional shares of Common Stock of the Company, then in each such case the number of Warrant Shares then underlying this Warrant shall be divided by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, provided, however, that if such record date shall have been fixed and such dividend is not fully paid on the date fixed therefor, the number of Warrant Shares shall be recomputed accordingly as of the close of business on such record date and thereafter the Warrant Shares shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends. Any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph), (iii) rights or warrants to subscribe for or purchase any security, or (iv) cash or any other asset (in each case, "*Distributed Property*"), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, in which the Company is not the surviving entity or the stockholders of the Company immediately prior to such merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such merger or consolidation, (ii) the Company effects any sale to another Person of all or substantially all of its assets in one transaction or a series of related transactions, (iii) pursuant to any tender offer or exchange offer (whether by the Company or another Person), holders of capital stock who tender shares representing more than 50% of the voting power of the capital stock of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (iv) the Company consummates a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital stock of the Company (except for any such transaction in which the stockholders of the Company immediately prior to such transaction maintain, in substantially the same proportions, the

voting power of such Person immediately after the transaction) or (v) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property (other than as a result of a subdivision or combination of shares of Common Stock covered by Section 9(a) above) (in any such case, a "*Fundamental Transaction*"), then following such Fundamental Transaction the Holder shall have the right to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "*Alternate Consideration*"). The Company shall not effect any Fundamental Transaction in which the Company is not the surviving entity or the Alternate Consideration includes securities of another Person unless (i) the Alternate Consideration is solely cash and the Company provides for the simultaneous "cashless exercise" of this Warrant pursuant to Section 10 below or (ii) prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or other Person (including any purchaser of assets of the Company) shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this paragraph (c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type. Notwithstanding the foregoing and for the avoidance of doubt, the consummation of the Fundamental Transaction will not cause any of the terms hereof to be affected, including that the definition of Exercise Price shall not be altered, adjusted or modified, and the number of Parent Common Stock issuable upon the exercise of this Warrant will be calculated pursuant to the Exchange Ratio.

(d) Calculations. All calculations under this Section 9 shall be made to the nearest share.

(e) Notice of Adjustments. Promptly following the Effective Time of the Merger and upon occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable) and the Exercise Price, describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(f) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; *provided, however*, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. In addition, if while this Warrant is outstanding, the Company authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction contemplated by Section 9(c), other than a Fundamental Transaction under clause (iii) of Section 9(c), the Company shall deliver to the Holder a notice of such

Fundamental Transaction at least thirty (30) days prior to the date such Fundamental Transaction is consummated. Holder agrees to maintain any information disclosed pursuant to this Section 9(f) in confidence until such information is publicly available, and shall comply with applicable law with respect to trading in the Company's securities following receipt any such information.

10. Payment of Exercise Price. Notwithstanding anything contained herein to the contrary, the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price through a "cashless exercise," in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised;

"A" equals the Closing Sale Price of the shares of Common Stock (as reported by Nasdaq Stock Market) on the date immediately preceding the Exercise Date; and

"B" equals the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a "cashless exercise" transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the Commission continues to take the position that such treatment is proper at the time of such exercise). Except as set forth in Section 5(b) (Buy-In remedy) and Section 12 (payment of cash in lieu of fractional shares), in no event will the exercise of this Warrant be settled in cash.

11. Limitations on Exercise.

(a) Notwithstanding anything to the contrary contained herein, the number of Warrant Shares that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, does not exceed 9.99% of the total number of then issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise), it being acknowledged by the Holder that the Company is not representing to such Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and such Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 11(a) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of

whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which portion of this Warrant is exercisable, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination under this Section 11(a) as to any group status shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 11(a), in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company's most recent Form 10-Q or Form 10-K, as the case may be, (y) a more recent public announcement by the Company or (z) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of the Holder, the Company shall, within three (3) Trading Days, confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. By written notice to the Company, which will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, the Holder may waive the provisions of this Section 11(a) or increase the beneficial ownership limitation to such percentage of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant as the Holder shall determine, in its sole discretion, subject to Section 11(b), and the provisions of this Section 11(a) shall continue to apply. Upon such a change by a Holder of the beneficial ownership limitation from such 9.99% limitation to such other percentage limitation, the beneficial ownership limitation may not be further waived or increased by such Holder without first providing the minimum notice required by this Section 11(a). Notwithstanding the foregoing, at any time following notice of a Fundamental Transaction under Section 9(e) with respect to a Section 9(b)(iii) Fundamental Transaction, the Holder may waive and/or change the beneficial ownership limitation effective immediately upon written notice to the Company and may reinstitute a beneficial ownership limitation at any time thereafter effective immediately upon written notice to the Company.

