UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

Commission File Number 001-38052

FORTE BIOSCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

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

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

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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Stock Market on June 30, 2020 was $71.5 million.

The number of shares of Registrant's Common Stock outstanding as of March 11, 2021 was 13,508,862.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant's 2021 Annual Meeting of Stockholders, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such proxy statement will be filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2020.

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are based on current expectations and beliefs and involve numerous risks and uncertainties that could cause actual results to differ materially from expectations. These forward-looking statements should not be relied upon as predictions of future events as it cannot be assured that the events or circumstances reflected in these statements will be achieved or will occur. You can identify forward-looking statements by the use of forward-looking terminology including "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "pro forma," "should," "will," "would," or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. For example, forward-looking statements include, but are not limited to statements about:

- any statements of the plans, strategies and objectives of management for future operations;
- any statements concerning proposed new products, services or developments;
- any statements regarding any business disruption or potential impact to our business due to COVID-19;
- any statements regarding future economic conditions or performance;
- any statements regarding future regulatory approvals;
- any statements regarding future regulatory approvals;
- our expectations regarding the timing of product launches, as well as product features and specifications;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the timing, scope and likelihood of regulatory filings and approvals or our current or future product candidates;
- our estimates regarding the sufficiency of our cash resources and our need for additional funding;
- our expectations regarding the market size, market growth and growth potential for our business;
- our ability to grow our business;
- our internal control environment; and
- our intended use of the net proceeds from offerings of our securities or other financings we may complete from time to time.

Forward-looking statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. We cannot guarantee that we actually will achieve the plans, intentions or expectations expressed in our forward-looking statements and you should not place undue reliance on these statements. There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those discussed under the heading "Risk Factors" contained or incorporated in this Annual Report. These factors and the other cautionary statements should be read as being applicable to all related forward-looking statements whenever they appear in this Annual Report. Except as required by law, we do not assume any obligation to update any forward-looking statement. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and other similar sources.

Item 1. Business

Overview

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

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

In September 2020, we initiated a multi-center double-blinded placebo-controlled Phase 2 clinical trial of FB-401 which is enrolling children (2 years of age and older), adolescents and adults with AD. For additional information about the trial, see ClinicalTrials.gov using the identifier NCT04504279.

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

About AD

There is currently no cure for AD. AD is a relapsing and remitting inflammatory skin disorder that affects all age groups. It is chronic, incurable and characterized by skin-barrier disruption and immune dysregulation. AD is clinically characterized by xerosis (dry skin), erythematous crusted eruptions, lichenification (skin becomes thick and leathery), an impaired skin barrier function and intense pruritus (severe itching). AD flares are frequently triggered by exposure to environmental factors, irritants, and allergens.

Patients with AD have a high disease burden and their quality of life is significantly affected. AD has been shown to have a greater negative effect on patient mental health than diabetes and hypertension. Patients with moderate-to-severe AD have a higher prevalence of social dysfunction and sleep impairment, which are directly related to the severity of the disease. Depression, anxiety, and social dysfunction not only affect patients with AD, but also affect their caregivers. Compared with psoriasis, another common and debilitating skin disease, patients with AD have lower physical, vitality, social functioning, role-emotional, and mental health scores.

Market for Treating AD

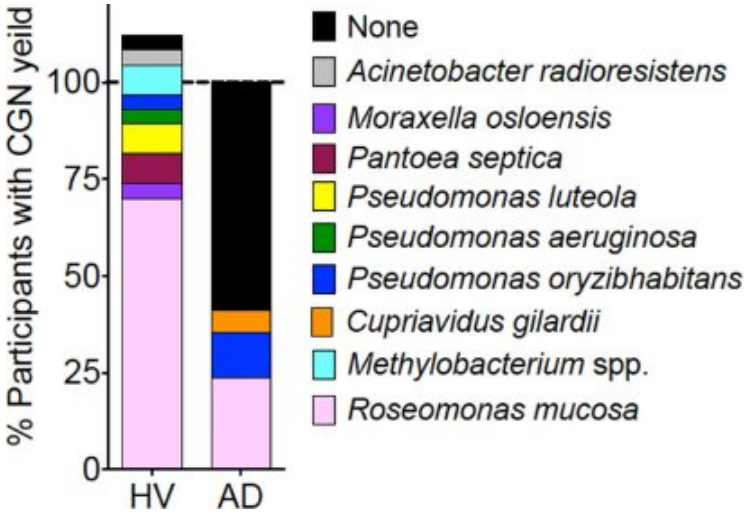
Although estimates of AD prevalence vary widely across different studies due to differences in data collection methodology, inconsistent age group assessment, and study periods, AD is one of the most common dermatologic diseases in the United States. We believe that approximately 17 million people have been diagnosed with AD in the United States, of which more than half are pediatric patients (<18 years old) and that 15%-30% of children and 2%-10% of adults are afflicted. A 2010 study in the United States evaluating AD severity in children found that 67% had mild disease, 26% had moderate disease and 7% had severe disease. Approximately 85% of all cases of AD begin before age five. Treatment options in particular are very limited for pediatric patients with AD.

Our Approach

We are developing a novel approach for treating inflammatory skin disease using a topical live biotherapeutic. Although bacteria are often associated with infection and disease, much of the bacteria that colonize the human body are essential for life. A few recent scientific studies have focused on the benefits of commensal bacteria which act on the human body's immune system to induce protective responses that prevent colonization and invasion by pathogens.

The NIH was the first to culture Gram-negative bacteria from the skin and has been a thought leader in understanding the bacterial composition of the skin. The work at NIH has:

- Identified substantial differences in the Gram-negative microbiome present on the skin of AD patients versus those of healthy volunteers ("HV") using genetic-based microbiome analysis;
- Found that the predominant species of skin commensal Gram-negative bacteria in HV was Roseomonas mucosa; and
- Discovered that over 50% of Atopic Dermatitis patients did not have any culturable Gram-negative flora (see bar chart below), consistent with DNA-based analysis.



Myles IA, Williams KW, Reckhow JD, et al. *JCI Insight.* 2016;1(10)

Kong HH et al. *Genome research.* 2012;22(5):850-859

Our product candidate, FB-401, consists of three therapeutic strains of a commensal Gram-negative bacteria, *Roseomonas mucosa*, which were specifically selected for their impact on key parameters of inflammatory skin disease. Our extensive preclinical and mechanism of action data demonstrate that FB-401 improves AD disease parameters by driving tissue repair and anti-inflammation. Specifically, we believe that FB-401:

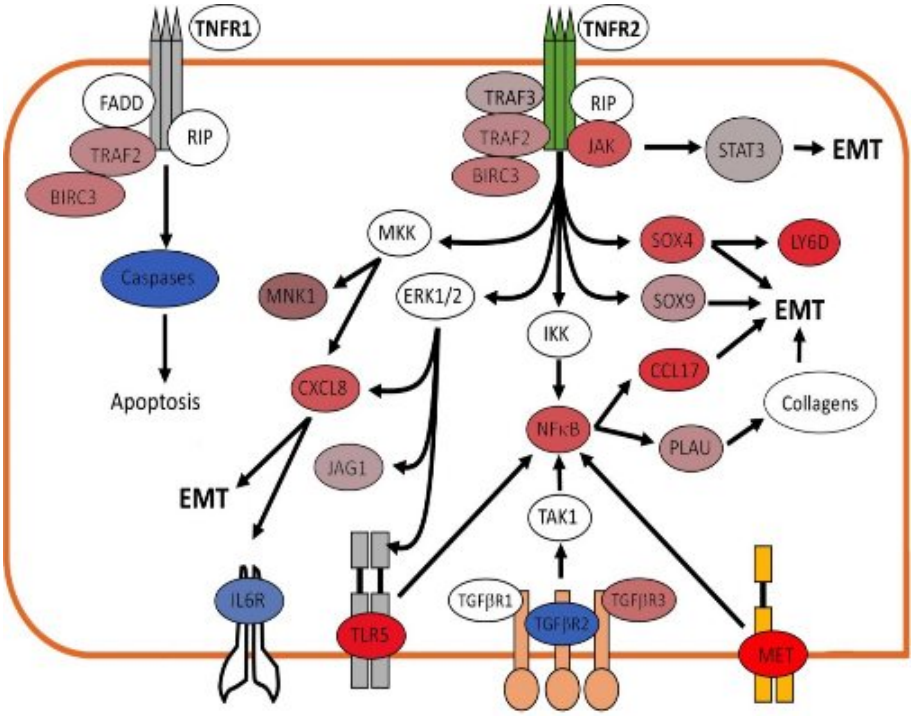
- drives immune pathways that are defective;
- potentially suppresses *Staphylococcus aureus ("S. aureus")* growth; and
- improves skin barrier function.

Mechanism of Action

Rigorous preclinical testing established a causal connection between the three strains of *R. mucosa* that comprise FB-401 and skin healing in AD patients. More specifically, extensive preclinical work of FB-401 by Forte, in collaboration with the NIH, has demonstrated that:

- Gene sequencing and mRNAseq highlights show that following exposure to FB-401, fibroblasts, keratinocytes, embryonic stem cells and dendritic cells drive tissue repair by activating the TLR5, TNFR and CXCR2 (IL-8 signaling) pathways which induce epithelial to mesenchymal transition ("EMT") resulting in tissue repair and anti-inflammatory activity; and

- FB-401 inhibits different strains of *S. aureus,* including methicillin resistant *S.aureus* ("MRSA"), through the phosphatidylcholine and phosphatidylethanolamine metabolites produced by the 3 strains of *R. mucosa* that constitute FB-401.



Based on the therapeutic potential observed in preclinical testing, FB-401 was advanced into the clinic in a Phase 1/2a proof of concept study.

Clinical Development of FB-401

Phase 1/2a

To date, a Phase 1/2a study has been completed with pediatric and adult patients, demonstrating significant reduction in AD disease and pruritus (severe itching), as well as control of *S. aureus* while tapering or eliminating steroid use.

FB-401 is lyophilized (freeze-dried) and is reconstituted with an aqueous solution by the patient prior to use, which is then sprayed onto the affected areas of the skin. The open-label Phase 1/2a study enrolled two cohorts:

- Initial cohort enrolled 10 adult AD patients, 18 years and older; and
- Following positive safety assessment from the adult cohort, the second cohort consisted of 20 pediatric patients.

The primary objective of this study was to evaluate the safety and activity of *R. mucosa* as a live biotherapeutic for the treatment of AD. A secondary objective was to evaluate the effect of *R. mucosa* on the quality of life of AD patients.

<u>*Results*</u>

Adult Cohort

Ten adult AD patients were treated in two-week intervals with increasing dosages of 10^3, 10^4, and 10^5 colony-forming units ("CFU") of *R mucosa* twice per week for a total of six weeks. CFU is a measure of viable bacterial cells. The history and physical characteristics of each patient's AD was assessed at enrollment, including the measurement of AD in a blind manner using a clinical tool, SCORing Atopic Dermatitis ("SCORAD"), which assesses the extent and severity of AD. SCORAD quantifies on a scale of 0-3 each separate symptom of a patient's AD including dryness, redness, lichenification (thick or leathery skin), excoriation (urge to itch), crusting and edema (swelling). In addition to SCORAD, each patient's AD was measured and recorded using lab work, photographs and skin swabs. Each patient then self-reported their subjective score of pruritus (severe itching) on a scale of 0-10. An

antecubital SCORAD was then recorded which is SCORAD applied only to the antecubital area (inside of arm near the elbow). Antecubital SCORAD is calculated as the sum of (i) the intensity (as determined by SCORAD) and (ii) the reported pruritus for each patient. The adults were only treated at the antecubital fossa and one other body area selected by the patients. At the end of the six-week period, each patient's AD was again assessed.

No adverse events were observed in this first adult cohort study. In addition, even with a short duration of therapy, FB-401 demonstrated statistically significant improvements in this Phase I adult cohort study.

Pediatric Cohort

Twenty pediatric/adolescent patients with active AD were then treated in four four-week intervals for a total of 16 weeks as follows:

- 10^3 CFU twice per week for four weeks;
- 10^4 CFU twice per week for four weeks;
- 10^5 CFU twice per week for four weeks; and
- 10^5 CFU every other day for four weeks.

The dose escalation component of the study was designed to assess safety in a conservative manner. Assessments of each pediatric/adolescent patient's AD were made at the beginning of the study (baseline) and at the end of each four-week period using the same assessment methodology described for the adult cohort. Additionally, the number of steroid applications used by each pediatric patient was recorded.

Key clinical parameters included:

- % of subjects with 50% improvement in SCORAD
- % of subjects with 50%, 75% and 90% improvement in Eczema Area and Severity Index ("EASI") score
- % improvement in SCORAD
- % improvement in EASI score

In addition, the pediatric/adolescent study also explored the following objectives:

- Measure trans epidermal water loss ("TEWL"). TEWL measurements are of importance in evaluating the skin barrier function;
- Characterize changes to total and specific Immunoglobulin E ("IgE"), which are antibodies produced by the immune system that are typically elevated in AD patients;
- Evaluate potential changes to pre-diagnosed asthma and/or food allergies which share some of the pathways that trigger AD;
- Evaluate the incidence of *S. aureus* infections that require treatment; and
- Persistence of *R mucosa* colonization after treatment to assess the durable nature of the therapy.

