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 September 30, 2022

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	**26-1243872**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3060 Pegasus Park Drive, Building 6 Dallas, Texas	**75247**
(Address of principal executive offices)	**(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 November 11, 2022, the registrant had 21,000,069 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

		Page
PART I.	FINANCIAL INFORMATION	2
Item 1.	Financial Statements	2
	Condensed Consolidated Balance Sheets as of September 30, 2022 (unaudited) and December 31, 2021	2
	Condensed Consolidated Statements of Operations for the Three and Nine months ended September 30, 2022 and 2021 (unaudited)	3
	Condensed Consolidated Statements of Stockholders' Equity for the Three and Nine months ended September 30, 2022 and 2021 (unaudited)	4
	Condensed Consolidated Statements of Cash Flows for the Nine months ended September 30, 2022 and 2021 (unaudited)	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4.	Controls and Procedures	21
PART II.	OTHER INFORMATION	22
Item 1.	Legal Proceedings	22
Item 1A.	Risk Factors	22
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	67
Item 3.	Defaults Upon Senior Securities	67
Item 4.	Mine Safety Disclosures	67
Item 5.	Other Information	67
Item 6.	Exhibits	69
SIGNATURES		70

PART I – FINANCIAL INFORMATION

Item 1: Financial Statements

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

	September 30, 2022 (unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 44,048	$ 42,044
Prepaid expenses and other current assets	546	476
Total current assets	44,594	42,520
Other assets	534	786
Total assets	**$ 45,128**	**$ 43,306**
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,191	$ 946
Accrued liabilities	1,102	812
Total current liabilities	2,293	1,758
Commitments and contingencies (Note 4)		
Series A Convertible Preferred Stock, $0.001 par value; 10,000,000 shares authorized and 0 shares issued and outstanding as of September 30, 2022 (unaudited) and December 31, 2021; aggregate liquidation preference of $0 as of September 30, 2022 (unaudited) and December 31, 2021	—	—
Stockholders' equity		
Common stock, $0.001 par value: 200,000,000 shares authorized as of September 30, 2022 (unaudited) and December 31, 2021; 21,000,069 and 14,754,447 shares issued and outstanding as of September 30, 2022 (unaudited) and December 31, 2021, respectively	21	15
Additional paid-in capital	124,981	114,698
Accumulated deficit	(82,167)	(73,165)
Total stockholders' equity	42,835	41,548
Total liabilities, convertible preferred stock and stockholders' equity	**$ 45,128**	**$ 43,306**

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)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 1,379	$ 5,656	$ 3,106	$ 12,501
General and administrative	2,044	2,043	5,851	5,686
Total operating expenses	3,423	7,699	8,957	18,187
Loss from operations	(3,423)	(7,699)	(8,957)	(18,187)
Other income (expense), net	23	(52)	(45)	(180)
Net loss	$ (3,400)	$ (7,751)	$ (9,002)	$ (18,367)
Per share information:				
Net loss per share - basic and diluted	$ (0.18)	$ (0.54)	$ (0.56)	$ (1.34)
Weighted average shares outstanding, basic and diluted	18,927,446	14,241,220	16,164,770	13,702,727

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

FORTE BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance — December 31, 2020	12,830,598	$ 13	$ 110,424	$ (51,457)	$ 58,980
Exercise of employee stock options	7,655	—	27	—	27
Stock-based compensation	—	—	495	—	495
Cashless exercise of warrants	673,463	—	—	—	—
Net loss	—	—	—	(4,804)	(4,804)
Balance — March 31, 2021	13,511,716	13	110,946	(56,261)	54,698
Exercise of employee stock options	1,939	—	15	—	15
Issuance of common stock upon vesting of restricted stock units	5,000	—	—	—	—
Cashless exercise of warrants	560,402	1	(1)	—	—
Stock-based compensation	—	—	1,008	—	1,008
Net loss	—	—	—	(5,812)	(5,812)
Balance — June 30, 2021	14,079,057	14	111,968	(62,073)	49,909
Exercise of employee stock options	19,981	—	19	—	19
Cashless exercise of warrants	655,409	1	(1)	—	—
Stock based compensation	—	—	1,473	—	1,473
Net loss	—	—	—	(7,751)	(7,751)
Balance — September 30, 2021	14,754,447	$ 15	$ 113,459	$ (69,824)	$ 43,650
Balance — December 31, 2021	14,754,447	$ 15	$ 114,698	$ (73,165)	$ 41,548
Exercise of employee stock options	1,098	—	1	—	1
Issuance of common stock under ESPP	5,716	—	11	—	11
Stock-based compensation	—	—	1,055	—	1,055
Net loss	—	—	-	(2,567)	(2,567)
Balance — March 31, 2022	14,761,261	15	115,765	(75,732)	40,048
Stock-based compensation	—	—	1,194	—	1,194
Net loss	—	—	-	(3,035)	(3,035)
Balance — June 30, 2022	14,761,261	15	116,959	(78,767)	38,207
Issuance of common stock through public equity offering, net of offering costs of $595	6,142,158	6	7,116	—	7,122
Issuance of common stock upon vesting of restricted stock units	96,650	—	—	—	—
Stock based compensation	—	—	906	—	906
Net loss	—	—	—	(3,400)	(3,400)
Balance — September 30, 2022	21,000,069	$ 21	$ 124,981	$ (82,167)	$ 42,835

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)

	For the Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (9,002)	$ (18,367)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	—	36
Impairment of property and equipment	—	61
Stock-based compensation expense	3,155	2,976
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	76	718
Accounts payable	189	1,090
Accrued liabilities	290	391
Net cash used in operating activities	(5,292)	(13,095)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs, $434	7,284	—
Proceeds from exercise of stock options and ESPP	12	61
Payment of deferred financing costs	—	(66)
Net cash provided by (used in) by financing activities	7,296	(5)
Net increase (decrease) in cash and cash equivalents	2,004	(13,100)
Cash and cash equivalents — beginning of period	42,044	58,765
Cash and cash equivalents — end of period	$ 44,048	$ 45,665
Non-cash financing activities:		
Supplemental disclosure of non-cash investing and financing activities:		
Unpaid issuance costs	$ 55	$ 40
Deferred issuance costs	$ 107	$ -

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) and its subsidiaries, referred to herein as the “Company”, is a biopharmaceutical company focused on developing its FB-102 program which the Company believes has potentially broad applications for autoimmune diseases. FB-102 is currently in preclinical development.

The Company was incorporated in Delaware on May 3, 2017 as a privately-held company. The Company merged with Tocagen, Inc. ("Merger"), a publicly traded biotechnology company, on June 15, 2020. The Company’s common stock is traded on the Nasdaq stock exchange under the ticker symbol “FBRX.”

On February 12, 2021, the Company incorporated Forte Biosciences Emerald Limited in Dublin, Ireland. This subsidiary was dissolved on April 1, 2022.

Liquidity and Risks

The accompanying condensed consolidated 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 condensed consolidated 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 September 30, 2022, the Company had an accumulated deficit of $82.2 million. The Company used $5.3 million of cash in operating activities during the nine months ended September 30, 2022. Management expects to continue to incur additional losses in the foreseeable future as the Company focuses its development efforts on advancing FB-102 through preclinical trials.

The Company had cash and cash equivalents of approximately $44.0 million as of September 30, 2022. The Company's cash and cash equivalents are held at financial institutions and exceed federally insured limits. The Company believes that its existing cash and cash equivalents 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.

The Company will continue to need to raise additional capital or obtain financing from other sources. Management may fund future operations through the sale of equity and debt financings and may also seek additional capital through arrangements with strategic partners or other sources. There can be no assurance that additional funding will be available on terms acceptable to the Company, if at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it may be forced to delay or reduce the scope of its research and development programs and/or limit or cease its operations. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the conflicts in Eastern Europe, and otherwise.

There are numerous risks and uncertainties associated with pharmaceutical development and the Company is unable to predict the timing or amount of increased expenses on the development of future product candidates or when or if it will start to generate revenues. Even if the Company does 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 may be forced to reduce its operations.

The pandemic caused by outbreaks of new strains of coronaviruses, or COVID-19 and its variants, has resulted, and may 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 its operations, financial position, results of operations and cash flows for the foreseeable future.

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 its audited financial statements and accompanying notes thereto as of and for the year ended December 31, 2021 included in the Company's Form 10-K as filed with the U.S. Securities and Exchange Commission (the "SEC") on March 31, 2022. The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), as found in the Accounting Standards Codification ("ASC"), the Accounting Standards Update ("ASU"), of the Financial Accounting Standards Board ("FASB"), and the rules and regulations of the US Securities and Exchange Commission ("SEC").

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 subsidiaries, Forte Subsidiary, Inc and Forte Biosciences Emerald Limited. All intercompany accounts and transactions have been eliminated in the preparation of the condensed consolidated financial statements.

Cash and Cash Equivalents

Cash and cash equivalents include money market funds and deposits with commercial banks. Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. There is a three-level hierarchy that prioritizes the inputs used in determining fair value by their reliability and preferred use as follows:

- *Level 1* - Valuations based on quoted prices in active markets for identical assets or liabilities.
- *Level 2* – Valuations based on quoted prices in active markets for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data.
- *Level 3* – Valuations based on inputs that are both significant to the fair value measurements and are unobservable.

To the extent that a valuation is based on models or inputs that are less observable, or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized within Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

There have been no significant changes to the valuation methods utilized by the Company during the periods presented. There have been no transfers between Level 1, Level 2, and Level 3 in any periods presented.

The carrying amounts of financial instruments consisting of cash and cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities included in the Company's financial statements, are reasonable estimates of fair value, primarily due to their short maturities.

The Company had $35.0 million in money market funds as of September 30, 2022 and December 31, 2021, which are classified within Level 1. Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. Money market funds were included as cash and cash equivalents in the condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021.

