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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

**September 4, 2020**  
Date of Report (Date of earliest event reported)

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

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38052**  
(Commission  
File Number)

**26-1243872**  
(IRS Employer  
Identification No.)

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

**90502**  
(Zip Code)

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

(Former name or former address, if changed since last report.)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	FBRX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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## Cautionary Statement Regarding Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995 (“PLSRA”). All statements, other than statements of historical fact, included in this Current Report on Form 8-K regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Forte Biosciences, Inc. (the “Company” or “Forte”) undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, risks relating to the sufficiency of the Company’s cash balance to fund the Company’s activities, and the expectations with respect thereto; the business and prospects of the Company; the Company’s plans to develop and potentially commercialize its product candidates, including FB-401; the timing of initiation of the Company’s planned clinical trials; the timing of the availability of data from the Company’s clinical trials; the timing of any planned investigational new drug application or new drug application; the Company’s plans to research, develop and commercialize its current and future product candidates; the Company’s ability to successfully enter into collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of the Company’s product candidates; the Company’s commercialization, marketing and manufacturing capabilities and strategy; the Company’s ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to the Company’s competitors and its industry; the impact of government laws and regulations; the Company’s ability to protect its intellectual property position; the Company’s estimates regarding future revenue, expenses, capital requirements and need for additional financing following the proposed transaction; and the impact of COVID-19 on the Company, the Company’s industry or the economy generally.

### **Item 1.01. Entry into a Material Definitive Agreement.**

#### *At Market Issuance Sales Agreement*

On September 4, 2020, the Company entered into an At Market Issuance Sales Agreement (the “Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”). Under the Agreement, the Company may offer and sell its common stock, par value \$0.001 per share, from time to time having an aggregate offering price of up to \$30,000,000 (the “Shares”) during the term of the Agreement through Ladenburg. The Company will file a prospectus supplement relating to the offer and sale of the Shares pursuant to the Agreement. The Shares will be issued pursuant to the Company’s previously filed and effective Registration Statement on Form S-3 (File No. 333-224880), which was initially filed with the Securities and Exchange Commission on May 11, 2018, and declared effective on May 23, 2018. The Company intends to use the net proceeds from the offering, if any, to continue to fund the ongoing clinical development of its product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates.

The Company is not obligated to sell any Shares pursuant to the Agreement. Subject to the terms and conditions of the Agreement, Ladenburg will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market (“Nasdaq”), to sell Shares from time to time based upon the Company’s instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose.

Under the Agreement, Ladenburg may sell Shares by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act of 1933, as amended, and the rules and regulations thereunder, including, without limitation, sales made directly on or through Nasdaq, on or through any other existing trading market for the Shares or to or through a market maker. If expressly authorized by the Company, Ladenburg may also sell Shares in negotiated transactions.

The Agreement will terminate upon the earlier of (i) the issuance and sale of all of the Shares through Ladenburg on the terms and subject to the conditions set forth in the Agreement or (ii) termination of the Agreement as otherwise permitted thereby. The Agreement may be terminated at any time by either party upon ten days’ prior notice, or by Ladenburg at any time in certain circumstances, including the occurrence of a material adverse effect on the Company.

The Company has agreed to pay Ladenburg a commission equal to 3.0% of the gross proceeds from the sales of Shares pursuant to the Agreement and has agreed to provide Ladenburg with customary indemnification and contribution rights.

The foregoing summary of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which is filed as Exhibit 10.1 hereto and incorporated herein by reference. The Agreement contains representations and warranties that the parties made to, and solely for the benefit of, the other in the context of all of the terms and conditions of the Agreement and in the context of the specific relationship between the parties. The provisions of the Agreement, including the representations and warranties contained therein, are not for the benefit of any party other than the parties to the Agreement and are not intended as a document for investors and the public to obtain factual information about the Company’s current state of affairs. Rather, investors and the public should look to other disclosures contained in the Company’s filings with the SEC.

The opinion of the Company’s counsel regarding the validity of the Shares that may be issued pursuant to the Agreement is filed herewith as Exhibit 5.1.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy Shares, nor shall there be any sale of the Shares in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

#### **Item 1.02. Termination of Material Definitive Agreement.**

On September 4, 2020, the Company delivered written notice to Citigroup Global Markets Inc. that it was terminating its Equity Distribution Agreement, dated November 21, 2018 (the “Citi Agreement”), pursuant to Section 8(a) of the Citi Agreement. A copy of the Citi Agreement was filed as Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission (the “SEC”) on November 21, 2018.