Summary of Phase 1/2a Clinical Results

FB-401 was designed to improve AD symptoms by selecting three strains of *R. mucosa* that demonstrated improvements in the skin barrier function, enhanced immune balance, and the potential to inhibit *S. aureus* colonization on the skin.

To summarize, the study demonstrated:

- FB-401 was well tolerated with an excellent safety profile and with no significant adverse effects noted in either the pediatric/adolescent or adult cohorts;
- FB-401 resulted in statistically significant clinical improvement in the treated areas in adult subjects;
- Children treated with FB-401 had improvement in disease activity as measured by SCORAD, EASI, pruritus, TEWL and the Children's or Family Dermatology Life Quality Index ("CDLQI" and "FDLQI");

- EASI-50, meaning patients showing a 50% improvement, was achieved by 90% of the pediatric patients and by 100% of the subset of moderate-to-severe pediatric patients. The mean improvement in the EASI score was 77%, with improvements observed on all actively treated body regions;
- The therapeutic activity of FB-401 was durable through the follow-up period of up to 8 months after the end of treatment;
- Pruritus also improved by an average of 4 points (mean improvement of 58%);
- FB-401 was shown in this clinical study to drive tissue repair and anti-inflammatory activity while potentially controlling harmful bacteria like *S. aureus;*
- The degree of improvement was substantial and, despite the absence of a control group, appears to be substantially greater than would be expected from a placebo group; and
- These improvements were seen despite meaningful decreases in topical steroid use.

Phase 2 Clinical Trial

On September 29, 2020, we announced that the first patient had been dosed in a Phase 2 clinical trial of FB-401. The multi-center, double-blinded, placebo-controlled and randomized clinical trial is expected to enroll approximately 124 pediatric, adolescent and adult AD subjects aged 2 years of age and older.

The primary endpoint of the trial is the proportion of subjects that achieve EASI-50 at week 16. Patients have achieved EASI-50 if they achieve at least a 50% improvement in the AD disease burden as measured by the Eczema Area and Severity Index ("EASI").

Results of this trial are expected in approximately mid-2021.

Manufacturing

The manufacturing development of FB-401 is conducted following the general principle set forth in the FDA's June 2016 Guidance for Industry: "Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information".

Fermentation. FB-401 is currently being manufactured at scale in accordance with current applicable FDA current Good Manufacturing Practice ("cGMP").

Formulation. FB-401 drug substance is produced by mixing the three FB-401 *R. mucosa* strains. FB-401 is filled into vials prior to lyophilization (freeze drying). The lyophilized product is reconstituted by the patient prior to use by mixing the powder with diluent. FB-401 is administered topically by spraying it onto the affected areas of the skin.

Analytical. Each of the three *R mucosa* strain components in FB-401 is tested before being released for formulation of drug product.

Forte primarily uses contract manufacturing and testing organizations to support the manufacturing of its FB-401 drug product candidate. Forte currently expects to continue to rely on third parties for the manufacturing of FB-401 as it advances through clinical trials, as well as for commercial manufacture, if FB-401 or any of its product candidates obtain marketing approval. Forte believes that it has sufficient quantity of FB-401 to support its current and future planned clinical trial programs. Forte also believes it has multiple potential additional sources for the manufacturing of FB-401.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, strong competition and an emphasis on proprietary products. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, method of administration, cost, level of promotional activity and intellectual property protection.

Although there are currently many live bacterial product candidates in development by companies that target the microbiome (e.g., Seres Therapeutics, Inc., Synlogic, Inc. and Evelo Biosciences, Inc.), we believe that we have a differentiated approach and do not consider ourselves to be in direct competition with these bacterial microbiome approaches.

We are aware of several marketed and investigational products for AD including but not limited to:

- Dupixent marketed by Regeneron/Sanofi. Dupixent is administered systemically through an injection;
- Eucrisa marketed by Pfizer, Inc.; and
- Janus Kinase ("JAK") inhibitors marketed by various companies.

We believe that there is a role for additional agents that provide meaningful efficacy with an acceptable safety profile, especially for children, and a method of administration other than by injection.

Intellectual Property

We have 7 issued U.S. patents relating to our lead product candidate, FB-401, as well as our other product candidates. These issued patents have claims directed to the formulations, manufacturing and method of use for inflammatory skin conditions including atopic dermatitis, psoriasis, rosacea, and acne. These patents are expected to expire in April 2037, absent any patent term extensions.

In addition to our patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, through intellectual property assignment agreements with our employees, consultants and commercial partners.

Our intellectual property portfolio for our core technology was initially built through licenses from the U.S. Department of Health and Human Services as described below, the Agency for Healthcare Research and Quality and the NIH. We subsequently expanded our intellectual property portfolio by filing patent applications worldwide.

In-Licensed IP

In December 2017, the Company entered into an exclusive license agreement with the Department of Health and Human Services ("DHHS"). Under the agreement, the DHHS granted the Company an exclusive, sublicensable, worldwide license to certain patent rights under which the Company may develop and commercialize pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and conditions (the "DHHS License"). Under the DHHS License, the Company is obligated to meet certain development benchmarks within certain time periods. If the Company is unable to meet any of these development benchmarks, the DHHS could terminate the license. In addition, the DHHS may terminate or modify the DHHS License in the event of a material breach or upon certain insolvency events that remain uncured following a 90 day written notice of such material breach or insolvency event. The DHHS also has the right to require the Company to grant mandatory sublicenses to patent rights licensed from the DHHS to product candidates covered by other DHHS licenses under certain specified circumstances, including if it is necessary to meet health and safety needs that the Company is not reasonably satisfying, or if necessary, to meet requirements for public use specified by federal regulations which the Company is not reasonably satisfying.

Under the DHHS License, as amended in May 2020, the Company was obligated to pay the DHHS a minimum annual payment of $20,000 for 2020, which increased to $100,000 annually beginning January 1, 2021. The Company is required to reimburse the DHHS for certain patent-related expenses. In addition, the Company may also be obligated to make milestone payments to the DHHS based on achieving specified development and regulatory milestones for the first licensed product. Such development milestone payments are the completion of patient enrollment in a phase 3 clinical trial and the completion of a phase 3 clinical trial demonstrating a statistically significant efficacy benefit. The regulatory milestones are the receipt of the first FDA approval and the first non-USA regulatory agency approval. In addition, to the extent licensed products are approved for commercial sale, the Company is also obligated to pay the DHHS royalties based on net sales of licensed products sold by the Company and if applicable, its sublicensees. No milestones have been met as of December 31, 2020.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, export and import of drug and biological products. Generally, before a new drug or biologic can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

United States Biological Product Development

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations and biologics under the FDCA, the Public Health Service Act ("PHSA"), and their implementing regulations. Both drugs and biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-market may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval or license revocation, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties.

Forte's product candidates must be approved by the FDA through a Biologic License Application ("BLA") process before they may be legally marketed in the United States. The process generally involves the following:

- Completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP"), requirements;
- Submission to the FDA of an Initial New Drug ("IND") application, which must become effective before human clinical trials may begin;
- Approval by an Institutional Review Board ("IRB"), or independent ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, good clinical practice ("GCP") requirements and other clinical trial-related regulations to establish the safety and efficacy of the investigational product for each proposed indication;
- Submission to the FDA of a BLA;
- A determination by the FDA within 60 days of its receipt of a BLA to accept the filing for review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the biologic will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- Potential FDA audit of the clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the biologic in the United States.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events and in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies.

A sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA unless, before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

The clinical stage of development involves the administration of the investigational product to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her

legal representative and must monitor the clinical trial until completed. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials generally are conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, which may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase 2 clinical trials involve studies in disease-affected patients to determine the dose required to produce the desired benefits. During Phase 2 clinical trials, safety and further pharmacokinetic and pharmacodynamic information is collected, possible adverse effects and safety risks are identified, and a preliminary evaluation of efficacy is conducted.
- Phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of a BLA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug or biologic has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the trial. Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the chemistry and physical characteristics of the drug or biologic, as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product and, among other things, companies must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidates do not undergo unacceptable deterioration over their shelf life.

Further, as a result of the COVID-19 pandemic, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, the FDA has issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic, including certain reporting requirements, and additional guidance on the good manufacturing practice considerations for responding to COVID-19 infection and other topics. We may be required to make further adjustments to our clinical trials or business operations based on current or future guidance and regulatory requirements as a result of the COVID-19 pandemic.

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency for the biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as

well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from several alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

The FDA reviews all submitted BLAs before it accepts them for filing and may request additional information rather than accept a BLA for filing. The FDA must decide whether to accept a BLA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has 10 months from the filing date to complete its initial review of an original BLA and respond to the applicant, and six months from the filing date of an original BLA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements. The FDA will not approve the product unless it determines that the manufacturing processes and facilities comply with cGMP requirements to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers those recommendations when making decisions on approval. The FDA likely will reanalyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. After the FDA evaluates a BLA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if an applicant submits the requested data and information, the FDA may decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than an applicant does.

Pediatric Information

Under the Pediatric Research Equity Act, as amended ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP"), within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Post-marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote off-label uses. Prescription biologic promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the

biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy ("REMS"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS and the FDA will not approve the BLA without an approved REMS. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may also require the implementation of other risk management measures, including a REMS, or the conduct of post-marketing studies to assess a newly discovered safety issue.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. Forte relies, and expects to continue to rely, on third parties to produce clinical and commercial quantities of Forte's products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws.

Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, including the CMS, other divisions of the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other Healthcare Laws

Biopharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, anti-self-referral, false claims, transparency, including the federal Physician Payments Sunshine Act, consumer fraud, pricing reporting, data privacy, data protection, and security laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the biopharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state 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 and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of biopharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay product approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Actual or alleged violation of any such laws or regulations may lead to investigations and other claims and proceedings by regulatory authorities and in certain cases, private actors, and violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment.

Current and Future Healthcare Reform Legislation

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of Forte product candidates, restrict or regulate post-approval activities, and affect Forte's ability to profitably sell any product candidates for which it obtains marketing approval. Forte expects that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that Forte, or any of its collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, address a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increase the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establish annual fees and taxes on manufacturers of certain branded prescription drugs, and create a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and Forte expects there will be additional challenges and amendments to the ACA in the future. For example, in November 2020, the United States Supreme Court held oral arguments on the ACA case from the U.S. Court of Appeals for the 5th Circuit, which upheld the District Court ruling that the individual mandate is unconstitutional, and the Supreme Court is expected to issue a decision by mid-2021. It is uncertain how the Supreme Court will rule on this case. In January 2021, President Biden issued an executive order to initiate a special enrollment period to allow people to obtain health insurance coverage through the ACA marketplace, and instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among others. We cannot predict how the Supreme Court ruling, other litigation, or the healthcare reform measures of the Biden administration will impact our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting. Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020, the U.S. Department of Health and Human Services ("HHS") and the CMS issued various rules that are expected to impact, among others, price reductions from pharmaceutical manufacturers to plan sponsors under Part D, fee arrangements between pharmacy benefit managers and manufacturers, manufacturer price reporting requirements under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Multiple lawsuits have been brought against the HHS challenging various aspects of the rules. In January 2021, the Biden administration issued a "regulatory freeze" memorandum that directs department and agency heads to review new or pending rules of the prior administration. It is unclear whether these new regulations will be withdrawn or when they will become fully effective under the current administration. The impact of these lawsuits as well as legislative, executive, and administrative actions of the current administration on us and the pharmaceutical industry as a whole is unclear.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Individual states in the United States have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Packaging and Distribution in the United States

If Forte's products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

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 failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against Forte for violation of these laws, even if Forte successfully defend against it, could cause Forte to incur significant legal expenses and divert Forte's management's attention from the operation of its business. Prohibitions or restrictions on sales or withdrawal of future products marketed by Forte could materially affect its business in an adverse way.

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

Other U.S. Environmental, Health and Safety Laws and Regulations

Forte may be 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. From time to time and in the future, Forte's operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if Forte contracts with third parties for the disposal of these materials and waste products, Forte cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of Forte's hazardous materials, Forte could be held liable for any resulting damages, and any liability could exceed Forte's resources. Forte also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Forte maintains workers' compensation insurance to cover costs and expenses it may incur due to injuries to its employees, but this insurance may not provide adequate coverage against potential liabilities. However, Forte does not maintain insurance for environmental liability or toxic tort claims that may be asserted against it.