(b) Notwithstanding anything to the contrary contained herein, including Section 11(a), the Company shall not effect any exercise of this Warrant, and the Holder shall not be entitled to exercise this Warrant for a number of Warrant Shares in excess of that number of Warrant Shares which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of Common Stock beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, to exceed 19.99% of the total number of issued and outstanding shares of Common Stock of the Company following such exercise, or (ii) the combined voting power of the securities of the Company beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act to exceed 19.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise. For purposes of this Section 11(b), the aggregate number of shares of Common Stock or voting securities beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act shall include the shares of Common Stock issuable upon the exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (x) exercise of the remaining unexercised and non-cancelled portion of this Warrant by the Holder and (y) exercise or conversion of the unexercised, non-converted or non-cancelled portion of any other securities of the Company that do not have voting power (including without limitation any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including without limitation any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock), is subject to a limitation on conversion or exercise analogous to the limitation contained herein and is beneficially owned by the

Holder or any of its Affiliates and other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act.

(c) This Section 11 shall not restrict the number of shares of Common Stock which a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant.

12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based on the Closing Sale Price) for any such fractional shares.

13. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified below prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified below on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery.

14. Warrant Agent. The Company shall initially serve as warrant agent under this Warrant. Upon thirty (30) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. Miscellaneous.

(a) No Rights as a Stockholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) Authorized Shares.

(i) Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate or articles of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

(ii) Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(c) Successors and Assigns. Subject to the restrictions on transfer set forth in this Warrant and the restrictions on transfer set forth in this Warrant and compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant.

(d) Amendment and Waiver. Except as otherwise provided herein, the provisions of the Warrants may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holders of Warrants representing no less than a majority of the Warrant Shares obtainable upon exercise of the Warrants then outstanding; *provided that* such majority shall include the consent of each of the Alger Entities, the BVF Entities, and The OrbiMed Entities.

(e) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(f) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF LOS ANGELES, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY

SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PERSON AT THE ADDRESS IN EFFECT FOR NOTICES TO IT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

(g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(h) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed by its authorized officer as of the date first indicated above.

FORTE BIOSCIENCES, INC.

By:
Name: Paul A. Wagner, Ph.D.
Title: President & Chief Executive Officer

SCHEDULE 1

FORM OF EXERCISE NOTICE

[To be executed by the Holder to purchase shares of Common Stock under the Warrant]

Ladies and Gentlemen:

(1) The undersigned is the Holder of Warrant No. (the "*Warrant*") issued by Forte Biosciences, Inc., a Delaware corporation (the "*Company*"). Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The undersigned hereby exercises its right to purchase Warrant Shares pursuant to the Warrant.

(3) The Holder intends that payment of the Exercise Price shall be made as (check one):

☐ Cash Exercise

☐ "Cashless Exercise" under Section 10 of the Warrant

(4) If the Holder has elected a Cash Exercise, the Holder shall pay the sum of $ in immediately available funds to the Company in accordance with the terms of the Warrant.

(5) Except as set forth in paragraph (6), pursuant to this Exercise Notice, the Company shall deliver to the Holder Warrant Shares determined in accordance with the terms of the Warrant.

(6) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended) permitted to be owned under Section 11(a) or Section 11(b), as applicable, of the Warrant to which this notice relates.

Dated:

Name
of Holder:

By:
Name:
Title:

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. INFORMATION THAT HAS BEEN OMITTED HAS BEEN NOTED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[***]".

# NATIONAL INSTITUTES OF HEALTH

## SECOND AMENDMENT TO L-018-2018/0

This is the second amendment ("**Second Amendment**") of the agreement by and between the National Institute of Allergy and Infectious Diseases ("**NIAID**" or "**IC**"), and Forte Biosciences Inc, having an effective date of December 10, 2017 and having **NIAID** Reference Number L-018-2018/0 ("**Agreement**"). This **Second Amendment**, having **NIAID** Reference Number L-018-2018/2, is made between the **NIAID** through the Technology Transfer and Intellectual Property Office, **NIAID**, having an address at 5601 Fishers Lane, Suite 6D, Rockville, MD 20892-9804, and Forte Biosciences, having an address at [***]. This **Second Amendment** includes, in addition to the amendments made below, a Signature Page.

WHEREAS, the **NIAID** and the **Licensee** desire that the **Agreement** be amended a second time as set forth below in order to revise Appendix C ("Royalties") and Appendix D ("Benchmarks and Performance").

FURTHERMORE, the **NIAID** and the **Licensee** also desire to revise the Material Transfer Letter, dated April 20, 2018, between the parties, in order to ensure consistency of nomenclature between the Material Transfer Letter and **Licensed Patent Right**.