#### **Item 8.01. Other Events.**

As previously reported, on June 15, 2020, the Company completed its business combination with Forte Subsidiary, Inc. (“**Forte Subsidiary**”), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated February 19, 2020, as amended (the “**Merger Agreement**”), by and among the Company, Telluride Merger Sub, Inc. (“**Merger Sub**”), and Forte Subsidiary, pursuant to which Merger Sub merged with and into Forte Subsidiary, with Forte Subsidiary surviving as a wholly owned subsidiary of the Company (the “**Merger**”). Immediately prior to the closing of the Merger, the then outstanding shares of the Company’s common stock were adjusted with a reverse stock split of 15 to 1. 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 the Company’s common stock (before giving effect of the reverse split). Immediately prior to closing of the Merger, the Company changed its name from “Tocagen Inc.” to “Forte Biosciences, Inc.”

In connection with the Merger, the Company provides the following information set forth in this Item 8.01.

### **DESCRIPTION OF FORTE’S BUSINESS**

#### **Overview**

Forte 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”). Forte’s lead product candidate, FB-401, is a live biotherapeutic for the treatment of inflammatory skin disease developed in collaboration with the NIH and NIAID. The skin is a complex barrier organ characterized by complex interactions between microbial communities and host tissue via signaling provided by the innate and the adaptive immune systems. Exposure to various endogenous and exogenous factors impact the system balance potentially leading to inflammatory skin conditions comprising infections, allergies or autoimmune diseases. Researchers in microbiology and dermatology have identified and characterized the microorganisms present on the skin to evaluate the bacterial contribution to skin health and dermatological conditions.

Forte is developing a new approach to treating inflammatory skin disease using a topical live biotherapeutic, FB-401. FB-401, 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. Forte has extensive preclinical and mechanism of action data demonstrating that FB-401 improves atopic dermatitis disease parameters by driving tissue repair and anti-inflammation as well as suppressing potentially harmful bacteria like *S. aureus*. Specifically, Forte believes that FB-401:

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

To date, Forte has completed a Phase 1/2a study, including both adults and pediatrics, demonstrating a significant reduction in atopic dermatitis disease and pruritus, as well as control of *S. aureus* while tapering/eliminating steroid use. The full results from this study are expected to be published in the next month or two and are consistent with the published interim dataset. Forte is currently planning to initiate a Phase 2 clinical trial in the third quarter of 2020.

### **Market for Treating AD**

AD is a relapsing and remitting inflammatory skin disorder that affects all age groups. It is chronic and incurable, and is characterized by skin-barrier disruption and immune dysregulation. Clinically, AD is characterized by xerosis, erythematous crusted eruptions, lichenification, an impaired skin barrier and intense pruritus AD flares are frequently triggered by exposure to environmental factors, irritants, and allergens.

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, involving 10%-20% of children and 2%-10% of adults. 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.

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.

The therapeutic approach to AD primarily consists of trigger avoidance, skin hydration with bathing, and use of emollients and anti-inflammatory therapies consisting predominantly of topical corticosteroids ("TCS"). In many patients, treatment with TCS provides some measure of symptomatic relief but does not adequately control

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the disease. Potential local reactions observed with exposure to TCS include atrophy, striae, telangiectasia, irritation, folliculitis, acneiform eruptions, hypopigmentation, allergic contact dermatitis, and secondary infection. Potential systemic adverse reactions observed with exposure to TCS include hypothalamic-pituitary-adrenal axis suppression, Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus.

In addition to TCS, mild to moderate disease is treated with topical calcineurin inhibitors or with crisaborole (EUCRISA®), a topical PDE-4 inhibitor. Topical calcineurin inhibitors are indicated for the short-term and non-continuous chronic treatment of AD in the population age two years and older and not indicated for immunocompromised patients or patients less than two years of age. Topical calcineurin inhibitors carry a boxed warning regarding rare cases of malignancy (e.g., skin and lymphoma) and are labeled as second-line therapy. Crisaborole is associated with local irritation (pain and burning) and occasional hypersensitivity reactions. Therefore, there is a role for additional agents that provide meaningful efficacy with an acceptable safety profile, especially for children.