In addition, Forte may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair Forte's research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

U.S. Patent-Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of any of Forte's product candidates, some of Forte's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, Forte may apply for restoration of patent term for Forte's currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"). This

amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

A reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing regulatory exclusivity periods. This six-month exclusivity may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Rest of the World Regulation

For other countries outside of the United States, such as the European Union and countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If Forte fails to comply with applicable foreign regulatory requirements, Forte may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Additional Laws and Regulations Governing International Operations

If Forte further expands its operations outside of the United States, Forte must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate. The FCPA prohibits any U.S. individual or business from offering, paying, promising to pay, or authorizing payment of money or anything of value, to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any foreign official, political party or candidate to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage 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.

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 owned and operated by the government, and doctors and other hospital employees are considered foreign officials for the purposes of the statute. Certain payments made 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, Forte will need to dedicate additional resources to complying with these laws, and these laws may preclude Forte from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit Forte's 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 SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage and Reimbursement

Sales of Forte's approved products will depend, in part, on the extent to which Forte's approved products, will be covered by third-party payors, such as government health programs, commercial insurers and managed healthcare organizations, as well as the level of reimbursement such that those third-party payors provide for Forte's products. Patients and providers are unlikely to use Forte's products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of Forte's products. In the United States, no uniform policy of coverage and reimbursement for drugs or biological products exists, and one payor's determination to provide coverage and adequate reimbursement for a product does not assure that other payors will make a similar determination. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of Forte's product candidates, if approved, will be made on a payor-by-payor basis. As a result, the coverage determination process may be a time-consuming and costly process that will require Forte to provide scientific clinical, and cost-effective data to support the use of Forte's approved products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical products, in addition to questioning their safety and efficacy.

As noted above, the marketability of any products for which Forte receives regulatory approval for commercial sale may suffer if the government and other third-party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased and Forte expects will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which Forte receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for our product if approved.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices Forte may obtain for any of its product candidates for which Forte may obtain regulatory approval or the demand for any such approved products.

In addition, in most foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, Forte may be required to conduct a clinical study or other studies that compare the cost-effectiveness of any of Forte's product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of Forte's approved products. Historically, products launched in the EU do not follow price structures of the United States and, generally, prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries.

Employees and Human Capital

As of February 28, 2021, we had 9 full-time employees, primarily engaged in research and development, manufacturing and administration. None of Forte's employees are represented by labor unions or covered by collective bargaining agreements. Forte considers its relationship with its employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Forte's corporate headquarters are located in Torrance, California, where it currently leases office and laboratory space on a monthly basis. Forte believes that this space is adequate for Forte's present and planned future operations.

Corporate Information and History

Forte (previously named "Tocagen, Inc.") was incorporated in Delaware in August 2007. Forte Subsidiary was incorporated under the laws of the State of Delaware in May 2017. Upon the closing of the Merger, Forte's name was changed from "Tocagen, Inc." to "Forte Biosciences, Inc." and the name of Forte Subsidiary was changed from "Forte Biosciences, Inc." to "Forte Subsidiary, Inc.".

Our principal executive office is located at 1124 W Carson Street MRL Building 3-320, Torrance, California 90502, and our telephone number at that address is (310) 618-6994. Our corporate website is located at www.fortebiorx.com. We make available on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). Our SEC reports can be accessed through the investor relations page of our website located at https://www.fortebiorx.com/investor-relations/sec-filings/default.aspx. The SEC also maintains a website that contains our SEC filings. The address of that site is www.sec.gov.

We may webcast our earnings calls and certain events we participate in or host with members of the investment community on our investor relations page of our website. In addition, we use our website as a means of disclosing information about our company, our products, our planned financial and other announcements, our attendance at upcoming investor conferences, and other matters. It is possible that the information we post on our website could be deemed material information. We may use our website to comply with our disclosure obligations under Regulation FD. Therefore, investors should monitor our website in addition to following our press releases, SEC filings, public conference calls, and webcasts. Corporate governance information, including our board committee charters and code of ethics, is also available on our investor relations page of our website. The contents of our website are not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As an emerging growth company, we intend to take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- Allowance to provide only two years of audited consolidated financial statements in addition to any required unaudited interim consolidated financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- Reduced disclosure about our executive compensation arrangements;
- Exemption from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1.07 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected not to avail ourself of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 1A. Risk Factors.

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 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 product candidate, FB-401.
- Forte has a limited operating history, which may make it difficult to evaluate its technology and product development capabilities and predict its future performance.
- If Forte fails to comply with its obligations under the license agreement with the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases ("DHHS") or otherwise experience disruptions to its business relationship with DHHS, Forte could lose license rights that are important to its business.
- Forte's near-term prospects are highly dependent on future revenues from a single product candidate, FB-401, and Forte may be unable to achieve regulatory approval for FB-401 and its commercialization.
- Topical live biotherapeutic is a novel approach and negative perception of any product candidate that Forte develops could adversely affect its ability to conduct its business or obtain regulatory approvals for FB-401.
- Forte's initial product candidate targeting atopic dermatitis ("AD") in adults will require significant additional clinical development before it can seek regulatory approval for and launch a therapeutic product commercially.
- 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 clinical trials or those of its future collaborators may reveal significant adverse events not seen in its preclinical studies or other clinical trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidate.
- Positive results from early preclinical studies and clinical trials of FB-401 are not necessarily predictive of the results of any future clinical trials of its product candidate. If Forte cannot replicate the positive results from its earlier preclinical studies and clinical trials of its product candidate in its future clinical trials, Forte may be unable to successfully develop, obtain regulatory approval for and commercialize its product candidate.
- If Forte encounters difficulties enrolling patients in its clinical trials, its clinical development activities could be delayed or otherwise adversely affected.
- Interim top-line and preliminary data from its clinical trials that Forte announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The market opportunities for FB-401 may be limited and its estimates of the incidence and prevalence of its target patient populations may be inaccurate.
- Forte faces significant competition from other healthcare companies, and its operating results will suffer if Forte fails to compete effectively.
- Even if FB-401 or any other product candidate that Forte develops receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, consumers and others in the medical or healthcare community necessary for commercial success.
- Forte will need to grow the size of its organization, and Forte may experience difficulties in managing this growth.
- 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.
- A variety of risks associated with testing and developing its product candidate internationally could materially adversely affect Forte's business.

- 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.
- 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 will rely on third parties to conduct its clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, Forte may not be able to obtain regulatory approval of or commercialize any potential product candidate.
- Forte expects to rely on third parties to manufacture its clinical supply of product candidate, and Forte intends to rely on third parties to produce and process its products, if approved.
- Forte's product candidate requires specialized manufacturing capabilities. If Forte or any of its third-party manufacturers encounter difficulties in manufacturing its product candidate, its ability to provide supply of its product candidate for clinical trials or its products for patients, if approved, could be delayed or stopped, or Forte may be unable to maintain a commercially viable cost structure.

Risks related to Forte's business, technology and industry

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

Forte is a clinical stage healthcare company with a limited operating history. Investment in product development in the healthcare industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Forte's lead product candidate, FB-401, is currently in clinical development. Forte has no products approved for commercial sale and has not generated any revenue from product sales to date, and Forte continues to incur significant research and development and other expenses related to its ongoing operations. As a result, Forte is not profitable and has incurred losses in each period since its inception in 2017. For the years ended December 31, 2020 and 2019, Forte reported net losses of $46.5 million, which includes a $32.1 million charge for in-process research and development expenses, and $4.1 million, respectively. As of December 31, 2020, Forte had an accumulated deficit of $51.5 million. Forte expects to continue to incur significant losses for the foreseeable future, and Forte expects these losses to increase as Forte continues its research and development of, and seeks regulatory approvals for, its product candidate, FB-401. Forte anticipates that its expenses will increase substantially if, and as, it:

- conducts clinical trials for its product candidate, FB-401;
- continues to discover and develop additional applications for FB-401;
- maintains, expands and protects its intellectual property portfolio;
- hires or contracts additional clinical, scientific, manufacturing and commercial personnel to support its product development and commercialization efforts;
- validates a manufacturing process and specifications for FB-401;
- establishes in-house manufacturing capabilities;
- establishes a commercial manufacturing source and secures supply chain capacity sufficient to provide clinical trial material and commercial quantities of any product candidate for which Forte may obtain regulatory approval;
- acquires or in-licenses other product 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 clinical trials, obtaining marketing approval for FB-401, manufacturing, marketing and selling products for which Forte may obtain marketing approval and satisfying any post-marketing

requirements. Forte may never succeed in any or all of these activities and, even if Forte does, Forte may never generate revenue that is significant enough to achieve profitability. If Forte does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Forte's failure to become and remain profitable would decrease the value of the company and could impair its ability to raise capital, maintain its research and development efforts, expand its business or continue its operations.

Even if Forte succeeds in obtaining regulatory approval and commercializing its current product candidate, FB-401, Forte may continue to incur substantial research and development and other expenditures to develop and market additional applications for its current product candidate or any future product candidates. Forte may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The size of its future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenue. Forte's prior losses and expected future losses have had and will continue to have an adverse effect on its stockholders' equity and working capital.

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

Forte's operations have consumed substantial amounts of cash since inception. Forte expects to continue to spend substantial amounts to conduct clinical trials of its current and future programs, to validate the manufacturing process and specifications for its product candidate, to seek regulatory approvals for its product candidate and to launch and commercialize any products for which Forte receives regulatory approval, including potentially building its own commercial organization. As of December 31, 2020, Forte had $58.8 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, capital expenditure requirements through at least twelve months from the issuance date of this Form 10-K. 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-401. Forte's monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of FB-401 is highly uncertain, Forte is unable to estimate the actual funds it will require for development and any approved marketing and commercialization activities. Forte's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

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

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

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

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

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

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

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

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

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

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

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

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

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

Microbiome therapies and therapy candidates in general are a relatively new and novel approach. In the United States and the European Union, Forte is not aware of any products to date have been approved specifically demonstrating an impact on the microbiome as part of their therapeutic effect. Microbiome therapies in general may not be successfully developed or commercialized or gain the acceptance of the public or the medical community. Forte's success will depend upon physicians who specialize in the treatment of diseases targeted by Forte's product candidate prescribing potential treatments that involve the use of its product candidate in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Forte's success will also depend on consumer acceptance and adoption of its products that Forte commercializes. Adverse events in clinical trials of its product candidate or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of the microbiome, could result in delay in regulatory approval for its product candidate or a decrease in demand for any product that Forte may develop. In addition, responses by the U.S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit its ability to develop or commercialize any product candidate, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on Forte's business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of FB-401 or demand for any products Forte may develop.

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

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

Additionally, its Phase 2 clinical trial, which commenced in September 2020, is intended to allow it to evaluate the efficacy and safety of FB-401 in reducing AD in adults and pediatrics. It may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols. Forte's inability to enroll a sufficient number of pediatric patients in a clinical trial could result in significant delays, could require it to abandon one or more clinical trials altogether, could impact its ability to raise additional capital and could delay or prevent its ability to obtain regulatory approvals for FB-401 in pediatric patients. In addition, if Forte is unable to obtain regulatory approval for FB-401 for an indication in pediatric patients, the commercial prospects or viability could be materially harmed, even if Forte obtains regulatory approval for an indication in adult patients.

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

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

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

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

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

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

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

In addition, if any of Forte's drug product candidates, including FB-401, are approved for marketing, Forte will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration. If approved, any of its drug products would be subject to restrictions on its products' labels and other conditions of regulatory approval that may limit its ability to market its products. Forte will also need to comply (and ensure that its third-party

contractors comply) with cGMPs, and Good Clinical Practice ("GCP"), as Forte (and its third-party contractors) will be required to comply with these requirements for the products or product candidates used in its clinical trials or post-approval studies. In addition, Forte will need to comply with GCPs for any clinical trial conducted for any therapeutic indications Forte may develop for approval, including any additional therapeutic indications Forte develop after approval of its first drug candidate for treatment in AD. In addition, there is always the risk that Forte or a regulatory authority might identify previously unknown problems with a drug product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements and other regulatory requirements is costly and any failure to comply or other issues with its product post-approval could have a material adverse effect on its business, financial condition and results of operations.

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

To obtain the requisite regulatory approvals to commercialize any product candidate, Forte must demonstrate through extensive clinical trials that its product candidate is safe and effective in humans for its intended use. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Forte may be unable to establish clinical endpoints, dose levels and regimens or bioanalytical assay methods that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of these studies or trials do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidate performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidate.