Use of Estimates

The preparation of the Company's condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, expenses and the disclosure of contingent assets and liabilities in the Company's condensed consolidated financial statements and accompanying notes. Significant management estimates that affect the reported amounts of assets, liabilities and expenses include stock-based compensation expense, accruals 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.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, clinical trials and drug manufacturing. Non-refundable advance payments for goods or services that will be used in future research and development activities are deferred and capitalized and are only expensed when the goods have been received or when the service has been performed rather than when the payment is made.

Drug manufacturing, clinical and preclinical costs are a component of research and development expenses. The Company expenses costs for its drug manufacturing activities performed by Contract Manufacturing Organizations ("CMOs"), preclinical and clinical trial costs performed by Contract Research Organizations ("CROs") and other service providers, as they are incurred, based upon estimates of the work completed over the

life of the individual study in accordance with associated agreements. The Company uses information it receives from internal personnel and outside service providers to estimate the percentage of completion and therefore the expense to be incurred.

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. Comprehensive loss was equal to net loss for the three and nine months ended September 30, 2022 and 2021.

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 in accordance with the treasury stock method. The following number of unexercised stock options, warrants and restricted stock units, 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 and Nine Months Ended September 30,	
	2022	**2021**
Options	2,329,918	1,509,256
Restricted stock units	162,201	15,000
Warrants	4,434	4,434
Total	2,496,553	1,528,690

Recently Issued Accounting Standards Not Yet Adopted

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 August 2020, the FASB issued ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in an Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"). ASU 2020-06 eliminates the beneficial conversion and cash conversion accounting models for convertible instruments. It also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, ASU 2020-06 modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the diluted earnings per share computation. The amendments in ASU 2020-06 are effective for smaller reporting companies as defined by the SEC for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but not earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its condensed consolidated financial statements and does not expect the adoption of this amended guidance to have a material impact on the Company's condensed consolidated financial statements.

3. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of September 30, 2022 and December 31, 2021 consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Prepaid insurance	$ 427	$ 387
Other	119	89
Total prepaid expenses and other current assets	$ 546	$ 476

Other Assets

Other assets as of September 30, 2022 and December 31, 2021 consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Prepaid insurance	$ 521	$ 667
Prepaid offering costs	—	106
Other	13	13
Total other assets	$ 534	$ 786

Accrued Liabilities

Accrued liabilities as of September 30, 2022 and December 31, 2021 consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Accrued legal and professional fees	$ 150	$ 75
Accrued compensation	642	681
Accrued manufacturing and clinical expenses	276	40
Other	34	16
Total accrued liabilities	$ 1,102	$ 812

4. 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 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”). The Company terminated the license agreement with DHHS effective April 2, 2022 without meeting any milestones.

The Company incurred $0 and $25,000 in minimum royalty expenses for the three months ended September 30, 2022 and 2021, and $25,000 and $75,000 for the nine months ended September 30, 2022 and 2021, respectively.

Lease Agreements

The Company has entered into month-to-month lease agreements for certain office and laboratory space. The lease agreements are cancellable by the Company at any time with a 30-day notice. Total rent expense for all

locations for the three and nine months ended September 30, 2022 was $6 thousand and $12 thousand, respectively. Total rent expense for all locations for the three and nine months ended September 30, 2021 was $9,000 and $0, respectively. Rent expense for the nine months ended September 30, 2021 included a net credit of $9,000 of a refund from operating expenses.

Preclinical Services

The Company has entered into various agreements with third party vendors for preclinical services. The estimated remaining commitments as of September 30, 2022 under these agreements were approximately $134,000.

5. Equity

Common Stock

In February 2021, warrants to purchase 978,858 shares of common stock were exercised on a cashless basis resulting in 673,463 shares being issued. In June 2021, warrants to purchase 760,572 shares of common stock were exercised on a cashless basis resulting in 560,402 shares being issued. In September 2021, warrants to purchase 1,013,116 shares of common stock were exercised on a cashless basis resulting in 655,409 shares being issued. 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, Inc. survived the merger with Tocagen and remained outstanding as of September 30, 2022.

In June 2021, the Company filed a shelf registration statement on Form S-3 that went effective in June 2021 which will allow the Company to raise up to $300 million in additional capital. On March 31, 2022, the Company entered into an "at-the-market" equity offering program ("ATM Facility") whereby the Company may from time to time offer and sell shares of its common stock up to an aggregate offering price of $25.0 million during the term of the ATM Facility. On April 1, 2022, the Company filed a prospectus supplement to the June 2021 Form S-3 relating to the offer and sale of the shares pursuant to the ATM Facility covering sales of up to $7.0 million of shares of common stock. On August 12, 2022, the Company filed an additional prospectus supplement relating to the offer and sale of shares pursuant to the ATM Facility covering sales of up to an additional $2.7 million of shares of common stock. The Company is not obligated to sell any shares under the ATM Facility. The ATM Facility may be terminated at any time upon ten days' prior notice, or at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. The Company has agreed to pay the sales agent a commission equal to 3.0% of the gross proceeds from the sales of shares under the ATM Facility and has agreed to provide the sales agent with customary indemnification and contribution rights. The Company issued 6.1 million shares of common stock for gross proceeds of approximately $7.7 million under the ATM Facility from July 1, 2022 through September 30, 2022 and incurred $595,000 in issuance costs related to the ATM Facility and shelf registration statement.

Rights Plan

On July 11, 2022, the Company authorized and declared a dividend distribution of one right (each, a "Right") for each outstanding share of common stock of the Company to stockholders of record as of the close of business on July 21, 2022. Each Right entitles the registered holder to purchase from the Company one one-thousandth of a share of Series A Participating Preferred Stock, par value $0.001 per share (the "Preferred Stock"), of the Company at an exercise price of $16.00 per one one-thousandth of a share of Preferred Stock, subject to adjustment. The Rights are not exercisable until the Distribution Date. The Distribution Date is the 10th business day after the public announcement that a person or group of affiliated or associated persons has acquired beneficial ownership of 10 percent or more of our common stock or the 10th business day after a person or group announces a tender or exchange offer that would result in ownership by a person or group of 10 percent or more of our common stock.

The Rights will be redeemable at the Company's option for $0.001 per Right at any time on or prior to the 10th business day after the public announcement that an Acquiring Person has acquired beneficial ownership of 10 percent or more of the Common Stock.

The Rights expire on the earliest of July 12, 2023 or on the redemption or exchange of the Rights. There is no financial statement impact until such time as the rights become exercisable.

6. 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 were defined at the sole discretion of the Forte Subsidiary's board of directors. Service-based awards vesting over a defined period of service and performance-based awards that vest upon the achievement of defined conditions have been issued under the 2018 Incentive Plan. 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 with 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 Incentive Plan were exchanged into options to purchase common stock of Tocagen, which changed its name to Forte Biosciences Inc. upon the closing of the Merger. Subsequent to the Merger, the 2018 Incentive Plan was suspended and no more stock-based awards will be granted from that plan.

In connection with the Merger, the Company assumed Tocagen's 2017 Equity Incentive Plan, which was effective on April 12, 2017, was subsequently amended on September 30, 2018 and further amended on February 12, 2019 (the "2017 Plan"). 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 grants under the 2020 Inducement Plan. As of September 30, 2022, there were 115,000 shares available for issuance under the 2020 Inducement Plan.

In May 2021, the 2017 Plan was terminated and replaced by the 2021 Equity Incentive Plan (the "2021 Plan"). The 2021 Plan had an initial reserve of 1,000,000 shares available for grant. The 2021 Plan was amended in June 2022 to increase the shares available for grant by an additional 1,500,000 shares. The 2021 Plan provides for the grant of incentive stock options ("ISOs"), non-statutory 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 vested over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service with 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 for initial grants and in twelve equal monthly installments over a twelve-month period for subsequent grants. As of September 30, 2022, there were 1,370,554 shares available for issuance under the 2021 Plan.

Stock Options

The risk-free interest rate valuation 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 a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. Prior to the Merger, the fair value per share was 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. Subsequent to the Merger, the fair value per share is the closing stock price on the option grant date.

There were no stock options granted during the three months ended September 30, 2022. The weighted average grant-date fair value of stock options granted in the nine months ended September 30, 2022 was $0.92, and $18.49 and $21.89 in the three and nine months ended September 30, 2021, respectively.

The weighted-average assumptions used to value these stock options using the Black-Scholes option-pricing model were as follows.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Fair value of common stock	$ —	$ 30.63	$ 1.49	$ 35.78
Risk-free interest rate	—	0.91%	2.25%	0.94%
Dividend yield	—	0.00%	0.00%	0.00%
Expected term of options (years)	—	6.08	5.88	5.95
Volatility	—	67.20%	68.57%	69.00%

The table below summarizes the stock option activity during the nine months ended September 30, 2022:

	Number of Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2021	1,281,396	$ 18.18	7.94	
Granted	1,149,166	$ 1.49		
Exercised	(1,098)	$ 1.06		
Cancelled/Forfeited	(99,546)	$ 30.10		
Balances at September 30, 2022	2,329,918	$ 9.45	8.37	$ 98
Vested and expected to vest at September 30, 2022	2,329,918	$ 9.45	8.37	$ 98
Exercisable at September 30, 2022	468,581	$ 20.85	7.90	$ 9

The aggregate intrinsic value of options at September 30, 2022 is based on the Company's fair value of its stock price on that date of $1.07 per share.

Restricted Stock Unit Awards

There were no restricted stock units granted during the nine months ended September 30, 2022. The Company made a change in accounting estimate in the three months ended March 31, 2022 related to the vesting of performance-based restricted stock units. As a result of this change in accounting estimate, $158,000 of expense that had been previously recognized in 2021 was reversed in the three months ended March 31, 2022.