NOW, THEREFORE, in consideration of the mutual covenants and promises contained herein, the **NIAID** and the **Licensee**, intending to be bound, hereby mutually agree to the following:

1) Amendment to the **Agreement**:

Appendix C ("Royalties")

2) is hereby amended as follows (additions are shown underlined and deletions are shown in ~~strikethrough~~):

**Royalties:**

I. The **Licensee** agrees to pay to the **IC** a noncreditable, nonrefundable license issue royalty in the amount of [***] dollars ($[***]) within sixty (60) days from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **IC** a nonrefundable minimum annual royalty in the amount of twenty-thousand dollars ($20,000) and beginning on January 1, 2021, this minimum annual royalty shall be increased to one hundred thousand dollars ($100,000), as follows:

(a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. The **Licensee** agrees to pay the **IC** earned royalties of [***] ~~percent ([***]%) on **Net Sales**~~[***] percent ([***]%) on Net Sale up to $[***], [***] percent ([***]%) on Net Sales between $[***] and $[***] and [***] percent ([***]%) on Net Sales over $[***] by or on behalf of the **Licensee** and its sublicensees.

[***] Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

IV. The **Licensee** agrees to pay the **IC Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:

(a) [***] dollars ($[***]) upon completion of patient enrollment of a Phase III clinical trial in the **Licensed Field of Use**

(b) [***] dollars ($[***]) upon the completion of a Phase III clinical trial demonstrating statistical significant efficacy benefit of **Licensed Product**

(c) [***] dollars ($[***]) upon first FDA approval of **Licensed Product**. An additional [***] dollars ($[***]) shall be paid for each additional FDA approved **Licensed Product**

(d) [***] dollars ($[***]) upon first non-U.S. territory approval of **Licensed Product**. An additional [***] dollars ($[***]) shall be paid for each additional non-U.S. territory approval of **Licensed Product**

~~(e)~~ [***]

~~(f)~~ [***]

~~(g)~~ [***]

V. The **Licensee** agrees to pay the **IC** additional sublicensing royalties of [***] percent ([***]%) on the **Fair Value** of any consideration received for each sublicense in accordance with Article 4 of this **Agreement** within sixty (60) days of the execution of each sublicense. In the event the **Fair Value** of consideration is received by **Licensee** in installments, then the sublicensing royalty is due within sixty (60) days of receipt of each such payment by **Licensee**.

Appendix D ("Benchmarks and Performance")

3) is hereby amended as follows (additions are shown underlined and deletions are shown in ~~strikethrough~~):

Licensee agrees to the following Benchmarks for its performance under this Agreement and, within thirty (30) days of achieving a Benchmark, shall notify the IC that the Benchmark has been achieved.

']

2) Amendment to the Material Transfer Letter dated April 20, 2018, between the parties:

references to the Roseomonas *mucosa* strains transferred under the Letter, [***] ("Material") shall be replaced with [***].

3) All terms and conditions of the **Agreement** not herein amended remain binding and in effect.

4) This **Second Amendment** is effective upon execution by both parties. This **Second Amendment** may be executed in one or more counterparts, each of which will be deemed an original and all of which together will constitute one and the same agreement. Delivery of an executed counterpart by facsimile or other electronic means of transmission (including .PDF file) shall have the same effect as the delivery of an original. This **Second Amendment** shall not be enforceable against either Party unless each Party executes the **Second** Amendment and delivers it to the other.



[***] Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

**SIGNATURES BEGIN ON NEXT PAGE**



[***] Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

**SECOND AMENDMENT TO L-018-2018/0**

**SIGNATURE PAGE**

In Witness Whereof, the parties have executed this **Second Amendment** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For the **NIAID**:

/Michael R.
Mowatt 5/26/2020
Michael R. Mowatt, Ph.D. Date
Director, Technology Transfer and Intellectual Property Office
National Institute of Allergy and Infectious Diseases

Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: [***]

For the **Licensee** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

/Paul
Wagner
5/26/2020
Signature of Authorized
Official Date
Name:
Title:

I. Official and Mailing Address for **Agreement** notices:

Paul Wagner, Ph.D.
Member

Mailing Address:
1124 W. Carson St.
MRL Building 3-320
Torrance, CA 90502
Email Address: [***]
Phone: [***]
Fax: N/A



[***] Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments):

Paul Wagner
Member

Mailing Address:

1124 W. Carson St.
MRL Building 3-320
Torrance, CA 90502
Email Address: [***]
Phone: [***]
Fax: N/A

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).



[***] Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Dr. Paul Wagner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Forte Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

By: /s/ Paul Wagner

**Dr. Paul Wagner**
**Chief Executive Officer**

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Antony Riley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Forte Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2020

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

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Forte Biosciences, Inc. on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2020

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

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Forte Biosciences, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 10, 2020

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