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

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

- regulators or IRBs, or ethics committees may not authorize Forte or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- Forte may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or produce negative or inconclusive results and Forte may decide, or regulators may require it, to conduct additional preclinical studies or clinical trials or Forte may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidate may be larger than Forte anticipates, enrollment in these clinical trials may be slower than Forte anticipates, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than Forte anticipates;
- clinical trials of its product candidates may produce negative or inconclusive results, and Forte may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- regulators may require Forte to perform additional or unanticipated clinical trials to obtain approval or Forte may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving its product candidates, or such requirements may not be as Forte anticipate;
- Forte's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to it in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that Forte add new clinical trial sites or investigators;

- the cost of clinical trials of its product candidate may be more than Forte anticipates or more than its available financial resources, and Forte may need to delay or suspend one or more trials until Forte completes additional financing transactions or otherwise receives adequate funding;
- the supply or quality of Forte's product candidate or other materials necessary to conduct clinical trials of its product candidate may be insufficient or inadequate and may not achieve compliance with applicable cGMPs;
- Forte's product candidate may have undesirable side effects or other unexpected characteristics, causing it or its investigators, regulators or IRBs or ethics committees to suspend or terminate clinical trials, or reports may arise from clinical testing of its product candidate that raise safety or efficacy concerns about its product candidate;
- clinical trials of Forte's product candidate may produce negative or inconclusive results, which may result in it deciding, or regulators requiring it, to conduct additional clinical trials or suspend or terminate its clinical trials;
- the FDA or other regulatory authorities may disagree with the design, implementation or results of its clinical trials, or require Forte to submit additional data such as long-term toxicology studies or impose other requirements before permitting it to initiate a clinical trial;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- Forte's limited experience in filing and pursuing a BLA necessary to gain regulatory approval;
- any failure to develop substantial evidence of clinical efficacy and safety, and to develop quality standards and manufacturing processes to demonstrate consistent safety, purity, identity, and/or potency standards;
- a decision by Forte, IRBs, or regulators to suspend or terminate its clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulatory inspections of its clinical trials, clinical trial sites or manufacturing facilities, which may, among other things, require Forte to undertake corrective action or suspend or terminate its clinical trials if regulators find it not to be in compliance with applicable regulatory requirements;
- Forte's ability to produce sufficient quantities of the product candidate to complete its clinical trials;
- varying interpretations of the data generated from its clinical trials; and
- changes in governmental regulations or administrative action.

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

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

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

Before obtaining regulatory approvals for the commercial sale of any products, Forte must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that FB-401 is both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The results of preclinical studies as well as early clinical trials of its product candidate may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not

be indicative of results obtained when such clinical trials are completed. There is typically an extremely high rate of attrition from the failure of product candidate proceeding through clinical trials. Forte believes that its product candidate will be well tolerated by participants in its clinical trials, but there is no certainty that it will be able to dose trial participants at a high enough dose that will demonstrate efficacy without unacceptable safety risk, such as an unanticipated immune response in clinical trial participants.

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

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

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

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

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

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

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

- the severity of the disease or condition under investigation;
- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the study patient population required for analysis of the primary endpoint(s) of the clinical trial;
- the proximity of patients to trial sites;
- the design of the clinical study or trial;
- Forte's ability to recruit investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications Forte is investigating;

- the efforts to facilitate timely enrollment in clinical studies or trials;
- physicians' willingness to recommend applicable patients to our clinical trial;
- the ability to monitor patients adequately during and after treatment;
- Forte's ability or the ability of its CRO to ensure regulatory compliance and to obtain and maintain patient consents for its clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before completion.

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

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

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

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

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

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

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

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

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

- inability to bring a product candidate to the market;
- decreased demand for its products;
- damage to its reputation;
- withdrawal of clinical trial participants and patients and inability to enroll future participants or continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and its resources;
- substantial monetary awards to participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and its capital resources;
- the inability to commercialize any product candidate via any regulatory pathway; and
- decline in its share price.

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

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

The market opportunities for FB-401 may be limited and 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 the product candidate that Forte develop obsolete. Mergers and acquisitions in the healthcare industry may result in even more resources being concentrated amongst its competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Forte's competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis microbiome therapies that are more effective, safer, more easily commercialized or less costly than FB-401 or may develop proprietary technologies or secure patent protection that Forte may need for the development of its technologies and products. Forte believes the key competitive factors that will affect the development and commercial success of its product candidate are efficacy, safety, tolerability, reliability, convenience of use, compliance with regulatory requirements, acceptance by patients or prescribers, competitive pricing and reimbursement.

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

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

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

If any product candidate Forte develops receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, consumers and others in the medical community. If any such product candidate Forte develops does not achieve an adequate level of acceptance, Forte may not generate significant product revenues and Forte may not become profitable. The degree of market acceptance of any 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, has spread to most countries across the world, including all 50 states within the United States, resulting in the World Health Organization characterizing COVID-19 as a pandemic. While the extent of the impact of the 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 clinical trial recruiting and participants could also be slowed or delayed, or in a more severe scenario, its business, financial condition and operating results could be more severely affected. Given the dynamic nature of these circumstances, the duration of any business disruption or potential impact to 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 February 28, 2021, Forte had 9 full-time employees. As its research, development, manufacturing and commercialization plans and strategies develop, and as Forte continues to transition into operating as a public company following the Merger, Forte expects to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- managing its internal research and development efforts effectively, including 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-401 will depend, in part, on its ability to effectively manage any future growth, and its management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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

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

Forte's current operations are located in California, and Forte or the third parties upon whom Forte depends may be adversely affected by natural disasters or the COVID-19 outbreak 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 California. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 outbreak, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in it being unable to fully utilize its facilities, or the manufacturing facilities of its third-party contract manufacturers, may have a material and adverse effect on its ability to operate its business, particularly on a daily basis, and have significant negative consequences on its financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of its product candidate or interruption of its business operations. Earthquakes or other natural disasters could further disrupt its operations and have a material and adverse effect on its business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented it from using all or a significant portion of its headquarters, that damaged critical infrastructure, such as its research facilities or the manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for Forte to continue its business for a substantial period of time. The disaster recovery and business continuity plans Forte has in place may prove inadequate in the event of a serious disaster or similar event. Forte may incur substantial expenses as a result of the limited nature of its disaster recovery and business continuity plans, which, could have a material adverse effect on its business. As part of its risk management policy, Forte maintains insurance coverage at levels that Forte believes are appropriate for its business. However, in

the event of an accident or incident at these facilities, Forte cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If its facilities, or the manufacturing facilities of its third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of its research and development programs may be harmed. Any business interruption may have a material and adverse effect on its business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recent changes to U.S. tax laws, as well as changes to U.S. tax laws that may be enacted in the future, could impact the tax treatment of its business and financial condition. For example, on December 22, 2017, 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 our 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, 2020, Forte has federal net operating loss carryforwards of $256.5 million, of which $136.6 million begin expiring in 2028 unless previously utilized and $120.0 million that do not expire but are limited to 80% of taxable income in a given year. Forte has state net operating loss carryforwards of $269.1 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 anticipate that Forte will continue to incur significant losses for the foreseeable future; and therefore, Forte does not know whether or when Forte will generate the U.S. federal or state taxable income necessary to utilize its NOL carryforwards that are subject to limitation by Sections 382.

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

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

Risks related to government regulation

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

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

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

- acceptance of FB-401, if and when approved, by patients, the medical community and third-party payors;

  Effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims;
- the marketing of FB-401; and
- maintaining a continued acceptable safety profile of FB-401 following approval or commercialization.

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

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

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

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

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute can constitute a false or fraudulent claim under the False Claims Act ("FCA"). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and a referral source on the other, including prescribers, purchasers, and formulary managers. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;
- federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, and its implementing regulations, which require applicable manufacturers of certain drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; effective January 1, 2022, such reporting obligations with respect to covered recipients

will be extended to include payments and transfers of value made during the previous year to certain non-physician providers, such as physician assistants and nurse practitioners, among others;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- GDPR and other ex-U.S. protections.

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

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

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of its operations, as well as additional reporting obligations and oversight if Forte becomes subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

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

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

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

conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that Forte intends to charge for its products may also be subject to approval.

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

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

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design, including study population, dose level, dose regimen, endpoint measure of efficacy, and bioanalytical assay methods, or implementation of its clinical trials;
- Forte may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that its product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- Forte may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with its interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of its product candidate may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which Forte contracts for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering its clinical data insufficient for approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with its product candidate, including adverse events of unanticipated severity or frequency, or with its third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of its products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled enforcement letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by Forte or suspension or revocation of license approvals;

- product seizure or detention or refusal to permit the import or export of its product candidate; and
- injunctions or the imposition of civil or criminal penalties.

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

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate. 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.

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

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

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

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

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

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

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

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

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

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

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in November 2020, the United States Supreme Court held oral arguments on the ACA case from the U.S. Court of Appeals for the 5th Circuit, which upheld the District Court ruling that the individual mandate is unconstitutional, and is expected to issue a decision by mid-2021. We cannot predict how the Supreme Court ruling, other litigation, or the healthcare reform measures of the Biden administration will impact our business. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

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

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

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

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

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

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

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

Risks related to Forte's intellectual property

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

Forte's success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to its product candidate and other technologies Forte may develop. Forte seeks to protect its proprietary position by filing patent applications in the United States and abroad relating to FB-401, as well as other technologies that are important to its business. Given that the development of its technology and product candidate is at an early stage, its intellectual property portfolio with respect to certain aspects of its technology and product candidate is also at an early stage. Forte has filed or intends to file patent applications on these aspects of its technology and its product candidate; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, Forte has only filed provisional patent applications on certain aspects of its technology and product candidate and each of these provisional patent applications is not eligible to become an issued patent until, among other things, Forte files a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause Forte to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

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

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

Moreover, any changes Forte makes to cause its product candidates to have what Forte may view as more advantageous properties may not be covered by existing patents and patent applications, and Forte may be required to file new applications and/or seek other forms of protection for any such altered product candidates. There can be no assurance that Forte would be able to secure patent protection that would adequately cover altered product candidates.

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

Changes in either the patent laws or their interpretation in the United States and other countries may diminish its ability to protect its inventions, obtain, maintain, and enforce its intellectual property rights and, more generally, could affect the value of its

intellectual property or narrow the scope of its owned or licensed patents. With respect to owned intellectual property, Forte cannot predict whether the patent applications Forte is currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming, and complex, and Forte may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. It is also possible that Forte will fail to identify patentable aspects of its research and development output in time to obtain patent protection. Although Forte enters into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of its research and development output, such as its employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing its ability to seek patent protection. In addition, Forte's ability to obtain and maintain valid and enforceable patents depends on whether the differences between its inventions and the prior art allow its inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, Forte cannot be certain that it was the first to make the inventions claimed in any of its owned or pending patent applications, or that Forte was the first to file for patent protection of such inventions.

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

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

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and patents that Forte own may be challenged in the courts or patent offices in the United States and abroad. Forte may be subject to a third party preissuance

submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings or other similar proceedings challenging its owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, Forte's owned patent rights, allow third parties to commercialize Forte's product candidate or other technologies, and compete directly with Forte, without payment to Forte, or result in Forte's inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, Forte may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge its priority of invention or other features of patentability with respect to its owned patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit its ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its product candidate and other technologies. Such proceedings also may result in substantial cost and require significant time from its scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidate, patents protecting such product candidate might expire before or shortly after such product candidate are 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 its product candidate may be subject, in part, to the terms and conditions of future licenses granted to it by others.

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

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

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

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

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

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

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of its owned patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment, and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent

rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on Forte's business, financial condition, results of operations, and prospects.

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

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

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

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

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

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

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

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

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

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

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

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

Despite Forte's efforts, any of the aforementioned parties may breach the agreements and disclose Forte's proprietary information, including its trade secrets, or there may be a lapses or failures in its physical and electronic security systems which lead to its proprietary information being disclosed, and Forte may not be able to obtain adequate remedies in the event of any such breaches. Monitoring unauthorized uses and disclosures is difficult, and Forte does not know whether the steps it has taken to protect its proprietary technologies will be effective. If any of its scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, Forte may not have adequate remedies for any such breach or violation, and Forte could lose its trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to Forte by its partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, Forte may be exposed to liability to the owner of that confidential information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of its trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, Forte would have no right to prevent them from using that technology or information to compete with us. If any of its trade secrets were to be disclosed to or independently developed by a competitor or other third party, Forte's competitive position would be materially and adversely harmed.

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

Forte currently has rights to certain intellectual property, through licenses from third parties, to develop its product candidate. If we fail to comply with our obligations under our license agreements, the licensor may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology, or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

Moreover, some healthcare companies and academic institutions are competing with Forte in the field of microbiome therapies and may have patents and have filed and are likely filing patent applications potentially relevant to Forte's business. In order to avoid infringing these third-party patents, Forte may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. Forte may also require licenses from third parties for certain technologies that Forte may evaluating for use with its current or future product candidate. However, Forte may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes, or other intellectual property rights from third parties that Forte identifies as necessary for its current or any future product candidate at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue

strategies to license or acquire third party intellectual property rights that Forte may consider attractive or necessary. These established companies may have a competitive advantage over Forte due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive Forte to be a competitor may be unwilling to assign or license rights to us. Forte also may be unable to license or acquire third party intellectual property rights on terms that would allow Forte to make an appropriate return on its investment or at all.