Restricted stock unit awards outstanding as of September 30, 2022 were as follows:

	Shares	Weighted Avg Grant Date Fair Value
Outstanding at December 31, 2021	258,851	$ 3.36
Granted	—	—
Forfeited/Cancelled	—	—
Issued as Common Stock	(96,650)	3.36
Outstanding at September 30, 2022	162,201	$ 3.36

2017 Employee Stock Purchase Plan

In May 2021, the Company's board of directors reactivated the Company's 2017 Employee Stock Purchase Plan ("ESPP") which had previously been suspended. The ESPP allows eligible employees to withhold up to 15% of their earnings to purchase shares of the Company's common stock at a price per share equal to the lower of (i) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (ii) 85% of the fair market value of a share of the Company's common stock on the date of purchase. The Company had 318,522 shares available for future issuance under the ESPP as of September 30, 2022. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year through January 1, 2027, by the lesser of (a) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (b) 300,000 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). The Company issued 5,716 shares under the ESPP during the nine months ended September 30, 2022. The ESPP is considered a compensatory plan. The Company recorded stock-based compensation expense related to its ESPP of $2 thousand for the three and nine months ended September 30, 2022. The Company recorded stock-based compensation expense related to its ESPP of $20 thousand for the three and nine months ended September 30, 2021.

Stock-Based Compensation Expense

Stock-based compensation expenses included in the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2022 and 2021 were (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 327	$ 522	$ 993	$ 1,191
General and administrative	579	951	2,162	1,785
Total	$ 906	$ 1,473	$ 3,155	$ 2,976

As of September 30, 2022, there was unrecognized stock-based compensation expense related to stock options with service conditions of $7.1 million, which is expected to be recognized over a weighted-average period of 2.35 years. Total unrecognized stock-based compensation expenses related to stock options and restricted stock units with performance conditions were approximately $233,000.

7. Related Party Transactions

Two members of the Company's board of directors received cash payments of $4 thousand and $16 thousand for scientific consulting services during the three and nine months ended September 30, 2022, respectively.

One member of the Company's board of directors received cash payments of $1,000 for scientific consulting services for the three and nine months ended September 30, 2021.

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 elsewhere in this Form 10-Q and in our Form 10-K as filed with the Securities and Exchange Commission, or SEC, on March 31, 2022. 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-102; the timing of initiation of Forte's planned preclinical studies and potential future clinical trials and the timing of the availability of data from such preclinical studies and potential future 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; 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, our Form 10-K filed with the SEC on March 31, 2022, and other SEC filings. 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. and its subsidiary (www.fortebiorx.com) ("Forte", "we", "our") is a biopharmaceutical company focused on developing its FB-102 program which the Company believes has potentially broad applications for autoimmune diseases. We had $44.0 million in cash and cash equivalents as of September 30, 2022.

In June 2021, the Company filed a shelf registration statement on Form S-3 that went effective in June 2021 which will allow the Company to raise up to $300 million in additional capital. On March 31, 2022, the Company entered into an "at-the-market" equity offering program ("ATM Facility") whereby the Company may from time to time offer and sell shares of its common stock up to an aggregate offering price of $25.0 million during the term of the ATM Facility. On April 1, 2022, the Company filed a prospectus supplement to the June 2021 Form S-3 relating to the offer and sale of the shares pursuant to the ATM Facility covering sales of up to $7.0 million of shares of common stock. On August 12, 2022, the Company filed an additional prospectus supplement relating to the offer and sale of shares pursuant to the ATM Facility covering sales of up to an additional $2.7 million of shares of common stock. The Company is not obligated to sell any shares under the ATM Facility. The ATM Facility may be

terminated at any time upon ten days' prior notice, or at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. The Company has agreed to pay the sales agent a commission equal to 3.0% of the gross proceeds from the sales of shares under the ATM Facility and has agreed to provide the sales agent with customary indemnification and contribution rights. The Company issued 6.1 million shares of common stock for gross proceeds of approximately $7.7 million under the ATM Facility from July 1, 2022 through September 30, 2022 and incurred $595,000 in issuance costs related to the ATM Facility and shelf registration statement.

Intellectual Property

In December 2017, Forte entered into an exclusive license agreement with the DHHS, as amended in May 2020. Under the agreement, the DHHS granted Forte an exclusive, sublicensable and worldwide license to certain rights in 12 patents under which we may develop and commercialize pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and conditions. The Company terminated its license agreement with DHHS effective April 2, 2022.

We own one US patent for administering a combination of Gram-positive and Gram-negative bacteria along with metabolites for treatment of a wide variety of skin conditions. The patent's estimated expiration date is 2039. This patent is not material to Forte's FB-102 program.

COVID-19

The pandemic caused by an outbreak of a new strain of coronavirus, or COVID-19 and its variants, 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 our 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, results of operations and cash flows.

Components of Operating Results

Revenue

We have no products approved for commercial sale or in active development and have not generated any revenue from product sales. In the future, we may generate revenue from product sales, royalties on product sales, 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 costs are expensed as incurred. Research and development costs consist primarily of salaries and benefits of research and development personnel and costs related to research activities, preclinical studies, clinical trials, drug manufacturing, and, in 2021, wind down costs incurred following the announcement of our unfavorable clinical trial results and the write-off of manufacturing property and equipment. Non-refundable advance payments for goods or services that will be used in future research and development activities are deferred and capitalized and are only expensed when the goods have been received or when the service has been performed rather than when the payment is made.

Drug manufacturing and clinical trial costs are a component of research and development expenses. The Company expenses costs for its drug manufacturing activities performed by Contract Manufacturing Organizations ("CMOs"), costs for its preclinical and clinical trial activities performed by Contract Research Organizations ("CROs") and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company uses information it receives from internal personnel and outside service providers to estimate the percentage of completion and therefore the expense to be incurred.

The Company significantly reduced its research and development expenses as it wound down the FB-401 program, however, we anticipate research and development expenses to continue to increase in the future as we develop our current lead product candidate, FB-102.

General and Administrative Expenses

General and administrative expenses consist primarily of professional fees such as legal, auditing, tax and business consulting services, personnel expenses and travel costs, costs associated with being a publicly traded company such as Sarbanes-Oxley compliance, accounting fees, and directors' and officers' liability insurance premiums. Our general and administrative expenses may increase due to increases in professional and advisory fees and as we build out our infrastructure to develop FB-102.

Other Income (Expense), Net

Other expense, net, consists of net foreign exchange gains and losses and franchise taxes, partially offset by interest earned on our cash and cash equivalents balances.

Critical Accounting Policies and Estimates

There have been no significant changes during the nine months ended September 30, 2022 to our critical accounting policies, significant judgments and estimates as disclosed in our management's discussion and analysis of financial condition and results of operations included in our Annual Report on our Form 10-K for the year ended December 31, 2021 as filed with the SEC on March 31, 2022.

Results of Operations

Comparison of Three and Nine months ended September 30, 2022 and 2021

The following tables summarize our results of operations for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	For the Three Months Ended September 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 1,379	$ 5,656	$ (4,277)
General and administrative	2,044	2,043	1
Total operating expenses	3,423	7,699	(4,276)
Other income (expense), net	23	(52)	75
Net Loss	$ 3,400	$ 7,751	$ (4,351)

	For the Nine Months Ended September 30,		
	2022	2021	Change
Operating expenses:			
Research and development	$ 3,106	$ 12,501	$ (9,395)
General and administrative	5,851	5,686	165
Total operating expenses	8,957	18,187	(9,230)
Other income (expense), net	(45)	(180)	135
Net Loss	$ 9,002	$ 18,367	$ (9,365)

Research and Development Expenses

Research and development expenses were $1.4 million for the three months ended September 30, 2022, compared to $5.7 million for the same period in 2021. The decrease of $4.3 million was primarily due to a net decrease of approximately $3.1 million in manufacturing expenses, a net decrease of approximately $0.5 million in preclinical and clinical expenses as we terminated our FB-401 program following the announcement of our unfavorable clinical trial results, and a decrease of $0.7 million in other expenses.

Research and development expenses were $3.1 million for the nine months ended September 30, 2022 compared to $12.5 million for the same period in 2021. The decrease of $9.4 million was primarily due to a net decrease of approximately $5.0 million in manufacturing expenses, a net decrease of approximately $2.9 million in preclinical and clinical expenses as we terminated our FB-401 program following the announcement of our unfavorable clinical trial results, a net decrease in payroll and related expenses of approximately $0.7 million as a result of reduced average headcount and a net decrease of $0.8 million in other expenses.

While research and development expenses decreased for the three and nine months ended September 30, 2022 compared to the same periods last year, we anticipate research and development expenses to increase in the future as we continue to develop our current lead product candidate, FB-102.

General and Administrative Expenses

General and administrative expenses were $2.0 million for the three months ended September 30, 2022, and 2021. General and administrative expenses remained relatively flat as an increase in legal and professional expenses of $0.4 million was mostly offset by a decrease of approximately $0.4 million in payroll and related expenses.

General and administrative expenses were $5.9 million for the nine months ended September 30, 2022, compared to $5.7 million for the same period in 2021. The increase of $0.2 million was primarily due to an increase in stock-based compensation expenses.

Our general and administrative expenses may increase in the future due to increases in professional and advisory fees as we build out our infrastructure to develop FB-102.

Other Income (Expenses), Net

The change in other income (expenses), net for the three and nine months ended September 30, 2022, compared with the same periods in the prior year were primarily driven by changes in foreign currency transaction and remeasurement losses related to contracts denominated in currencies other than the U.S. dollar due to differences between the exchange rates on the billing and payment dates, and franchise taxes.