There is currently no cure for AD. In the United States, approximately 17 million people have been diagnosed with AD, of which more than half are pediatric patients (<17 years old). Treatment options for pediatrics in particular are very limited.

### **Strategy**

Forte's goal is to become a leading dermatology focused biopharmaceutical company. Forte intends to focus its initial efforts on completing the FB-401 clinical development to show its safety and efficacy in treating inflammatory skin diseases including AD. After obtaining FDA approval for FB-401, Forte's focus will be on bringing FB-401 market in order to address the significant unmet need for safe and effective AD therapy for pediatric as well as adult patients.

### **Background**

Although bacteria are often associated with infection and disease, much of the bacteria that colonize the human body are essential for life. Until recently, few scientific studies focused on the benefits of commensal bacteria.

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. That work at NIH demonstrated:

- significant differences in the Gram-negative skin biome between AD patients and healthy volunteers, using genetic-based microbiome identification;
- identified substantial differences in the Gram-negative microbiome present on the skin of AD patients and healthy volunteers;
- found that the predominant species of skin commensal Gram-negative bacteria in healthy volunteers was *Roseomonas mucosa*; and
- discovered that over 50% of AD patients did not have any culturable Gram-negative flora, consistent with DNA-based analysis.

Rigorous preclinical testing established a causal connection between specific strains of *R. mucosa* and skin healing in AD. Subsequent screening based on key parameters of inflammatory skin disease resulted in the identification and selection of three unique therapeutic strains of *R. mucosa* that comprise FB-401. Based on the therapeutic potential observed in preclinical testing, FB-401 was advanced into clinically testing in a Phase 1/2a proof of concept study.

## Clinical Trial

### Design

FB-401 is lyophilized (freeze-dried) in vials 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 FB-401 as a live biotherapeutic for treatment of AD, and a secondary objective was to evaluate the effect of FB-401 on quality of life of participants with AD.

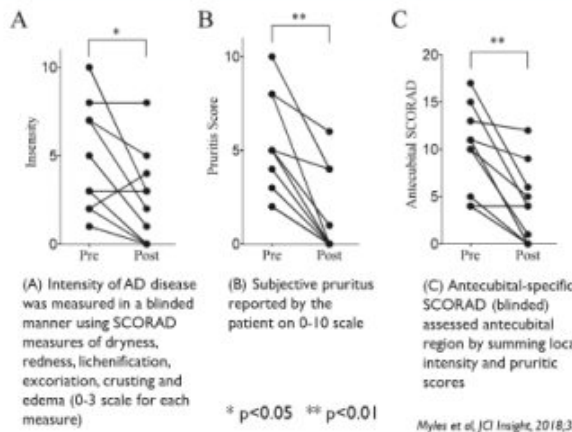
### Results

#### 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. At enrollment, the history and physical characteristics of each patient’s AD was assessed, including the measurement of AD in a blind manner using a clinical tool, SCORing Atopic Dermatitis (“SCORAD”), to assess the extent and severity of AD. SCORAD measures, on a scale of 0-3 for each measure, dryness, redness, lichenification (thick or leathery skin as a result of itching), excoriation (urge to itch), crusting and edema (swelling) of each patient’s AD. In addition to SCORAD, each patient’s AD was measured and recorded using lab work, photographs and skin swabs. Each patient then also gave their subjective score of pruritus on a scale of 0-10. An A.C. SCORAD was then recorded; A.C. SCORAD is the sum of (i) the intensity (as determined by SCORAD) and (ii) the reported pruritus for each patient for the antecubital area (inside of arm near the elbow). 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 improvements in this Phase I adult cohort study:

## STATISTICALLY SIGNIFICANT, DOSE-DEPENDENT IMPROVEMENTS OBSERVED IN ADULT COHORT OF PHASE I/II STUDY



**Only treated areas responded. No AD lesions that were untreated resolved over the course of the study**

Results from Cohort I indicate that six patients responded (60%) with mean improvement of 85%, one patient reported partial response with 44% improvement and three were non responders with 9% mean improvement

## 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.

Assessments of each patient's AD were made at the beginning of the study and at the end of each four-week period using the same assessment methodology described above plus recording the number of steroid applications used by each pediatric patient.