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

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

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

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

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

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

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

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to microbiome technologies and in the fields in which Forte is developing its product candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that its product candidate and other technologies may give rise to claims of infringement of the patent rights of others. Forte cannot assure you that its product candidate and other technologies that Forte has developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. Forte may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which Forte is developing its product candidate and other technologies might assert are infringed by its current or future product candidate or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover its product candidate or other technologies. It is also possible that patents owned by third parties of which Forte is aware, but which Forte does not believe are relevant to its product candidate or other technologies, could be found to be infringed by its product candidate or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent

applications that may later result in issued patents that its product candidate or other technologies may infringe. Forte cannot provide any assurances that third-party patents do not exist which might be enforced against its current technology, manufacturing methods, product candidate, or future methods or products resulting in either an injunction prohibiting its manufacture or future sales, or, with respect to its future sales, an obligation on its part to pay royalties and/or other forms of compensation to third parties, which could be significant.

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

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

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

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

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

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

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Forte's ability to compete in the marketplace.

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

Forte's registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Forte may not be able to protect its rights to these trademarks and trade names, which Forte needs to build name recognition among potential partners or customers in its markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to Forte's, thereby impeding Forte's ability to build brand identity and possibly leading to market confusion. If Forte asserts trademark infringement claims, a court may determine that the marks Forte has asserted are invalid or unenforceable, or that the party against whom Forte has asserted trademark infringement has superior rights to the marks in question. In this case, Forte could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of Forte's registered or unregistered trademarks or trade names. Over the long term, if Forte is unable to establish name recognition based on its trademarks and trade names, then Forte may not be able to compete effectively, and its business may be adversely affected. Forte's efforts to enforce or protect its proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect its business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to Forte's product candidate or utilize similar technology but that are not covered by the claims of the patents that Forte may own;
- Forte, or its current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that Forte own now or in the future;
- Forte, or its current or future licensors or collaborators, might not have been the first to file patent applications covering certain of its or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of Forte's technologies without infringing Forte's owned intellectual property rights;
- it is possible that Forte's current or future pending owned patent applications will not lead to issued patents;
- issued patents that Forte 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

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

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

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

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

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

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

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

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

The facilities used to manufacture Forte's product candidate must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that will be conducted after Forte submits a marketing application to the FDA or other foreign regulatory agencies. Forte does not currently control all aspects of the manufacturing process of, and are currently largely dependent on, its contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for manufacture of its product candidate. If and when its manufacturing facility becomes operational, Forte will be responsible for compliance with cGMP requirements. If Forte or its contract manufacturers cannot successfully manufacture in conformance with its specifications and the strict regulatory requirements of the FDA or other regulatory authorities, Forte and they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to the manufacture of its product candidate. In addition, Forte has no control over the ability of its contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of its product candidate or if it withdraws any such approval in the future, Forte may need to find alternative manufacturing facilities, which would significantly impact its ability to develop, obtain regulatory approval for or market its product candidate, if approved.

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

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

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

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

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

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

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

Risks related to manufacturing and supply

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

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

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

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

Forte's manufacturing process may be susceptible to manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other

contaminations are discovered in Forte's product candidate or in the manufacturing facilities in which its product candidate are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidate are developed through preclinical to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause its product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials. Further, changes made to its manufacturing process will require prior approval by the FDA, which can delay Forte's clinical trials and regulatory approval of its product candidate.

Although Forte continues to optimize its manufacturing process for its product candidate, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, and timely availability of reagents and/or raw materials. Forte ultimately may not be successful in transferring its production system from its contract manufacturer to any manufacturing facilities Forte establishes itself, or its contract manufacturer may not have the necessary capabilities to complete the implementation and development process. If Forte is unable to adequately validate or scale-up the manufacturing process for its product candidate with its current manufacturer, Forte will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If Forte is able to adequately validate and scale-up the manufacturing process for its product candidate with a contract manufacturer, Forte will still need to negotiate with such contract manufacturer an agreement for commercial supply, and it is not certain Forte will be able to come to agreement on terms acceptable to it. As a result, Forte may ultimately be unable to reduce the cost of goods for its product candidate to levels that will allow for an attractive return on investment if and when that product candidate is commercialized upon approval.

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

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

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

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

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

Forte may establish a manufacturing facility for its product candidate for production as investigational new drugs for purposes of clinical trials. Forte has limited experience in cGMP compliant manufacturing of its drug product candidate for purposes of clinical trials or at a commercial scale. In the future, Forte may develop its manufacturing capacity in part by expanding its current facility or

building additional facilities. This activity will require substantial additional funds, and Forte would need to hire and train a significant number of qualified employees to staff these facilities. Forte may not be able to develop cGMP-compliant manufacturing facilities that are adequate to produce materials for additional later-stage clinical trials or commercial use. The equipment and facilities employed in the manufacture of pharmaceuticals are subject to stringent qualification requirements by regulatory agencies, including validation of facility, equipment, systems, processes and analytics. Forte may be subject to lengthy delays and expense in conducting validation studies, if Forte can meet the requirements at all.

General Risks

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

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

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

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

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

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

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

Forte's certificate of incorporation provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for any derivative action or proceeding brought on Forte's behalf, any action asserting a breach of fiduciary duty owed by any of its directors, officers or other employees to Forte or its stockholders, any action asserting a claim against it arising pursuant to any provisions of the DGCL, its certificate of incorporation or its bylaws, or any action asserting a claim against it that is governed by the internal affairs doctrine; *provided*, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with Forte or its directors, officers or other employees, which may discourage such lawsuits against Forte and its directors, officers and other employees. If a court were to find the choice of forum provision contained in the certificate of incorporation to be inapplicable or unenforceable in an action, Forte may incur additional costs associated with resolving such action in other jurisdictions.

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

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

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

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

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

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

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

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

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

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

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

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

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

Forte's ability to compete in the highly competitive pharmaceuticals industry depends on its ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. Forte is highly dependent on its management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of Forte's product pipeline, completion of its planned clinical trials, commercialization of its product candidates or in-

licensing or acquisition of new assets and could impact negatively its ability to implement successfully its business plan. If Forte loses the services of any of these individuals, it might not be able to find suitable replacements on a timely basis or at all, and its business could be harmed as a result. Forte might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses.

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

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

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

As of December 31, 2020, 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 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We entered into a lease in April 2019 for office and laboratory space in Torrance, California. The lease agreement is cancellable by the Company at any time with a 30-day notice. We believe that our existing facilities are adequate to meet our current business requirements and that if additional space is required, it will be available on commercially reasonable terms. In addition, we believe that our existing facilities are in good condition and are adequate and suitable for their intended purposes.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the Nasdaq Capital Market under the ticker symbol "FBRX" on June 16, 2020. Prior to that date, our common stock traded under the ticker symbol "TOCA" and reflected the pre-Merger company.

Holders of Record

As of March 11, 2021, there were approximately 6 stockholders of record. We are unable to estimate the actual number of stockholders represented by these record holders, as many of our shares are held by brokers and other institutions on behalf of our stockholders.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Stock Price Performance Graph

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Securities authorized for issuance under equity compensation plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2020.

Sales of Unregistered Securities

There were no sales of unregistered securities by us during the fourth quarter of 2020. Prior to the fourth quarter of 2020, sales of unregistered securities, if any, were previously reported in our quarterly reports on Form 10-Q and current reports on Form 8-K filed with the SEC during 2020.

Item 6. Selected Financial and Other Data.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide this information.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the consolidated financial statements and the related notes contained elsewhere in this Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. The known risks and uncertainties include, but are not limited to, those identified and described in detail under the caption "Risk Factors" and elsewhere in this Form 10-K.

Overview

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

On June 15, 2020, Forte completed a business combination ("Merger") with Tocagen, Inc. ("Tocagen"), a publicly traded biotechnology company, with Forte being the surviving business. As part of the Merger, the then outstanding Tocagen common stock was adjusted with a reverse split ratio of 1-for-15 and each share of Forte's common stock was converted into the right to receive approximately 3.1624 shares of Tocagen common stock (prior to giving effect to the Merger). Immediately prior to the closing of the Merger, the Tocagen legal entity that survived the Merger changed its name to Forte Biosciences, Inc. Our common stock is publicly traded on the Nasdaq Capital Market under the ticker symbol FBRX. Prior to the Merger, Forte was a privately held company incorporated in Delaware on May 3, 2017.

On September 4, 2020, we entered into an "at-the-market" equity offering program ("ATM Facility"), as amended on October 28, 2020, whereby we may from time to time offer and sell shares of our common stock up to an aggregate offering price of $10,000,000 during the term of the ATM Facility. We are 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 event. As of the filing date of this Form 10-K, we have not issued any common stock under the ATM Facility.

On November 2, 2020, we closed an underwritten public offering of 1,614,035 shares of common stock at $28.50 per share, which includes the over-allotment option exercised by the underwriters to purchase an additional 210,526 shares. Total net proceeds were $42.7 million after deducting underwriting discounts and other offering expenses of approximately $3.3 million.

FB-401

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

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

To date, a Phase 1/2a study has been completed with pediatric and adult patients, demonstrating significant reduction in AD disease and pruritus (severe itch), as well as control of *S. aureus* while tapering or eliminating steroid use.

In September 2020, Forte initiated a multi-center, placebo-controlled and double-blinded clinical trial of FB-401 which is expected to enroll adolescent and adult AD subjects aged 2 years of age and older. For additional information about the trial, see ClinicalTrials.gov using the identifier NCT04504279.

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

Intellectual Property

On June 18, 2020, we announced the issuance of our seventh U.S. patent (10,682,379), broadening protection to include methods for culturing Gram-negative bacteria from the skin. Together with the six U.S. patents previously issued, we now have extensive patent protection covering the composition and method of use of our technology which is focused on inflammatory skin conditions.

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

Components of Operating Results

Revenue

We have no products approved for commercial sale and have not generated any revenue from product sales. In the future, we may generate revenue from product sales, royalties on product sales, 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, 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 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.

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

General and Administrative Expenses

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

Acquired In-Process Research and Development Expense

The Company acquired in-process research and development assets in connection with its Merger with Tocagen. As the acquired in-process research and development assets were deemed to have no current or alternative future use, an expense of $32.1 million was recognized in the consolidated statements of operations for the year ended December 31, 2020.

Other Expenses, net

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

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in Note 2 of our consolidated financial statements included elsewhere in this Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our research and development expenses. This process involves reviewing open contracts and commitments, communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our research and development expenses in our consolidated financial statements based on facts and circumstances known to us at that time. If our estimates of the status and timing of services performed differs from the actual status and timing of services performed, we may report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, directors and non-employees in accordance with Accounting Standards Codification ("ASC") 718, *Stock Compensation*. Stock-based awards issued by us have been primarily stock options with time-based vesting or performance-based vesting and restricted stock units. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all stock-based awards. To determine the grant-date fair value of stock-based awards with time-based vesting, we utilize the Black-Scholes option pricing model, which is impacted by the fair value of our common stock as well as other variables including, but not limited to, the expected term that stock-based awards will remain outstanding, expected common stock price volatility over the expected term of the stock-based awards, risk-free interest rates and expected dividends. Prior to the Merger with Tocagen, there was no public market for Forte Biosciences' common stock. As such, the estimated fair values of our common stock underlying our stock-based awards were determined at each grant date by our board of directors, with input from management, based on the information known to us on the grant date, including a review of any recent events and their potential impact on the estimated per share fair value of our common stock. Valuations of our common stock were prepared by a third-party valuation firm in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation (the "Practice Aid").

For stock-based awards with time-based vesting, stock-based compensation is recognized over the period during which an awardee is required to provide services in exchange for the stock-based award, known as the requisite service period (usually the vesting period), on a straight-line basis. For stock-based awards with performance-based vesting, the fair value of the award is recognized as expense when the achievement of the associated performance criteria becomes probable. For both time-based and performance-based stock-based awards, stock-based compensation expense is recognized based on the fair value determined on the date of grant.

Estimates of the fair value of stock-based awards as of the grant date using the Black-Scholes option pricing model are affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. These inputs are:

Expected term – The expected term represents the period that our stock-based awards granted is expected to be outstanding and is determined using the simplified method which is based on the mid-point between the vesting period and the end of the contractual term. We have very limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock-based awards.

Expected volatility – Prior to the Merger, we did not have any trading history for our common stock, so the expected volatility was estimated based on the average volatility for comparable publicly traded biopharmaceutical companies over a period, where available, equal to the expected term of the stock-based awards. The comparable companies were chosen based on their similar size, life cycle stage or area of specialty.

Risk-Free Interest Rate – The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock-based awards.

Expected Dividend – We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we use an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected volatility, expected terms and interest rates utilized for our stock-based compensation expense calculations on a prospective basis.

Income Taxes

We provide for income taxes under the asset and liability method. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities, net operating loss and credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized.