Liquidity and Capital Resources

We have no products approved for commercial sale and have not generated any revenue from product sales or out-licenses. We have never been profitable and have incurred operating losses each year since inception. Our net loss was approximately $9.0 million for the nine months ended September 30, 2022. As of September 30, 2022, we had an accumulated deficit of approximately $82.2 million. We had cash and cash equivalents of approximately $44.0 million as of September 30, 2022. We believe that our existing cash and cash equivalents will be sufficient to allow us to fund our operations for at least 12 months from the filing date of this Form 10-Q. We expect to incur operating losses in the future as we develop our current lead product candidate, FB-102.

In June 2021, the Company filed a shelf registration statement on Form S-3 that went effective in June 2021 which will allow the Company to raise up to $300 million in additional capital. On March 31, 2022, the Company entered into an “at-the-market” equity offering program (“ATM Facility”) whereby the Company may from time to time offer and sell shares of its common stock up to an aggregate offering price of $25.0 million during the term of the ATM Facility. On April 1, 2022, the Company filed a prospectus supplement to the June 2021 Form S-3 relating to the offer and sale of the shares pursuant to the ATM Facility covering sales of up to $7.0 million of shares of common stock. On August 12, 2022, the Company filed an additional prospectus supplement relating to the offer and sale of shares pursuant to the ATM Facility covering sales of up to an additional $2.7 million of shares of common stock. The Company is not obligated to sell any shares under the ATM Facility. The ATM Facility may be terminated at any time upon ten days’ prior notice, or at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. The Company has agreed to pay the sales agent a commission equal to 3.0% of the gross proceeds from the sales of shares under the ATM Facility and has agreed to provide the sales agent with customary indemnification and contribution rights. The Company had issued 6.1 million shares of common stock for gross proceeds of approximately $7.7 million under the ATM Facility from July 1, 2022 through

September 30, 2022 and incurred $595,000 in issuance costs related to the ATM Facility and shelf registration statement.

Future Capital Requirements

We have not generated any revenue from product sales or from out-licensing. We do not know when, or if, we will generate any revenue. We expect to incur ongoing losses as we develop our current lead product candidate, FB-102, which has potentially broad application for autoimmune diseases such as alopecia areata, graft-vs-host disease and vitiligo. FB-102 is in preclinical development. Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

- the initiation and progress of preclinical studies and any clinical trials for our product candidates;
- the terms and timing of any strategic alliance, licensing and other arrangements that we may establish;
- the number of programs we pursue;
- the outcome, timing and cost of regulatory approvals;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in patent filing, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of our 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. In addition, our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflicts in Eastern Europe, and otherwise. 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.

See the “Risk Factors” section on this Form 10-Q for additional risks associated with our substantial capital requirements.

The following table shows a summary of our cash flows for the nine months ended September 30, 2022 and 2021 (in thousands):

	For the Nine Months Ended September 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (5,292)	$ (13,095)
Financing activities	7,296	(5)
Net increase (decrease) in cash and cash equivalents	$ 2,004	$ (13,100)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 was $5.3 million and consisted primarily of a net loss of $9.0 million adjusted for non-cash stock-based compensation of $3.1 million and decreases in net operating assets of $0.6 million.

Net cash used in operating activities for the nine months ended September 30, 2021 was $13.1 million and consisted primarily of a net loss of $18.4 million adjusted for non-cash items of $3.1 million which were primarily related to stock-based compensation and decreases in net operating assets of $2.2 million.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 consisted of $7.3 million in net proceeds from the sale of shares of our common stock under our ATM Facility and $12 thousand received from proceeds from stock option exercises and the issuance of shares of our common stock under the ESPP.

Net cash used in financing activities of $5 thousand for the nine months ended September 30, 2021 was primarily from $66 thousand in additional fees paid for our shelf registration statement partially offset by net proceeds of $61 thousand received from the exercise of stock options.

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 4 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 September 30, 2022.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended September 30, 2022 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 even though 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.

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully below in this section. You should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- Forte's business is almost entirely dependent on the success of developing FB-102, which may not be successful.
- Results from early preclinical studies may not be predictive of results from later stage studies or clinical trials.
- Forte has no approved products and has a limited operating history, which may make it difficult to evaluate its technology and product development capabilities and predict its future performance.
- 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 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 current lead product candidate, FB-102, or any future product candidates
- Forte's ability to successfully develop any product candidate is highly uncertain
- 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.
- Forte's planned preclinical studies or future clinical trials or those of its future collaborators may reveal significant adverse events and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidates.
- Positive results from early preclinical studies are not necessarily predictive of the results of any future clinical trials of product candidates. Forte may be unable to successfully develop, obtain regulatory approval for and commercialize any product candidates.
- Interim top-line and preliminary data from future 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.
- The market opportunities for FB-102 may be limited and Forte's estimates of the incidence and prevalence of its target patient populations may be inaccurate.

- Forte is very early in its development efforts. FB-102 will require significant additional preclinical and clinical development before Forte seeks regulatory approval of any product candidate. If Forte is unable to advance FB-102 to clinical development, obtain regulatory approval and ultimately commercialize a product candidate or experiences significant delays in doing so, its business will be materially harmed.
- 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 expects to rely on third parties to conduct its preclinical studies and any future clinical trials and to manufacture its product candidates.
- The market price of Forte's common stock is expected to be volatile. 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.
- A variety of risks associated with public health threats and epidemics, including the COVID-19 pandemic and related public health emergency could materially adversely affect Forte's business.

Risks related to Forte's business, technology and industry

Forte's business through to 2021 had been almost entirely dependent on the success of FB-401 and Forte subsequently decided to discontinue the advancement of FB-401. In 2022, Forte decided to devote significant time and resources to developing FB-102, which may not be successful.

Through 2021, Forte invested substantially all of its efforts and financial resources into the research and development of FB-401, which was its only product candidate to enter clinical trials. In September 2021, Forte announced that it would not be continuing the advancement of FB-401.

Following the announcement of the FB-401 trial results, the Company ceased further development of FB-401 and conducted an extensive process to evaluate strategic alternatives. Following such process, the Company determined to focus on developing its FB-102 program, which is currently in preclinical development. We will be required to devote significant time and resources to developing FB-102, which may not be successful.

Results from early-preclinical studies may not be predictive of results from later-stage studies or clinical trials.

We are early in our testing of FB-102, and we have no product candidates in clinical development. Preclinical studies may produce negative or inconclusive results. The FDA or a non-US regulatory authority may require us to conduct additional preclinical testing. Success in early preclinical studies does not mean that future clinical trials will be successful. In addition, preclinical data are often susceptible to various interpretations and analyses, and many companies whose product candidates performed satisfactorily in preclinical studies have nonetheless failed to obtain marketing approval. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after obtaining promising results in pre-clinical studies and early clinical trials. Any of these events could limit the commercial potential of our product candidate and have a material adverse effect on our business, prospects, financial condition and results of operations.

Forte's prospects are highly dependent on a single product candidate, FB-102, as we discontinued FB-401 in 2021. If we are unable to complete further development of, obtain approval for and commercialize FB-102 for one or more indications in a timely manner, our business will be harmed.

After we discontinued clinical development of FB-401, Forte's long-term prospects are highly dependent on future acceptance and revenues from a single product, FB-102. As discussed above, in September 2021, Forte announced that topline data from its Phase 2 clinical trial of FB-401 for the treatment of atopic dermatitis failed to

meet statistical significance for the primary endpoint of EASI-50 (the proportion of patients with at least a 50% improvement in atopic dermatitis disease severity as measure by EASI) and that, given that result, Forte would not be continuing development of FB-401. Our prospects are thus highly dependent on the success of FB-102, our only product candidate at this time, which is currently in preclinical stage and is being evaluated for multiple indications. Any further development of FB-102 would require substantial capital and time to complete and there is no guarantee that any future clinical trial, if pursued, would be timely or successful, or that FB-102 would be approved or, if approved, that commercialization would be successful.

Forte has no approved products and has a limited operating history, which may make it difficult to evaluate its technology and product development capabilities and predict its future performance.

We are very early in our development efforts of FB-102 and, prior to discontinuing the advancement of FB-401, were early in our clinical development efforts of FB-401.

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 was dependent on the successful development and eventual commercialization of FB-401 prior to Forte's decision to discontinue development of FB-401 and, following Forte's decision to focus on development of FB-102, Forte's prospects are currently highly dependent on Forte's ability to successfully develop FB-102. Given the early stage of FB-102, which is currently in preclinical development, and the highly uncertain nature of preclinical drug development, 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, any 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, or any new, 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, for example the failure of the FB-401 trial. 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.

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 preclinical 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 current lead product candidate, FB-102, is currently in preclinical development. Forte has no products approved for commercial sale and has not generated any revenue from product sales to date, and Forte will continue 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 nine months ended September 30, 2022, Forte reported a net loss of $9.0 million. As of September 30, 2022, Forte had an accumulated deficit of $82.2 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 current lead product candidate, FB-102, and any future product candidates Forte may seek to develop. Forte anticipates that its expenses will increase substantially if, and as, it:

- conducts preclinical studies and clinical trials for FB-102 and any future product candidates;
- continues to discover and develop additional applications for FB-102 and any future product candidates;
- 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-102 and any future product candidates;
- 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 candidates 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 preclinical studies and clinical trials, obtaining marketing approval for FB-102 or any future product candidates, 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-102, 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 current lead product candidate, FB-102, or any future product candidates.