Due to our lack of earnings history and uncertainties surrounding our ability to generate future taxable income, the net deferred tax assets have been fully offset by a valuation allowance. The deferred tax assets were primarily comprised of federal and state tax net operating losses ("NOLs"). Utilization of NOLs may be limited by the "ownership change" rules, as defined in Section 382 of the Internal Revenue Code. Similar rules may apply under state tax laws.

We account for uncertain tax positions in accordance with ASC 740-10, *Accounting for Uncertainty in Income Taxes*. We assess all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and we will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

The following tables summarize our results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		
	2020	2019	Change
Operating expenses:			
Research and development	$ 10,004	$ 2,684	$ 7,320
General and administrative	4,221	1,380	2,841
In-process research and development assets acquired	32,057	—	32,057
Total operating expenses	46,282	4,064	42,218
Other expenses, net	205	5	200
Net Loss	$ 46,487	$ 4,069	$ 42,418

Research and Development Expenses

Research and development expenses were $10.0 million for the year ended December 31, 2020, compared to $2.7 million during the same period in 2019. The increase of $7.3 million was primarily due to an increase of approximately $5.4 million of manufacturing, clinical and regulatory expenses as we advanced our FB-401 program through FDA clinical trials, an increase of approximately $1.4 million in payroll and related expenses including stock-based compensation expense as we expanded our research and development headcount in 2020, and an increase of approximately $0.5 million in other research and development expenses. We expect our research and development expenses to increase substantially during the next few years as we advance FB-401 through US FDA clinical trials and possibly initiate additional trials.

General and Administrative Expenses

General and administrative expenses were $4.2 million for the year ended December 31, 2020 compared to $1.4 million for the same period of 2019. This increase of $2.8 million was primarily due to an increase of approximately $1.2 million in legal and professional expenses driven by the increased expense of being a public company, an increase of approximately $1.0 million in payroll and related expenses including stock-based compensation expense as we expanded our headcount, an increase of approximately $0.4 million in insurance expenses primarily for directors and officers, and an increase of approximately $0.2 million in other general and administrative expenses. We expect our general and administrative expenses to increase substantially during the next few years as a result of staff expansion, costs associated with being a public company, including higher insurance premiums, legal and accounting fees and other compliance costs associated with operating a public company.

In-process research and development assets acquired

In connection with the Merger, we recognized a charge of $32.1 million of acquired in-process research and development expenses for assets with no alternative use for the year ended December 31, 2020.

Other Expenses, net

The increase in other expenses, net of approximately $0.2 million was primarily due to foreign currency transaction losses related to contracts denominated in currencies other than the U.S. dollar as a result of differences between the exchange rates on the billing dates and the payment dates.

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 in each year since inception. Our net losses were approximately $46.5 million for the year ended December 31, 2020, which includes a $32.1 million charge for in-process research and development expenses. As of December 31, 2020, we had an accumulated deficit of approximately $51.5 million. We expect to incur significant expenses and increasing operating losses for the foreseeable future as we continue the clinical development of FB-401. In addition, operating as a SEC registrant may involve the hiring of additional financial and other personnel, upgrading financial information systems, and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to the timing of clinical development programs.

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

On September 4, 2020, as amended on October 28, 2020, we entered into an “at-the-market” equity offering program (“ATM Facility”) whereby we may from time to time offer and sell shares of our common stock up to an aggregate offering price of $10.0 million during the term of the ATM Facility. We are 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 event. We have not issued any common stock under the ATM Facility as of the filing date of this Form 10-K.

On November 2, 2020, we completed a public offering of 1,614,035 shares of our common stock at $28.50 per share, which includes the over-allotment option exercised by the underwriters to purchase an additional 210,526 shares. Total net proceeds were $42.7 million after deducting underwriting discounts and other offering expenses of approximately $3.3 million.

In February 2021, we issued 673,463 shares of our common stock pursuant to cashless exercises by certain warrant holders.

We had cash and cash equivalents of approximately $58.8 million as of December 31, 2020. 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-K.

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 from product sales or out-licensing. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval and commercialize our product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development and manufacturing activities, particularly as we continue the research, development, manufacturing and clinical trials of, and seek regulatory approval for FB-401. We expect to incur additional costs associated with operating as a SEC registrant. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we continue to advance FB-401 in the clinic.

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

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

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

See "Risk Factors" for additional risks associated with our substantial capital requirements.

Summary Consolidated Statements of Cash Flows

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31, 2020	2019
Net cash (used in) provided by:		
Operating activities	$ (18,423)	$ (2,771)
Investing activities	3,582	(162)
Financing activities	66,667	4,856
Net increase in cash	$ 51,826	$ 1,923

Operating Activities

Net cash used in operating activities for the year end December 31, 2020 was $18.4 million and consisted primarily of a net loss of $46.5 million adjusted for non-cash items primarily related to acquired in-process research and development expense of $30.9

million, depreciation and stock-based compensation expense of $1.0 million, and cash used by increases in net operating assets of $3.8 million.

Net cash used in operating activities for the year ended December 31, 2019 was $2.8 million and consisted primarily of a net loss of $4.1 million adjusted for decreases in net operating assets of $1.3 million.

Investing activities

Cash provided by investing activities of $3.6 million for the year ended December 31, 2020 consisted of cash acquired from the reverse merger with Tocagen, Inc. that closed on June 15, 2020. Cash used in investing activities for the year ended December 31, 2019 consisted of cash paid for the acquisition of property and equipment.

Financing Activities

Net cash provided by financing activities was $66.7 million for the year ended December 31, 2020, which was primarily from net proceeds of $66.7 million received from the sale of shares of the Company's common stock, $0.3 million of proceeds received from the exercise of employee stock options, and cash used for prepaid financing costs of $0.3 million. Net cash provided by financing activities for the year ended December 31, 2019 of $4.9 million was from net proceeds received from the sale of our preferred stock.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity pursuant to indemnification agreements. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of December 31, 2020 and 2019.

Contractual Obligations

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

Recent Accounting Standards

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

Item 7A. Quantitative and Qualitative 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, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are included after the Signatures page of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the most recent fiscal quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, believes that our disclosure controls, procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally,

controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by management override of controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information called for by this item will be set forth in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2020 (the "Definitive Proxy Statement") and is incorporated herein by reference. Our board of directors has adopted a Business and Ethics Code of Conduct (the "Code of Conduct") that applies to our officers, directors and employees which is available on our website at www.fortebiorx.com. The Code of Conduct contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K.

Item 11. Executive Compensation.

The information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is hereby incorporated by reference to our Definitive Proxy Statement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) ***The following documents are filed as part of this Annual Report on Form 10-K***

(1) The Financial Statements of Forte Biosciences Inc. and Report of Independent Registered Public Accounting Firm are included after the Signatures page of this Annual Report on Form 10-K beginning on page F-1.

(2) Financial Statement Schedules have been omitted because the required information is included in the financial statements or notes thereto or because they are not applicable or not required.

(b) ***Exhibits***

Exhibits are filed as part of this Annual Report on Form 10-K and are hereby incorporated by reference. Refer to Exhibit Index included herein.

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Quarterly Report on Form 10-Q filed on June 15, 2020.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on June 15, 2020.
3.3	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on April 19, 2017.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
4.2†	Description of Common Stock, incorporated by reference to Exhibit 4.2 of the Registrant's Report on Form 10-K filed on February 27, 2020.
4.3†	Research and Development Grant Agreement, dated June 5, 2013, by and between the Registrant and Voices Against Brain Cancer, incorporated by reference to Exhibit 4.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
4.4	Warrant to Purchase Stock, dated October 30, 2015, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
4.5	Warrant to Purchase Stock, dated October 30, 2015, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574) , as amended, originally filed on March 9, 2017.
4.6	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.6 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.7	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.7 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.8	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.8 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.9	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.9 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.10	Form of Warrant to Purchase Common Stock of the Registrant issued on June 15, 2020, incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q filed on August 10, 2020.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.2+	Tocagen Inc. 2009 Equity Incentive Plan and Forms of Option Grant Notice, Option Agreement and Notice of Exercise thereunder, as amended, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.3+	Tocagen Inc. 2017 Equity Incentive Plan, as amended, and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder, incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K filed on February 27, 2019.
10.4+	Tocagen Inc. 2017 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.

10.5†	Laboratory Services and License Agreement, effective as of November 17, 2011, by and between the Registrant and Siemens Healthcare Diagnostics Inc., incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.6†	First Amendment to Laboratory Services and License Agreement, effective as of June 19, 2015, by and between the Registrant and Siemens Healthcare Diagnostics Inc., incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.7†	License Agreement, effective as of October 22, 2007, by and between the Registrant and University of Southern California, incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.8	Tocagen Inc. Annual Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2017.
10.9	Tocagen Inc. Amended and Restated Non-Employee Director Compensation Policy, incorporated by reference to Exhibit 10.11 of the Registrant's Annual Report on Form 10-K filed on March 9, 2018.
10.10+	Amended and Restated Executive Employment Agreement, dated February 21, 2020, by and between the Registrant and Martin J. Duvall, incorporated by reference to Exhibit 10.10 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.
10.11+	Amended and Restated Executive Employment Agreement, dated February 21, 2020, by and between the Registrant and Mark Foletta, incorporated by reference to Exhibit 10.11 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.
10.12+	Amended and Restated Executive Employment Agreement, dated February 21, 2020, by and between the Registrant and Douglas Jolly, Ph.D., incorporated by reference to Exhibit 10.12 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.
10.13	Lease Agreement by and between the Registrant and AP3-SD1 Campus Point LLC, dated December 21, 2017, incorporated by reference to Exhibit 10.16 of the Registrant's Annual Report on Form 10-K filed on March 9, 2018.v
10.14†	License Agreement, dated April 18, 2018, by and among the Registrant, Beijing Apollo Venus Biomedical Technology Limited and ApolloBio Corp., incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
10.15	Amended and Restated Loan and Security Agreement, dated May 18, 2018, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.v
10.16	First Amendment to Amended and Restated Loan and Security Agreement, dated August 3, 2018, by and amount the Registrant, Oxford Finance LLC and Silicon Valley Bank, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.v
10.17+	Executive Employment Agreement, dated April 8, 2019, by and between the Registrant and Harry E. Gruber, M.D., incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2019.v
10.18	Form of Restricted Stock Unit Grant Notice and Agreement, incorporated by reference to Exhibit 10.18 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.v
10.19	Consent and Second Amendment to Amended and Restated Loan and Security Agreement, dated October 31, 2019, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on November 12, 2019.v
10.20	First Amendment to Lease Agreement, dated December 16, 2019, by and between the Registrant and AP3-SD1 Campus Point LLC, incorporated by reference to Exhibit 10.20 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.
10.21+	Amended and Restated Executive Employment Agreement, dated February 21, 2020, by and between the Registrant and Fairooz Kabbinavar M.D., incorporated by reference to Exhibit 10.21 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.v

10.22	At Market Issuance Sales Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated September 4, 2020, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on September 4, 2020.
10.23+	2020 Inducement Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 11, 2020.
10.24+	Form of stock option agreements under the 2020 Inducement Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 11, 2020.
10.25†	License Agreement, dated December 10, 2017, by and between Forte Subsidiary, Inc. and the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases, incorporated by reference to Exhibit 10.18 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.26+	Forte Subsidiary, Inc. 2018 Equity Incentive Plan, as amended, and Forms of Stock Option Agreement, Exercise Notice and Investment Representation Statement thereunder, incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.27+	Offer Letter, dated December 14, 2018, by and between Forte Subsidiary, Inc. and Paul A. Wagner, Ph.D., incorporated by reference to Exhibit 10.20 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.28+	Offer Letter, dated March 16, 2020, by and between Forte Subsidiary, Inc. and Antony Riley, incorporated by reference to Exhibit 10.21 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.29†^	Asset Purchase Agreement, dated April 9, 2020, by and between the Registrant and Abintus Bio, Inc., as amended on April 10, 2020, incorporated by reference to Exhibit 10.22 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.30†^	Asset Purchase Agreement, dated April 17, 2020, by and between the Registrant and Denovo Biopharma LLC, incorporated by reference to Exhibit 10.23 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.31†	Amendment No. 2 to License Agreement by and between Forte Subsidiary, Inc. and the U.S. Department of Health and Human Services, as represented by the National Institute of Allergy and Infectious Diseases, dated May 26, 2020, incorporated by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q, filed August 10. 2020.v
10.32	Agreement for Termination of Lease and Voluntary Surrender of Premises, dated June 10, 2020, by and between Tocagen, Inc. and ARE-SD Region No. 61, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 15, 2020.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1*	Powers of Attorney (contained in the signature page to this Annual Report on Form 10-K).
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 within the Inline XBRL document)

* Filed herewith.