Forte's operations have consumed substantial amounts of cash since inception. Forte expects to continue to spend substantial amounts to conduct preclinical studies and 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 September 30, 2022, Forte had $44.0 million of cash and cash equivalents on hand. Based on its current operating plan, Forte believes that its current cash available will enable it to fund its operating expenses and 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 the clinical development of FB-102. 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-102 and any future product candidates 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 preclinical studies and clinical trials for FB-102 and any future product candidates and any need to conduct additional such studies as may be required by a regulator;
- the clinical development plans Forte establishes for FB-102 and any future product candidates;
- 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 Good Clinical Practice ("GCP");
- 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, FB-102 ;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- the effect of potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflicts in Eastern Europe, and otherwise;
- 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. In addition, our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic, the conflicts in Eastern Europe, and otherwise. 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-102, or one or more of its other current or future 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's ability to successfully develop any product candidate is highly uncertain.

Forte's ability to successfully develop FB-102 or any other future product candidate 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:

- preclinical study or 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, delays in 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 that make FB-102 or any future product candidate uneconomical; and

- proprietary rights of others and their competing products and technologies that may prevent FB-102 or any future product candidate 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-102 or any future product candidate, in large part because of its limited regulatory history.

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. For example, in August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the Biden administration on us and the pharmaceutical industry as a whole is unclear. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors. 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-102, 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. 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. As seen with the FB-401 trial, 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 may experience delays in initiating or completing any future 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 candidates 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 candidates 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 candidates 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 candidates 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 preclinical studies or future clinical trials or those of its future collaborators may reveal significant adverse events and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidates.

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-102 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 a 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's FB-102 may fail to show the desired safety and efficacy profile. 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 future clinical trials would be successful or support further clinical development of any product candidates.

If significant adverse events or other side effects are observed in any of its current or potential future preclinical studies or clinical trials, Forte may have difficulty recruiting patients to its clinical trials, patients may drop out of such 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 are not necessarily predictive of the results of any future clinical trials of product candidates. Forte may be unable to successfully develop, obtain regulatory approval for and commercialize any product candidates.

Any positive results from its preclinical studies and clinical trials of any product candidates may not necessarily be predictive of the results from required later clinical trials. Similarly, even if Forte is able to complete preclinical development and any future clinical trials of FB-102 or any other product candidates according to its current development timeline, the positive results from such preclinical studies or future clinical trials may not be replicated in subsequent clinical trial results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in 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, 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.

Interim top-line and preliminary data from future 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, any such 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.

The market opportunities for FB-102 may be limited and Forte's 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 any product candidate that Forte develops 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 therapies that are more effective, safer, more easily commercialized or less costly than FB-102 or may develop proprietary technologies or secure patent protection that Forte may need for the development of potential 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 will also compete with those companies whose products target the same indications as FB-102 or any future product candidate Forte develops. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by its competitors could be superior to any product candidates Forte develops. It is possible that these competitors will succeed in developing technologies that are more effective than Forte's potential products or that would render any of Forte's 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 FB-102 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 FB-102 or any other future 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 of Forte's product candidates, 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) or other pandemics.

COVID-19, the infectious disease caused by the most recently discovered coronavirus, and its variants have 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 COVID-19 pandemic on Forte's business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a negative impact on its business, financial condition and operating results. Due to the global pandemic impacting the United States, its preclinical studies 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 Forte's business as a result of the COVID-19 pandemic is difficult to predict, which may increase its costs or expenses.

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

As of November 11, 2022, Forte had 6 full-time employees. As its research, development, manufacturing and commercialization plans and strategies develop to focus on the development of FB-102 and any future product candidates, and as Forte continues to transition into operating as a public company, 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 identifying 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-102 or any future product candidate 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 preclinical studies and clinical trials may be extended, delayed or terminated, and Forte may not be able to obtain regulatory approval of FB-102 or any other future product candidate 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 any product candidate and, accordingly, may not achieve its research, development and commercialization goals.

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

Forte's current operations are located in Texas. Any unplanned event, such as flood, fire, tornado, 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. Any 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. 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.

To retain valuable employees 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 equity awards that vest over time may be significantly affected by decreases in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. We may face challenges in retaining and recruiting such individuals due to sustained declines in our stock price that could reduce the retention value of equity awards. 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.

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. 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 product candidates 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 any 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 product candidate and begin commercializing such product 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 a 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 and its variants.

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 a product candidate 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 a product candidate 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. If and when Forte reaches the commercialization stage, 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.

There can be no assurance that Forte would 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.

Comprehensive tax reform legislation could adversely affect Forte's 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 Forte's business and financial condition. For example, on December 22, 2017, former 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"). The new presidential administration and

Congress could make changes to existing tax law, including an increase in the corporate and other tax rates. In addition, many countries in Europe, as well as a number of other countries and organizations, have recently considered changes to existing tax law that could adversely affect Forte's financial condition and results of operations.

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, 2021, Forte has federal net operating loss carryforwards of $24.6 million, which begin expiring in 2028 and state net operating loss carryforwards of $11.6 million that begin to expire in 2027, unless utilized. 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 anticipates 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 preclinical and 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-102 will require significant additional preclinical and clinical development before Forte seeks regulatory approval of any product candidate. If Forte is unable to advance FB-102 to clinical development, obtain regulatory approval and ultimately commercialize a product candidate or experiences significant delays in doing so, its business will be materially harmed.

Forte is very early in its development efforts and will invest substantially all of its efforts and financial resources in the development of FB-102. 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 a 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-102 will depend on several factors, including the following:

- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for FB-102;
- 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-102;
- launching commercial sales of FB-102, if and when approved or allowed for marketing, whether alone or in collaboration with others;
- acceptance of FB-102, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims;
- the marketing of FB-102; and
- maintaining a continued acceptable safety profile of FB-102 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-102, which would materially harm its business. If Forte does not receive regulatory approvals for FB-102, 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 product candidates 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. In response to the COVID-19 public health emergency, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. While the FDA has largely caught up with domestic preapproval inspections, it continues to work through its backlog of foreign inspections. However, the FDA may not be able to continue its current inspection pace, and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions, the FDA is unable to complete such required inspections during the review period. If a prolonged government shutdown or other disruption occurs, including due to travel restrictions, foreign COVID-19-related policies, staffing shortages, or if global health or other concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities in a timely manner, 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 covered recipients, including U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) , certain non-physician healthcare professionals (such as physician

assistants and nurse practitioners, among others), and teaching hospitals, as well as information regarding 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.

Preclinical and clinical development is uncertain. Forte's preclinical studies and 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-102, Forte will be required to conduct preclinical studies and clinical trials. 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 development of its clinical programs.

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

Any product candidate Forte may develop and the activities associated with the development and commercialization of such product candidate, 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 any product candidate, Forte must obtain marketing approval. Forte has never received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that no 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 expects 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. Any product candidate Forte develops 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. Any product candidate Forte seeks to develop 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.

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 any product candidate Forte develops.

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

Forte's product candidate, FB-102, or any future product candidate Forte develops, 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 any of its product candidates 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-102 or any other product candidate Forte develops 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 a 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 any product candidate Forte develops, 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 a 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 any product candidate Forte develops, 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 any 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 any product candidate Forte develops. 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 any product candidate Forte develops. The government may also implement additional measures in response to the COVID-19 pandemic. 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. To the extent any legislative, administrative, or executive actions impose constraints on the 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.

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 any 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 any product candidate and other technologies Forte may develop. Given that the development of its technology is at an early stage, its intellectual property portfolio with respect to certain aspects of its technology and any product candidates is also at an early stage. Forte intends to file patent applications on these aspects of its technology and any product candidates; however, there can be no assurance that any such patent applications will issue as granted patents.

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 future patent applications covering the composition of matter of any product candidates 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.

Furthermore, in some cases, Forte may not be able to obtain issued claims covering compositions of matter relating to any product candidates it develops 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 any product Forte develops 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 any product candidate Forte develops could have a material adverse effect on Forte's business, financial condition, results of operations, and prospects.

If the scope of any patent protection Forte obtains is not sufficiently broad, or if Forte loses any future patent protection, its ability to prevent its competitors from commercializing similar or identical technology and product candidates 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 any future patent rights are highly uncertain. Forte's future patent applications may not result in patents being issued which protect any product candidates Forte develops, 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 patent applications filed by it in the future, nor can Forte be sure 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 any patents that may issue to Forte 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 any future product candidates. Any patents that may issue to Forte 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 any product candidate it develops. In addition, the rights granted under any patents that may issue to Forte 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 any product candidate it develops. 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 that may issue to Forte may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Any patents that Forte may own in the future may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, Forte does not know whether any product candidate or other technologies it develops will be protectable or remain protected by valid and enforceable patents. Forte's competitors or other third parties may be able to circumvent Forte's future 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 may obtain 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 future patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, Forte's future patent rights, allow third parties to commercialize any product candidates Forte develops 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 any future 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 any product candidates Forte develops. 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 future product candidates, Forte's future patents protecting such a product candidate might expire before or shortly after any such product candidate is approved and 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 any future product candidates 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 any product candidate Forte develops. 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.

If Forte fails to comply with its obligations in agreements under which we option or license intellectual property rights from future collaborators or licensors or otherwise experience disruptions to our business relationships with future collaborators or licensors, we could lose intellectual property rights that are important to our business.

Forte may enter into agreements with future collaborators that impose various economic, development, diligence, commercialization, and other obligations on us. Such collaboration agreements may also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products. Our future collaborators might conclude that we have materially breached our obligations under such agreements and might therefore terminate or seek damages under the agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these agreements. Termination of these agreements could cause Forte to lose the rights to certain patents or other intellectual property, or the underlying patents could fail to provide the intended exclusivity, and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products similar to or identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and growth prospects.

Moreover, disputes may arise regarding intellectual property subject to a collaboration agreement, including:

- the scope of the option or license rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the collaborator that is not subject to the option or license rights granted under the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- Forte's diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our collaborators and us and our other partners; and
- the priority of invention of patented technology.

Forte may enter into agreements to option or license intellectual property or technology from third parties that are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. Moreover, if disputes over intellectual property that Forte has optioned or licensed prevent or impair our ability to maintain such arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and growth prospects.