\+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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

Item 16. Form 10-K Summary

The Company has elected to not include a summary.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Company Name

Date: March 15, 2021 By: /s/ Paul Wagner

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

Date: March 15, 2021 By: /s/ Antony Riley

Antony Riley
Chief Financial Officer
(Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Thomas E. Darcy **Thomas E. Darcy**	Director	March 15, 2021
/s/ Lawrence Eichenfield, M.D. **Lawrence Eichenfield**	Director	March 15, 2021
/s/ Steven Kornfeld **Steven Kornfeld**	Director	March 15, 2021
/s/ Antony Riley **Antony Riley**	Chief Financial Officer	March 15, 2021
/s/ Paul A. Wagner, Ph.D. **Paul A. Wagner**	President, Chief Executive Director and Director	March 15, 2021
/s/ Patricia Walker, M.D, Ph.D. **Patricia Walker**	Director	March 15, 2021
/s/ Donald A. Williams **Donald A. Williams**	Director	March 15, 2021

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Forte Biosciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of **Forte Biosciences, Inc.** (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2018.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 15, 2021

Forte Biosciences, Inc.
Consolidated Balance Sheets
(in thousands, except share and par value data)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 58,765	$ 6,939
Prepaid expenses and other current assets	1,133	567
Total current assets	59,898	7,506
Property and equipment, net	97	152
Other assets	1,244	—
Total assets	**$ 61,239**	**$ 7,658**
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,240	$ 1,569
Accrued liabilities	1,019	343
Total current liabilities	2,259	1,912
Commitments and contingencies (Note 5)		
Series A Convertible Preferred Stock, $0.001 par value; 10,000,000 shares authorized and 0 and 3,177,744 shares issued and outstanding as of December 31, 2020 and 2019, respectively; aggregate liquidation preference of $0 and $10,821 at December 31, 2020 and December 31, 2019, respectively	—	10,515
Stockholders' equity (deficit):		
Common stock, $0.001 par value: 200,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 12,830,598 and 2,108,266 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	13	2
Additional paid-in capital	110,424	199
Accumulated deficit	(51,457)	(4,970)
Total stockholders' equity (deficit):	58,980	(4,769)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	**$ 61,239**	**$ 7,658**

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

Forte Biosciences, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 10,004	$ 2,684
General and administrative	4,221	1,380
In-process research and development assets acquired	32,057	—
Total operating expenses	46,282	4,064
Loss from operations	(46,282)	(4,064)
Other expenses, net	(205)	(5)
Net loss	$ (46,487)	$ (4,069)
Per share information:		
Net loss per share - basic and diluted	$ (6.32)	$ (1.93)
Weighted average shares outstanding, basic and diluted	7,358,931	2,108,266

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

Forte Biosciences Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance — December 31, 2018	1,738,759	$ 5,659	2,108,266	$ 2	$ 163	$ (901)	$ (736)
Issuance of Series A convertible preferred stock, net of issuance cost of $44	1,438,985	4,856	—	—	—	—	—
Stock based compensation	—	—	—	—	36	—	36
Net loss	—	—	—	—	—	(4,069)	(4,069)
Balance — December 31, 2019	3,177,744	$ 10,515	2,108,266	$ 2	$ 199	$ (4,970)	$ (4,769)
Exercise of employee stock options	—	—	74,842	—	257	—	257
Stock based compensation	—	—	—	—	956	—	956
Conversion of preferred stocks into common stock	(3,177,744)	(10,515)	3,177,744	3	10,512	—	10,515
Sale of common stock, net of issuance costs of $3,361			5,829,964	6	66,693	—	66,699
Issuance of common stock in connection with reverse merger	—	—	1,656,076	2	31,807	—	31,809
Restricted stock awards withholdings for taxes	—	—	(16,294)	—	—	—	—
Net loss	—	—	—	—	—	(46,487)	(46,487)
Balance — December 31, 2020	—	$ —	12,830,598	$ 13	$ 110,424	$ (51,457)	$ 58,980

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

Forte Biosciences Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (46,487)	$ (4,069)
Adjustments to reconcile net loss to net cash used in operating activities:		
In process research and development acquired	30,885	—
Depreciation expense	54	11
Stock based compensation expense	956	36
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(263)	3
Accounts payable	(369)	976
Accrued liabilities	(3,199)	272
Net cash used in operating activities	(18,423)	(2,771)
Cash flows from investing activities:		
Cash and restricted cash acquired in reverse merger	3,582	—
Purchase of property and equipment	—	(162)
Net cash provided by (used in) investing activities	3,582	(162)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	66,699	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	4,856
Proceeds from exercise of employee stock options	257	—
Prepaid financing costs	(289)	—
Net cash provided by financing activities	66,667	4,856
Net increase in cash	51,826	1,923
Cash and cash equivalents — beginning of period	6,939	5,016
Cash and cash equivalents — end of period	$ 58,765	$ 6,939
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of preferred stock to common stock	$ 10,515	$ —
Issuance of common stock to Tocagen shareholders	$ 31,809	$ —

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

1. Organization and Description of Business

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

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

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

Liquidity and Risks

The accompanying 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 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 December 31, 2020, the Company had an accumulated deficit of $51.5 million, which includes a charge of $32.1 million for acquired in-process research and development assets in connection with the Merger. The Company used $18.4 million of cash in operating activities during the year ended December 31, 2020. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's research and development activities.

The Company had cash and cash equivalents of approximately $58.8 million as of December 31, 2020. 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-K.

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.

Because of the numerous risks and uncertainties associated with pharmaceutical development, the Company is unable to predict the timing or amount of increased expenses or when or if it will start to generate revenues. Even if the Company is able to generate revenues, it may not be able to achieve or maintain profitability. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and 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 is likely to continue to result, in significant national and global economic disruption and may adversely affect the Company's operations. The Company is actively monitoring the impact of COVID-19 and the possible effects on its financial condition, liquidity, operations, suppliers, industry, and workforce. However, the full extent, consequences, and duration of the COVID-19 pandemic and the resulting impact on the Company cannot currently be predicted. The Company will continue to evaluate the impact that these events could have on its operations, financial position, results of operations and cash flows during 2021.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company prepares its consolidated financial statements in accordance 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").

The Merger was accounted for as a reverse asset acquisition, as more fully described in Notes 1 and 4. Forte Subsidiary is deemed to be the acquirer for accounting purposes and Tocagen is the accounting acquiree.

Principles of Consolidation

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

Use of Estimates

The preparation of the Company's 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 consolidated financial statements and accompanying notes. Significant management estimates that affect the reported amounts of assets, liabilities and expenses include useful lives of property and equipment, stock-based compensation expense, accruals for clinical trials and drug manufacturing, 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.

Segment Information

The Company operates as a single operating segment. The Company's chief operating decision maker, its President and Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources, making operating decisions and evaluating financial performance.

Cash and cash equivalents

Cash and cash equivalents includes money market funds and deposits with commercial banks.

Fair Value of Financial Instruments

The carrying amount of the Company's financial instruments, including certain prepaid and accrued expenses, approximates fair value due to their short-term maturities.

Property and Equipment

Property and equipment are recorded at cost and depreciated over their estimated useful life using the straight-line method. Depreciation and amortization begin at the time the asset is placed in service. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon disposal, retirement, or sale of an asset, the related cost and accumulated depreciation is removed from the accounts and any resulting gain or loss is included in the results of operations. Estimated useful life for property and equipment is as follows:

	Estimated Useful Life
Manufacturing equipment	3 years

Acquired In-Process Research and Development Expense

The Company acquired in-process research and development assets in connection with its Merger with Tocagen. As the acquired in-process research and development assets were deemed to have no current or alternative future use, an expense of $32.1 million was recognized in the consolidated statements of operations for year ended December 31, 2020.

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 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"), 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.

Patent Costs

Costs to secure, defend and maintain patents are expensed as incurred, and are classified as general and administrative expenses due to the uncertainty of future benefits.

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, convertible preferred stock and warrants, which are common stock equivalents, have been excluded from the diluted net loss calculation as their effect would have been anti-dilutive for the periods presented:

	Year Ended December 31,	
	2020	2019
Options	1,123,496	516,521
Convertible preferred stock	—	3,177,744
Warrants	2,756,980	—
Total	3,880,476	3,694,265

Stock-Based Compensation

The Company issues stock-based awards to employees and non-employees, generally in the form of stock options and restricted stock units. The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*.

The Company measures compensation cost for all equity awards for employees, directors and non-employees at their grant-date fair value and recognizes compensation expense over the requisite service period, which is generally the vesting period, on a straight-line basis. The grant date fair value of stock options is estimated using the Black-Scholes option pricing model. The grant date fair value of restricted stock units is determined using the Company's closing stock price on the date of grant. Forfeitures are recognized as they occur.

Stock-based compensation expense for an award with a performance condition is recognized when the achievement of the performance condition has been determined to be probable. If the outcome of such performance condition has not been determined to be probable, or has not been met, no compensation expense is recognized and any previously recognized compensation expense is reversed.

The Company classifies stock-based compensation expense in its statement of operations in the same manner in which the award recipient's salary and related costs are classified in the case of employees, or in which the award recipient's service payments are classified in the case of director and non-employees.

Series A Convertible Preferred Stock

The Company records all convertible preferred stock at their respective transaction prices on the dates of issuance, less issuance costs. Series A convertible preferred stock, prior to its conversion into common stock (Note 6), was classified as temporary equity and excluded from stockholders' equity as the potential redemption, in the event of a deemed liquidation event, was not solely within the Company's control.

Foreign Currency Transactions

The Company is subject to foreign currency risk with respect to contracts denominated in currencies other than the U.S. dollar. Payments on contracts denominated in foreign currencies are made at the spot rate on the day of payment. Changes in the exchange rate between billing dates and payment dates are recorded to other expenses, net on the consolidated statements of operations.

Income Taxes

The Company uses an asset and liability approach to account for income taxes. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates that are expected to be in effect for the years in which differences are expected to reverse.

Valuation allowances are provided when the expected realization of deferred tax assets does not meet a "more likely than not" criterion. The Company makes estimates and judgments about its future taxable income that are based on assumptions that are consistent with its plans and estimates. Should the actual amounts differ from those estimates, the amount of the valuation allowance could be materially impacted. Changes in these estimates may result in significant increases or decreases to the Company's tax provision in a period in which such estimates are changed, which in turn would affect net income or loss.

The Company recognizes tax benefits from uncertain tax positions if it believes the position is more likely than not to be sustained on examination by the taxing authorities based on the technical merits of the position. The Company makes adjustments to these reserves when facts and circumstances change, such as the closing of a tax audit or the refinement of an estimate. The provision for income taxes includes the effects of any reserves for tax positions that are not more likely than not to be sustained, as well as the related net interest and penalties.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceed their fair value, which is measured based on the estimated discounted future net cash flows arising from the assets or asset groups. No impairment losses on long-lived assets have been recorded through December 31, 2020.

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive income (loss) for the periods presented. The Company did not have other comprehensive income (loss) items such as unrealized gains and losses and so for the years ended December 31, 2020 and 2019, comprehensive loss was equal to the net loss.

Recently Adopted Accounting Standards

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

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement.* The new guidance removes, modifies and adds certain disclosure requirements on fair value measurements. The Company adopted this ASU on January 1, 2020. The adoption of this amended guidance did not have a material effect on the Company's consolidated financial statements.

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 the Company as of a specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations.

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

3. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	December 31, 2020	December 31, 2019
Prepaid manufacturing and clinical expenses	$ 488	$ 514
Prepaid insurance	395	30
Prepaid license	100	20
Prepaid taxes	74	—
Other	76	3
Total Prepaid Expenses and Other Current Assets	$ 1,133	$ 567

Other Assets

Other assets as of December 31, 2020 consist of the following (in thousands). There were no other assets as of December 31, 2019.

	December 31, 2020
Prepaid insurance	$ 861
Deposits for manufacturing components	82
Prepaid offering costs	289
Other	12
Total Other Assets	$ 1,244

Accrued Liabilities

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

	December 31, 2020	December 31, 2019
Accrued legal and professional fees	$ 86	$ 140
Accrued compensation	646	175
Accrued manufacturing and clinical expenses	237	26
Accrued other expenses	50	2
Total Accrued Liabilities	$ 1,019	$ 343

4. Merger

On June 15, 2020, the Company completed the Merger (see Note 1). The Merger was accounted for as a reverse asset acquisition as Tocagen did not meet the definition of a business pursuant to *Topic 805, Business Combinations, as* Tocagen did not have the ability to create output, and substantially all of its fair value was concentrated in cash and in-process research and development ("IPR&D") assets. Forte Subsidiary is deemed to be the acquirer for accounting purposes as immediately following the merger: (i) Forte Subsidiary stockholders owned a substantial majority of the voting rights of the combined company; (ii) Forte Subsidiary designated a majority of the initial members of the board of directors of the combined company; and (iii) Forte Subsidiary's senior management held all key positions of the combined company and no employees were retained from Tocagen. Accordingly, for accounting purposes: (i) the merger has been treated as the equivalent of Forte Subsidiary issuing stock to acquire the net assets of Tocagen, (ii) the transaction price has been allocated over the acquired net assets of Tocagen based upon their relative fair value at the time of closing, (iii) the reported historical operating results of the combined company prior to the merger are those of Forte Subsidiary, and (iv) for periods prior to the transaction, shareholders' authorized capital of the combined company is presented based on the historical authorized capital of Tocagen.

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

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

The estimated fair value of total consideration given was $33.0 million based on 1,594,670 shares of Tocagen common stock, 61,406 vested restricted stock awards and in-the-money options to purchase 26,968 shares of common stock of Tocagen outstanding immediately prior to the merger date, multiplied by the Tocagen closing stock price of $18.90 on the date of the merger, and transaction costs of approximately $1.2 million. The fair value of the IPR&D assets is expensed as a charge in the consolidated statements of operations for the year ended December 31, 2020 as there is no alternative use to these assets.

5. Commitments and Contingencies

Concentrations of Credit Risk

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

Indemnifications

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

License to Patented Technology

In December 2017, the Company entered into an exclusive license agreement with the Department of Health and Human Services ("DHHS"). Under the agreement, the DHHS granted the Company an exclusive, sublicensable, worldwide license to certain patent rights under which the Company may develop and commercialize pharmaceutical and biological compositions comprising Gram-negative bacteria for the topical treatment of dermatological diseases and conditions (the "DHHS License"). Under the DHHS License, the Company is obligated to meet certain development benchmarks within certain time periods. If the Company is unable to meet any of these development benchmarks, the DHHS could terminate the license. In addition, the DHHS may terminate or modify the DHHS License in the event of a material breach or upon certain insolvency events that remain uncured following a 90 day written notice of such material breach or insolvency event. The DHHS also has the right to require the Company to grant mandatory sublicenses to patent rights licensed from the DHHS to product candidates covered by other DHHS licenses under certain specified circumstances, including if it is necessary to meet health and safety needs that the Company is not reasonably satisfying or if necessary to meet requirements for public use specified by federal regulations which the Company is not reasonably satisfying.

Under the DHHS License, as amended in May 2020, the Company is obligated to pay the DHHS a minimum annual payment of $20,000 for 2020, which increased to $100,000 beginning January 1, 2021. The Company is required to reimburse the DHHS for certain patent-related expenses and may also be obligated to make milestone payments to the DHHS based upon achieving specified development and regulatory milestones for the first licensed product. Such development milestone payments are the completion of patient enrollment in a phase 3 clinical trial and the completion of a phase 3 clinical trial demonstrating a statistically significant efficacy benefit. The regulatory milestones are the receipt of the first FDA approval and the first non-USA regulatory agency approval. In addition, to the extent licensed products are approved for commercial sale, the Company is also obligated to pay the DHHS royalties based on net sales of licensed products sold by the Company and if applicable, its sublicensees. No milestones have been met as of December 31, 2020.

The Company incurred $30,000 and $20,000 in minimum royalty expenses for the years ended December 31, 2020 and 2019, respectively.

Lease Agreement

In April 2019, the Company entered into a lease agreement for certain office and laboratory space in Torrance, California. The lease agreement is cancellable by the Company at any time with a 30-day notice. The Company recorded total rent expenses of $52,000 and $18,000 for the years ended December 31, 2020 and 2019, respectively.

Clinical Supply Agreements

The Company has entered into various agreements with Contract Manufacturing Organizations ("CMOs") for the manufacture of clinical trial materials and Contract Research Organizations ("CROs") for clinical trial services. These agreements provide the terms and conditions under which the CMOs and CROs will formulate, fill, inspect, package, label and test the Company's drug product candidate, FB-401. The estimated remaining commitment as of December 31, 2020 under these agreements was approximately $82,000.

6. Equity

Series A Convertible Preferred Stock

On November 27, 2018, the Company entered into a preferred stock purchase agreement with certain investors and issued 1,738,759 shares of Series A convertible preferred stock for net proceeds of $5.7 million, including $0.7 million from the conversion of convertible notes and accrued interest. In addition, on January 2, 2019, the Company completed a second round of Series A preferred stock financing and issued 1,438,985 shares at $3.41 per share for net proceeds of $4.9 million. All outstanding shares of Series A convertible preferred stock were converted into shares of common stock on a one for one ratio in connection with the closing of the Merger on June 15, 2020.

Common Stock

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

Warrants to purchase 4,434 shares of the Company's common stock at an exercise price of $140.25 per share which were previously issued by Tocagen, survived the Merger and remained outstanding as of December 31, 2020.

On September 4, 2020, the Company entered into an "at-the-market" equity offering program ("ATM Facility"), as amended on October 28, 2020, whereby the Company may from time to time offer and sell shares of its common stock up to an aggregate offering price of $10.0 million during the term of the ATM Facility. 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 not issued any common stock under the ATM Facility as of December 31, 2020.

On November 2, 2020, the Company completed a public offering of 1,614,035 shares of its common stock at $28.50 per share, which includes the over-allotment option exercised by the underwriters to purchase an additional 210,526 shares. Total net proceeds were $42.7 million after deducting underwriting discounts and other offering expenses of approximately $3.3 million.

7. Stock-Based Compensation

Equity Plans

In December 2018, Forte Subsidiary adopted the 2018 Equity Incentive Plan (the "2018 Incentive Plan"). The terms and conditions of stock-based awards were defined at the sole discretion of 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 to employees 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 remainder of the 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. after the Merger. Subsequent to the Merger, the 2018 Incentive Plan was frozen 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 and was subsequently amended on September 30, 2018 and further amended on February 12, 2019 (the "2017 Plan"). The 2017 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, other forms of equity compensation and performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, non-employee directors and consultants of the Company and its affiliates. Subsequent to the Merger, service-based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service with the remainder of the awards generally 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. As of December 31, 2020, there were 28,862 shares available for issuance under 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 grant under the 2020 Inducement Plan. As of December 31, 2020, there were 180,000 shares available for issuance under the 2020 Inducement Plan.

Stock Options

The risk-free interest rate assumption for stock 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 will continue to apply this process until sufficient amount of historical information regarding the volatility of its own stock price become available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption.

The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. 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.

The weighted average grant-date fair value of stock options granted to employees and non-employees for the year ended December 31, 2020 was $11.94. The weighted-average assumptions used to value these stock options using the Black-Scholes option-pricing were as follows.

	Year ended December 31, 2020
Fair value of common stock and exercise price	$ 19.43
Risk-free interest rate	0.49%
Dividend yield	0.00%
Expected term of options (years)	6.02
Volatility	70.00%

There were no stock options granted during 2019.

The table below summarizes the stock option activity during the year ended December 31, 2020:

	Number of Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2019	516,521	$ 0.85	9.00	
Granted	655,015	$ 19.43		
Assumed from reverse merger	26,968	$ 9.59		
Exercised	(74,842)	$ 3.44		$ 254
Cancelled/Forfeited	(166)	$ 9.59		
Balances at December 31, 2020	1,123,496	$ 11.72	8.85	$ 27,800
Vested and expected to vest at December 31, 2020	1,043,496	$ 10.92	8.78	$ 26,663
Exercisable at December 31, 2020	45,743	$ 9.58	7.79	$ 1,227

The aggregate intrinsic value of options at December 31, 2020 is based on the Company's closing stock price of $36.41 per share.

Restricted Stock Unit Awards

Restricted stock unit award transactions during the year ended December 31, 2020 are as follows:

	Shares	Weighted Avg Grant Date Fair Value
Outstanding at December 31, 2019	—	$ —
Granted	20,000	21.36
Forfeited/Cancelled	—	—
Issued as Common Stock	—	—
Outstanding at December 31, 2020	20,000	$ 21.36

Stock-Based Compensation Expense

Stock-based compensation expenses included in the Company's consolidated statements of operations for the years ended December 31, 2020 and 2019 are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Research and development	$ 585	$ 7
General and administrative	371	29
Total	$ 956	$ 36

As of December 31, 2020, there was unrecognized stock-based compensation expense of $6.9 million related to stock options with service conditions, which is expected to be recognized over a weighted-average period of 3.37 years. Total unrecognized stock-based compensation was approximately $233,000 related to stock options with performance conditions, which is expected to be recognized if and when performance conditions become probable.

As of December 31, 2020, there was $375,000 of total unrecognized compensation expense related to unvested restricted stock unit awards, which the Company expects to fully recognize over a period of 3.45 years.

8. Income Taxes

For the years ended December 31, 2020 and 2019, we did not record a current or deferred income tax expense or benefit due to our valuation allowance position.

The (benefit) provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate to pretax income as a result of the following differences (in thousands):

	Year Ended December 31,			
	2020		2019	
Income tax expense (benefit) at federal statutory rate	$ (9,765)	21.0%	$ (854)	21.0%
Increase/(decrease) in tax resulting from:				
State income taxes	(3,248)	7.0%	(284)	7.0%
Change in valuation allowance	4,390	-9.4%	1,145	-28.2%
Deferred adjustments	38	-0.1%	—	
Transaction adjustments	(392)	0.9%	—	
Permanent items	340	-0.7%	—	
Nondeductible transaction costs	8,643	-18.6%	—	
Other	(6)	0.0%	(7)	0.2%
Total	$ —	0.0%	$ —	0.0%

The primary components of temporary differences which give rise to the Company's net deferred tax assets and liabilities as of December 31, 2020 and 2019 are as follows:

	Year Ended December 31,	
	2020	2019
Deferred tax assets:		
Accrual to cash adjustment	$ 256	$ 402
Start-up costs	1,730	479
Patent costs	57	—
Stock option expense	275	—
Depreciation	—	3
Net operating loss	3,429	597
Tocagen acquisition	418	—
Total noncurrent deferred tax assets	6,165	1,481
Deferred tax liabilities:		
Depreciation	(3)	—
State taxes	(383)	(92)
Total noncurrent deferred tax liabilities	(386)	(92)
Valuation Allowance	(5,779)	(1,389)
Net deferred tax assets after valuation allowance	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based upon the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2020 and 2019. During 2020 and 2019, the valuation allowance increased by $4.4 million and increased by $1.1 million, respectively.

The Company has federal and California net operating loss carryforwards which may be available to offset future income tax liabilities. As of December 31, 2020, the Company has federal net operating losses of $256.5 million, of which, $136.5 million begin expiring in 2028 unless utilized and $120.0 million that do not expire but are limited to 80% of taxable income in a given year. The Company has state net operating carryforwards of $269.1 million that begin to expire in 2027 unless previously utilized.

As of December 31, 2020, the Company has federal and California research and development tax credit carryforwards of approximately $29.2 million and $7.1 million, respectively. The federal research and development tax credits begin to expire in 2028 unless previously utilized. The California credits do not expire.

The Company is subject to taxation in the U.S. and California. As of December 31, 2020, Tocagen's tax years beginning 2007 to date are subject to examination by federal and California taxing authorities due to the carry forward of unutilized net operating losses and research and development tax credits. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of a company's net operating loss and tax credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% (by value) within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several equity offerings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the IRC, or could result in a change in control in the future. The Company has not completed an IRC Section 382 and 383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until such an analysis has been completed, the Company has removed the deferred tax assets for net operating losses of $74.2 million and federal and California research and development credits of approximately $36.3 million from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits accordingly. The Company does not expect this analysis to be completed within the next 12 months and, as a result, the Company does not expect that the unrecognized tax benefits will change within 12 months of this reporting date. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

The Company's policy is to record interest and penalties relating to uncertain tax positions as a component of income tax expense. As of December 31, 2020, and 2019, there was no accrued interest or penalties for uncertain positions.

9. Related Party Transactions

Two members of the Company's board of directors received cash payments of $4,000 and $25,000 for scientific consulting services during the year ended December 31, 2020. As of December 31, 2020, the Company had no outstanding accounts payable to either of these directors.

10. Subsequent Event

In February 2021, the Company issued 673,463 shares of its common stock pursuant to cashless exercises by certain warrant holders.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Registration Statements:

1. Registration Statement (Form S-3 No. 333-224880) of Forte Biosciences, Inc.;
2. Registration Statement (Form S-8 No. 333-235852) of Forte Biosciences, Inc.;
3. Registration Statement (Form S-8 No. 333-244407) of Forte Biosciences, Inc.;
4. Registration Statement (Form S-8 No. 333-217300) of Forte Biosciences, Inc.;
5. Registration Statement (Form S-8 No. 333-223558) of Forte Biosciences, Inc.; and
6. Registration Statement (Form S-8 No. 333-229963) of Forte Biosciences, Inc.;

of our report dated March 15, 2021, relating to the consolidated financial statements of Forte Biosciences, Inc. included in this Annual Report (Form 10-K) as of December 31, 2020 and 2019, and for the two years then ended.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 15, 2021

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 Form 10-K/Annual Report 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: March 15, 2021

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 Form 10-K/Annual Report 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: March 15, 2021

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 annual report of Forte Biosciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 15, 2021

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 annual report of Forte Biosciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 15, 2021

By: /s/ Antony Riley

Antony Riley
Chief Financial Officer