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

Filing, prosecuting and defending patents on product candidates Forte develops 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 future 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 any products it develops.

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 is the first to file any patent application related to any product candidates it develops 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 future patent applications and the enforcement or defense of its owned future 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 future patent portfolio and its ability to protect and enforce its intellectual property in the future.

Forte's future issued patents covering product candidates Forte develops 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 future 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 any product candidates it develops 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.

Patent terms may be inadequate to protect our competitive position on our products and services for an adequate amount of time.

Patents have a limited lifespan. In the United States and abroad, if all maintenance fees/annuity fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date. The protection a patent affords is limited. Even if patents covering Forte's products are obtained, once the patent life has expired, Forte may be open to competition from competitive products. Given the amount of time required for the

development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, Forte's future owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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 future 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 future 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 in the future continue to, relies on third parties to assist it in developing and manufacturing its product candidates. 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 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 any product candidates Forte develops and other technologies.

The field of therapeutics targeting autoimmune diseases 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 future patents.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to autoimmune 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 identify third party patents in which it will determine that the best course of action is to challenge the validity of such third party patents in a post-grant proceeding at the USPTO, such as in a reexamination, or a post-grant and *inter partes* review. The outcome of such post-grant proceedings is uncertain and if the USPTO upholds the validity of these third party patents, it could have an adverse impact on Forte's ability to commercialize its future products, including 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. 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 future product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover future product candidates 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 future product candidates 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 candidates, 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 candidates 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 candidates 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 candidates 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 any future product candidate 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 future 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 future 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 future patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of its owned future 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.

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 may own 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 future pending owned patent applications will not lead to issued patents;
- future issued patents that Forte holds 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 does 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

We rely on third parties to conduct our preclinical studies, and plan to rely on third parties to conduct clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We plan to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, contract manufacturing organizations (CMOs), and strategic partners to conduct and support our preclinical studies under agreements with us and plan to continue to do so for our future clinical trials. These third parties have had and will continue to have a significant role in the conduct of our preclinical studies and planned clinical trials and the subsequent collection and analysis of data.

These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or our planned clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also expect to have to negotiate budgets and contracts with CROs, clinical trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines.

Our heavy reliance on these third parties for such drug development activities will reduce our control over these activities. As a result, we will have less direct control over the conduct, timing and completion of preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients, may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our 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.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We plan to contract with third parties for the manufacture of our product candidates for preclinical studies and expect to continue to do so for additional preclinical studies, clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quality and quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We plan to rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of any of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing preclinical studies or clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising or prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including cGMPs;
- the breach by the third-party contractors of our agreements with them;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMP regulations for manufacturing our product candidates. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable regulatory authorities, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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 enters 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.

General Risks

The market price of Forte's common stock is expected to be volatile. 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.

The market price of Forte's common stock could be subject to significant fluctuations. For example, Forte's announcement in September 2021 that the clinical trial of FB-401 for the treatment of AD failed to meet statistical significance for its primary endpoint of EASI-50 (the proportion of patients with at least a 50% improvement in atopic dermatitis disease severity as measure by EASI) resulted in a significant decline in the market price of Forte's common stock. Following the announcement on September 2, 2021, the price of Forte's common stock dropped $23.53 per share, or approximately 82%, from $28.59 per share as of the close of business on September 2, 2021 to $5.06 per share as of the close of business on September 3, 2021. The closing price of Forte's common stock on November 11, 2022, was $1.03 per share. Some of the factors that may cause the market price of Forte's common stock to fluctuate include:

- any strategic decisions that Forte pursues or announces, including Forte's decision to focus on the development of FB-102;
- Forte's ability to obtain regulatory approvals for any product candidates it develops, 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 product candidates Forte develops;
- any inability to obtain adequate supply of any product candidates Forte develops 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;
- claims or litigation related to the Rights Plan;
- 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 by 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 our 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 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 company may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If the 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our 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, 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 our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

Following the Merger completed in the second quarter of 2020, Forte has incurred and will continue to 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 requirements 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, 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 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 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.

The shareholders' rights plan adopted by our board of directors may discourage a third party from acquiring us in a manner that could result in a premium price to our shareholders.

On July 11, 2022, our board of directors authorized and declared a dividend distribution of a Right for each outstanding common share to shareholders of record as of the close of business on July 21, 2022. If a person or group acquires beneficial ownership of 10% or more of the Common Stock, or 20% in the case of certain institutional investors, each Right would entitle its holder (other than the person or group triggering the Rights Plan, whose Rights will become void and will not be exercisable) to purchase from the Company one one-thousandth of a share of the Preferred Stock of the Company at an exercise price of $16.00 per one one-thousandth of a share of Preferred Stock, subject to adjustment. The Rights Plan may make it more difficult or discourage a merger, amalgamation, arrangement, take-over bid, tender or exchange offer or other business combination involving the Company that is not approved by the board of directors. However, neither the Rights Plan nor the Rights should interfere with any merger, amalgamation, arrangement, take-over bid, tender or exchange offer or other business combination approved by the board of directors.

Forte's bylaws provide 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 bylaws provide 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 bylaws 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 company will have broad discretion in the use of proceeds from any capital raising efforts, including 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 private placement financings completed in 2020. 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. This requires 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.

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 September 30, 2022, Forte's executive officers, directors, holders of 5% or more of its 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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

Severance Agreements

Upon recommendation from the Compensation Committee of the board of directors, on November 10, 2022, the board of directors approved and adopted a form of change in control and severance agreement to be entered into by and between the Company and its current and future executive officers (each, a "Severance Agreement" and together the "Severance Agreements"). Each Severance Agreement supersedes any prior agreement or arrangement that each executive may have had with the Company that provides for severance or change in control payments and benefits. The Severance Agreements provide that if, other than during the period beginning three months before a change in control through the one-year anniversary of a change in control (the "CIC Period"), the executive is terminated either (x) by the Company without cause (as defined in the applicable Severance Agreement, and excluding by reason of his or her death or disability), or (y) by the executive for good reason (as defined in the Severance

Agreement), then the executive will receive the following severance payments and benefits if he or she timely executes and does not revoke a separation agreement and release of claims in the Company's favor:

- Continuing payments of such officer's base salary as in effect immediately before such termination, less applicable withholdings, for a period of 12 months, or 18 months in the case of the Chief Executive Officer.
- A lump sum cash payment equal to 100% of such officer's target bonus opportunity, or 150% in the case of the Chief Executive Officer, as in effect immediately before such termination.
- Company payment of the premiums required forcontinued coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") under the Company's group health, dental and vision care plans for the executive officer and his or her eligible dependents for up to 12 months, or 18 months in the case of the Chief Executive Officer.
- For the Chief Executive Officer only, 12 months accelerated vesting and exercisability of the outstanding and unvested Company equity as of the termination date.

If, during the CIC Period, the officer's employment with the Company is terminated either (x) by the Company without cause (as defined in the applicable Severance Agreement, and excluding by reason of his or her death or disability) or (y) by the executive for good reason (as defined in the respective Severance Agreement), the executive will receive the following severance payments and benefits if he or she timely executes and does not revoke a separation agreement and release of claims in the Company's favor:

- A lump sum cash payment equal to 150% of such executive's base salary as in effect immediately before such termination, or 200% in the case of the Chief Executive Officer.
- A lump sum cash payment equal to 150% of such officer's target bonus opportunity, or 200% in the case of the Chief Executive Officer, as in effect immediately before such termination or the applicable change in control, if greater.
- Company payment of the premiums required for continued coverage pursuant to COBRA under the Company's group health, dental and vision care plans for the executive officer and his or her eligible dependents for up to 18 months, or 24 months in the case of the Chief Executive Officer.
- 100% accelerated vesting and exercisability of the outstanding and unvested Company equity granted to the executive.

Each Severance Agreement provides that, if any of the amounts provided for under a Severance Agreement or otherwise payable to the executive would constitute "parachute payments" within the meaning of Internal Revenue Code Section 280G and could be subject to the related excise tax, the executive would receive (to the extent he or she is entitled to such receipt) either the full payment of benefits under the executive's Severance Agreement or such lesser amount that would result in no portion of the payments and benefits being subject to the excise tax, whichever results in the greater amount of after-tax benefits to the executive. The Severance Agreements do not provide for any tax gross-ups in connection with a change in control.

The foregoing description of the Severance Agreements does not purport to be complete and is qualified in its entirety by reference to the terms and conditions of the form of Severance Agreement, which is filed herewith as Exhibit 10.1, and incorporated herein by reference.

Item 6. Exhibits.

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

Exhibit Number	Description
10.1*#	Form of Change in Control and Severance Agreement
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.

Management contract or compensatory plan or arrangement

± 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: November 14, 2022

By: /s/ Paul Wagner
Paul Wagner, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2022

By: /s/ Antony Riley
Antony Riley
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

FORTE BIOSCIENCES, INC.

CHANGE IN CONTROL AND SEVERANCE AGREEMENT

This Change in Control and Severance Agreement (the "**Agreement**") is made between Forte Biosciences, Inc. (the "**Company**") and [_____] (the "**Executive**").

This Agreement provides certain protections to the Executive in connection with the involuntary termination of the Executive's employment under the circumstances described in this Agreement.

The Company and the Executive agree as follows:

1. Term of Agreement. This Agreement will continue indefinitely until terminated by written consent of the parties hereto, or if earlier, upon the date that all of the obligations of the parties hereto with respect to this Agreement have been satisfied.

2. At-Will Employment. The Company and the Executive acknowledge that the Executive's employment is and will continue to be at-will, as defined under applicable law.

3. Severance Benefits.

(a) Qualifying Non-CIC Termination. On a Qualifying Non-CIC Termination (as defined below), the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. Continuing payments of the Executive's Salary, less applicable withholdings, for a period of [ ].

(ii) Bonus Severance. A single, lump sum payment equal to [ ] of Executive's Target Bonus, less applicable withholdings.

(iii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive's eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "**COBRA Coverage**") until the earliest of (A) a period of [ ] from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iv) [Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to the shares subject to each of the Executive's then-outstanding compensatory equity awards issued by the Company which would have vested over the twelve (12) month period following the Qualifying Non-CIC Termination pursuant to time-based vesting conditions had Executive remained an employee through such period.]

(b) Qualifying CIC Termination. On a Qualifying CIC Termination, the Executive will be eligible to receive the following payments and benefits from the Company:

(i) Salary Severance. A single, lump sum payment equal to [ ] of the Executive's Salary, less applicable withholdings.

(i) Bonus Severance. A single, lump sum payment equal to [ ] of Executive's Target Bonus, less applicable withholdings.

(ii) COBRA Coverage. Subject to Section 3(d), the Company will pay the premiums for coverage under COBRA (as defined below) for the Executive and the Executive's eligible dependents, if any, at the rates then in effect, subject to any subsequent changes in rates that are generally applicable to the Company's active employees (the "**COBRA Coverage**") until the earliest of (A) a period of [ ] from the date of the Executive's termination of employment, (B) the date upon which the Executive (and the Executive's eligible dependents, as applicable) becomes covered under similar plans, or (C) the date upon which the Executive ceases to be eligible for coverage under COBRA.

(iii) Equity Vesting Acceleration. Vesting acceleration (and exercisability, as applicable) as to 100% of the then-unvested shares subject to each of the Executive's then-outstanding compensatory equity awards issued by the Company that are subject to time-based vesting conditions. In the case of an equity award subject to performance-based vesting conditions, such equity award will be treated as set forth in the applicable agreement evidencing such equity award.

(c) Termination Other Than a Qualifying Termination. If the termination of the Executive's employment with the Company Group is not a Qualifying Termination, then the Executive will not be entitled to receive severance or other benefits.

(d) Conditions to Receipt of COBRA Coverage. The Executive's receipt of COBRA Coverage is subject to the Executive electing COBRA continuation coverage within the time period prescribed pursuant to COBRA for the Executive and the Executive's eligible dependents, if any. If the Company determines in its sole discretion that it cannot provide the COBRA Coverage without potentially violating, or being subject to an excise tax under, applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of any COBRA Coverage, the Company will provide to the Executive a taxable monthly payment payable on the last day of a given month (except as provided by the immediately following sentence), in an amount equal to the monthly COBRA premium that the Executive would be required to pay to continue his or her group health coverage in effect on the date of his or her Qualifying Termination (which amount will be based on the premium rates applicable for the first month of COBRA Coverage for the Executive and any of eligible dependents of the Executive) (each, a "**COBRA Replacement Payment**"), which COBRA Replacement Payments will be made regardless of whether the Executive elects COBRA continuation coverage and will end on the earlier of (x) the date upon which the Executive obtains other employment or (y) the date the Company has paid an amount totaling the number of COBRA Replacement Payments equal to the number of months in the applicable COBRA Coverage period. For the avoidance of doubt, the COBRA Replacement Payments may be used for any purpose, including, but not limited to continuation coverage under COBRA, and will be subject to any applicable withholdings. Notwithstanding anything to the contrary under this Agreement, if the Company determines in its sole discretion at any time that it cannot

provide the COBRA Replacement Payments without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Executive will not receive the COBRA Replacement Payments or any further COBRA Coverage.

(e) Non-Duplication of Payment or Benefits. For purposes of clarity, in the event of a Qualifying Pre-CIC Termination, any severance payments and benefits to be provided to the Executive under Section 3(b) will be reduced by any amounts that already were provided to the Executive under Section 3(a). Notwithstanding any provision of this Agreement to the contrary, if the Executive is entitled to any cash severance, continued health coverage benefits, or vesting acceleration of any equity awards (other than under this Agreement) by operation of applicable law or under a plan, policy, contract, or arrangement sponsored by or to which any member of the Company Group is a party ("**Other Benefits**"), then the corresponding severance payments and benefits under this Agreement will be reduced by the amount of Other Benefits paid or provided to the Executive.

(f) Death of the Executive. In the event of the Executive's death before all payments or benefits the Executive is entitled to receive under this Agreement have been provided, the unpaid amounts will be provided to the Executive's designated beneficiary, if living, or otherwise to the Executive's personal representative in a single lump sum as soon as possible following the Executive's death.

(g) Transfer Between Members of the Company Group. For purposes of this Agreement, if the Executive is involuntarily transferred from one member of the Company Group to another, the transfer will not be a termination without Cause but may give the Executive the ability to resign for Good Reason.

(h) Exclusive Remedy. In the event of a termination of the Executive's employment with the Company Group, the provisions of this Agreement are intended to be and are exclusive and in lieu of any other rights or remedies to which the Executive may otherwise be entitled, whether at law, tort or contract, or in equity. The Executive will be entitled to no benefits, compensation or other payments or rights upon termination of employment other than those benefits expressly set forth in this Agreement.

4. Accrued Compensation. On any termination of the Executive's employment with the Company Group, the Executive will be entitled to receive all accrued but unpaid vacation, expense reimbursements, wages, and other benefits due to the Executive under any Company-provided plans, policies, and arrangements.

5. Conditions to Receipt of Severance.

(a) Separation Agreement and Release of Claims. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive signing and not revoking the Company's then-standard separation agreement and release of claims (which may include an agreement not to disparage any member of the Company Group, non-solicit provisions, an agreement to assist in any litigation matters, and other standard terms and conditions) (the "**Release**"), which must become effective and irrevocable no later than the sixtieth (60th) day following the Executive's Qualifying Termination (the "**Release Deadline**"). If the Release does

not become effective and irrevocable by the Release Deadline, the Executive will forfeit any right to severance payments or benefits under Section 3.

(b) Payment Timing. Any lump sum payments under Sections 3(a) and 3(b) will be provided, or in the case of installment payments, will commence, on the first regularly scheduled payroll date of the Company following the date the Release becomes effective and irrevocable (the "**Severance Start Date**"), subject to any delay required by Section 5(d) below. Any taxable installments of any COBRA-related severance benefits that otherwise would have been made to the Executive on or before the Severance Start Date will be paid on the Severance Start Date, and any remaining COBRA-related severance benefits installments thereafter will be provided as specified in the Agreement. Any restricted stock units, performance shares, performance units, and/or similar full value awards that accelerate vesting under Section 3 will be settled, as applicable (x) on a date no later than ten (10) days following the date the Release becomes effective and irrevocable, or (y) if later, in the event of a Qualifying Pre-CIC Termination, on a date no later than the Change in Control.

(c) Return of Company Property. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive returning all documents and other property provided to the Executive by any member of the Company Group (with the exception of a copy of the Company employee handbook and personnel documents specifically relating to the Executive), developed or obtained by the Executive in connection with his or her employment with the Company Group, or otherwise belonging to the Company Group.

(d) Section 409A. The Company intends that all payments and benefits provided under this Agreement or otherwise are exempt from, or comply with, the requirements of Section 409A of the Code and any guidance promulgated under Section 409A of the Code (collectively, "**Section 409A**") so that none of the payments or benefits will be subject to the additional tax imposed under Section 409A, and any ambiguities in this Agreement will be interpreted in accordance with this intent. No payment or benefits to be paid to the Executive, if any, under this Agreement or otherwise, when considered together with any other severance payments or separation benefits that are considered deferred compensation under Section 409A (together, the "**Deferred Payments**") will be paid or otherwise provided until the Executive has a "separation from service" within the meaning of Section 409A. If, at the time of the Executive's termination of employment, the Executive is a "specified employee" within the meaning of Section 409A, then the payment of the Deferred Payments will be delayed to the extent necessary to avoid the imposition of the additional tax imposed under Section 409A, which generally means that the Executive will receive payment on the first payroll date that occurs on or after the date that is six (6) months and one (1) day following the Executive's termination of employment. The Company reserves the right to amend this Agreement as it considers necessary or advisable, in its sole discretion and without the consent of the Executive or any other individual, to comply with any provision required to avoid the imposition of the additional tax imposed under Section 409A or to otherwise avoid income recognition under Section 409A prior to the actual payment of any benefits or imposition of any additional tax. Each payment, installment, and benefit payable under this Agreement is intended to constitute a separate payment for purposes of U.S. Treasury Regulation Section 1.409A-2(b)(2). In no event will any member of the Company Group reimburse, indemnify, or hold harmless the Executive for any taxes, penalties and interest that may be imposed, or other costs that may be incurred, as a result of Section 409A.

(e) Resignation of Officer and Director Positions. The Executive's receipt of any severance payments or benefits upon the Executive's Qualifying Termination under Section 3 is subject to the Executive resigning from all officer and director positions with all members of the Company Group and the Executive executing any documents the Company may require in connection with the same.

6. Limitation on Payments.

(a) Reduction of Severance Benefits. If any payment or benefit that the Executive would receive from any Company Group member or any other party whether in connection with the provisions in this Agreement or otherwise (the "**Payment**") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "**Excise Tax**"), then the Payment will be equal to the Best Results Amount. The "**Best Results Amount**" will be either (x) the full amount of the Payment or (y) a lesser amount that would result in no portion of the Payment being subject to the Excise Tax, whichever of those amounts, taking into account the applicable federal, state and local employment taxes, income taxes and the Excise Tax, results in the Executive's receipt, on an after-tax basis, of the greater amount. If a reduction in payments or benefits constituting parachute payments is necessary so that the Payment equals the Best Results Amount, reduction will occur in the following order: (A) reduction of cash payments in reverse chronological order (that is, the cash payment owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first cash payment to be reduced); (B) cancellation of equity awards that were granted "contingent on a change in ownership or control" within the meaning of Section 280G of the Code in the reverse order of date of grant of the awards (that is, the most recently granted equity awards will be cancelled first); (C) reduction of the accelerated vesting of equity awards in the reverse order of date of grant of the awards (that is, the vesting of the most recently granted equity awards will be cancelled first); and (D) reduction of employee benefits in reverse chronological order (that is, the benefit owed on the latest date following the occurrence of the event triggering the Excise Tax will be the first benefit to be reduced). In no event will the Executive have any discretion with respect to the ordering of Payment reductions. The Executive will be solely responsible for the payment of all personal tax liability that is incurred as a result of the payments and benefits received under this Agreement, and the Executive will not be reimbursed, indemnified, or held harmless by any member of the Company Group for any of those payments of personal tax liability.

(b) Determination of Excise Tax Liability. Unless the Company and the Executive otherwise agree in writing, the Company will select a professional services firm (the "**Firm**") to make all determinations required under this Section 6, which determinations will be conclusive and binding upon the Executive and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and the Executive will furnish to the Firm such information and documents as the Firm reasonably may request in order to make determinations under this Section 6. The Company will bear the costs and make all payments for the Firm's services in connection with any calculations contemplated by this Section 6. The Company will have no liability to the Executive for the determinations of the Firm.

7. Definitions. The following terms referred to in this Agreement will have the following meanings:

(a) "**Board**" means the Company's Board of Directors.

(b) "**Cause**" means

(i) Executive's material breach of any of Executive's obligations to the Company or any other member of the Company Group under the terms of Executive's offer letter or employment agreement with the Company or the Confidentiality Agreement;

(ii) Executive's gross negligence or willful failure or refusal to perform Executive's duties;

(iii) any material act of personal dishonesty taken by the Executive and intended to result in substantial personal enrichment of the Executive at the expense of the Company or any other member of the Company Group;

(iv) any willful or intentional act by the Executive that could reasonably be expected to injure the reputation, business or business relationships of the Company or any other member of the Company Group;

(v) perpetration by the Executive of an intentional and knowing fraud against or affecting the Company or any other member of the Company Group or any customer, supplier, client, agent or employee thereof; or

(vi) Executive's conviction of a felony or any crime involving fraud, dishonesty or moral turpitude;

provided that, with respect to any of the foregoing, the Board shall be required to give the Executive written notice of any termination for "Cause" with a detailed description of the alleged conduct constituting Cause, and the Executive shall be given an opportunity, together with legal counsel, to be heard before the Board within a reasonable period after receipt of such notice, together with a thirty (30) day ability to cure any such conduct, unless such conduct is non-curable.

(c) "**Change in Control**" means a "Change in Control" as defined in the Company's 2018 Equity Incentive Plan.

(d) "**Change in Control Period**" means the period beginning three (3) months prior to a Change in Control and ending twelve (12) months following a Change in Control.

(e) "**COBRA**" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(f) "**Code**" means the Internal Revenue Code of 1986, as amended.

(g) "**Company Group**" means the Company and any subsidiaries of the Company.

(h) "**Confidentiality Agreement**" means the At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement executed by the Company and the Executive on [ ].

(i) "**Disability**" means a total and permanent disability as defined in Section 22(e)(3) of the Code.

(j) "**Good Reason**" means the Executive's resignation within thirty (30) days following the expiration of any Company cure period (discussed below) following the occurrence of one or more of the following, without the Executive's consent: (i) a material reduction of the Executive's authority, title, duties or responsibilities relative to the Executive's authority, title, duties or responsibilities immediately prior to the reduction; (ii) a reduction by the Company (or its successor) in the Executive's annual base salary or target bonus, each as in effect immediately prior to such reduction, unless the Company also similarly reduces the annual rate of base cash compensation or annual incentive bonus targets of all other similarly situated employees of the Company; (iii) a material breach by the Company of this Agreement or any other material agreement between the Company and the Executive; or (iv) a material change in the geographic location of the Executive's primary work facility or location; provided, that a relocation of less than fifty (50) miles from the Executive's then-present location will not be considered a material change in geographic location. The Executive may not resign for Good Reason without first providing the Company with written notice of the acts or omissions constituting the grounds for "Good Reason" within ninety (90) days after Executive first learns of the initial existence of the grounds for "Good Reason" and a reasonable cure period of thirty (30) days following the date the Company receives such notice during which such condition must not have been cured.

(k) "**Qualifying Pre-CIC Termination**" means a Qualifying CIC Termination that occurs prior to the date of the Change in Control.

(l) "**Qualifying Termination**" means a termination of the Executive's employment either (i) by a Company Group member without Cause (excluding by reason of Executive's death or Disability) or (ii) by the Executive for Good Reason, in either case, during the Change in Control Period (a "**Qualifying CIC Termination**") or outside of the Change in Control Period (a "**Qualifying Non-CIC Termination**").

(m) "**Salary**" means the Executive's annual base salary as in effect immediately prior to the Executive's Qualifying Termination (or if the Qualifying Termination is due to a resignation for Good Reason based on a material reduction in base salary, then the Executive's annual base salary in effect immediately prior to the reduction) or, if the Executive's Qualifying Termination is a Qualifying CIC Termination and the amount is greater, at the level in effect immediately prior to the Change in Control.

(n) "**Target Bonus**" means Executive's annual (or annualized, as applicable) target bonus in effect immediately prior to Executive's Qualifying Termination or, if Executive's Qualifying Termination occurs during the Change in Control Period and the amount is greater, Executive's annual (or annualized, if applicable) target bonus in effect immediately prior to the Change in Control.

8. Successors. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of the Executive upon the Executive's death, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company. None of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of the Executive's right to compensation or other benefits will be null and void.

9. Notice.

(a) General. All notices and other communications required or permitted under this Agreement shall be in writing and will be effectively given (i) upon actual delivery to the party to be notified, (ii) upon transmission by email, (iii) twenty-four (24) hours after confirmed facsimile transmission, (iv) one (1) business day after deposit with a recognized overnight courier, or (v) three (3) business days after deposit with the U.S. Postal Service by first class certified or registered mail, return receipt requested, postage prepaid, addressed (A) if to the Executive, at the address the Executive shall have most recently furnished to the Company in writing, (B) if to the Company, at the following address:

Forte Biosciences, Inc.
3060 Pegasus Park Dr.
Building 6
Dallas, Texas
Attention: Chief Executive Officer

(b) Notice of Termination. Any termination by a Company Group member for Cause will be communicated by a notice of termination to the Executive, and any termination by the Executive for Good Reason will be communicated by a notice of termination to the Company, in each case given in accordance with Section 9(a) of this Agreement. The notice will indicate the specific termination provision in this Agreement relied upon, will set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination under the provision so indicated, and will specify the termination date (which will be not more than thirty (30) days after the giving of the notice).

10. Resignation. The termination of the Executive's employment for any reason will also constitute, without any further required action by the Executive, the Executive's voluntary resignation from all officer and/or director positions held at any member of the Company Group, and at the Board's request, the Executive will execute any documents reasonably necessary to reflect the resignations.

11. Miscellaneous Provisions.

(a) No Duty to Mitigate. The Executive will not be required to mitigate the amount of any payment contemplated by this Agreement, nor will any payment be reduced by any earnings that the Executive may receive from any other source except as specified in Section 3(e).

(b) Waiver; Amendment. No provision of this Agreement will be modified, waived or discharged unless the modification, waiver or discharge is agreed to in writing and signed by an authorized officer of the Company (other than the Executive) and by the Executive. No waiver by either party of any breach of, or of compliance with, any condition or provision of this Agreement by the other party will be considered a waiver of any other condition or provision or of the same condition or provision at another time.

(c) Headings. All captions and section headings used in this Agreement are for convenient reference only and do not form a part of this Agreement.

(d) Entire Agreement. This Agreement constitutes the entire agreement of the parties and supersedes in their entirety all prior representations, understandings, undertakings or agreements (whether oral or written and whether expressed or implied) of the parties with respect to the subject matter of this Agreement, including, for the avoidance of doubt, any other employment letter or agreement, severance policy or program, or equity award agreement.

(e) Choice of Law. This Agreement will be governed by the laws of the State of Texas without regard to Texas's conflicts of law rules that may result in the application of the laws of any jurisdiction other than Texas. To the extent that any lawsuit is permitted under this Agreement, Executive hereby expressly consents to the personal and exclusive jurisdiction and venue of the state and federal courts located in Texas for any lawsuit filed against the Executive by the Company.

(f) Arbitration. Any and all controversies, claims, or disputes with anyone under this Agreement (including the Company and any employee, officer, director, stockholder or benefit plan of the Company in their capacity as such or otherwise) arising out of, relating to, or resulting from the Executive's employment with the Company Group, shall be subject to arbitration in accordance with the provisions of the Confidentiality Agreement.

(g) Severability. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision of this Agreement, which will remain in full force and effect.

(h) Withholding. All payments and benefits under this Agreement will be paid less applicable withholding taxes. The Company is authorized to withhold from any payments or benefits all federal, state, local, and/or foreign taxes required to be withheld from the payments or benefits and make any other required payroll deductions. No member of the Company Group will pay the Executive's taxes arising from or relating to any payments or benefits under this Agreement.

(i) Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

By its signature below, each of the parties signifies its acceptance of the terms of this Agreement, in the case of the Company by its duly authorized officer.

COMPANY FORTE BIOSCIENCES, INC.

By:

Title:

Date:

EXECUTIVE

Date:

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: Novermber 14, 2022

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: November 14, 2022

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 ended September 30, 2022 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: November 14 , 2022

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 ended September 30, 2022 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: November 14 , 2022

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