Key clinical parameters included:

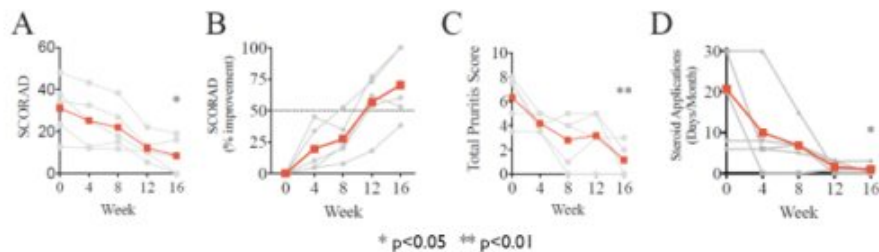
- % of subjects with 50% improvement in SCORAD
- % of subjects with 50%, 75% and 90% improvement in Eczema Area and Severity Index ("EASI") score
- % improvement in SCORAD
- % improvement in EASI score

In addition, this study also explored the following objectives:

- Measure trans epidermal water loss ("TEWL");
- Characterize changes to total and specific Immunoglobulin E ("IgE"), which are antibodies produced by the immune system;
- Evaluate potential changes to pre-diagnosed asthma and/or food allergies;
- Evaluate incidence of *S aureus* infections that require treatment; and
- Persistence of *R mucosa* colonization after treatment.

The following shows the results of this pediatric cohort study in the first five patients, ages 7-17:

### DATA FROM FIRST 5 PEDIATRIC PATIENTS SHOWS ACTIVITY ACROSS MULTIPLE PARAMETERS



- SCORAD score statistically significantly improved (A,B)
  - 4/5 show more than 50% improvement and strong trend towards improvement in 5th patient
- Pruritus shows statistically significant improvement (C)
- Both SCORAD and pruritus improvements achieved while steroid use tapered from an average of 20 applications (D)

In addition, significant improvement in one patient's AD is shown below:



FB-401 was designed to improve atopic dermatitis by selecting three strains of *R. mucosa* that demonstrated improvement in barrier function, enhanced immune balance, and inhibited *S. aureus*. As a commensal gram-negative bacterium, Forte believes FB-401 has the potential for an acceptable safety profile. This study was designed to evaluate the safety of FB-401 in subjects with atopic dermatitis. The dose escalation component of the study design allowed safety to be assessed in a conservative manner. Additionally, multiple efficacy parameters were measured to assess the impact of FB-401 on effected skin. The study demonstrated:

- FB-401 was well tolerated in both adult and pediatric/adolescent subjects.
- FB-401 resulted in clinical improvement in treated areas in adult subjects.
- Children treated with FB-401 had improvement in disease activity including as measured by SCORAD, EASI, pruritus, TEWL and the Children's, or Family, Dermatology Life Quality Index. The degree of improvement was substantial and, despite the absence of a control group, appears to be substantially greater than would be expected in a placebo group. Furthermore, these improvements were seen despite meaningful decreases in topical steroid use.

### Sales and Marketing

Given the current developmental stage of Forte's product candidates and platform, Forte has not yet established a commercial organization. If FB-401 is approved in the United States and/or Canada, Forte intends to commercialize Forte's products both through selectively building its own sales and marketing team and partnering or collaborating with third parties.

### Manufacturing

FB-401 is a live biotherapeutic product that contains live *R. mucosa*, a non-pathogenic normal skin commensal organism in healthy individuals. 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 cGMP. Based on the pilot and cGMP fermentation work to date, Forte expects that a typical commercial fermentation will yield on the order of thousands to tens of thousands of doses per liter.



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*Purification.* The FB-401 purification process utilizes tangential flow filtration (“TFF”) to recover, diafilter and concentrate the bacterial cultures. Process development work with TFF at the current manufacturing contractor achieved virtually 100% viability through the manufacturing steps.

*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. The lyophilized product is reconstituted by the patient prior to use. 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 and released for manufacturing; specifications include appearance, potency, bioburden, purity and identity including DNA sequencing of the strains.

Forte primarily uses contract manufacturing and testing organizations to support the manufacturing of FB-401 drug product. Forte does not own or operate, and currently have no plans to establish, any GMP manufacturing facilities. Forte expects to continue to rely on third parties for the manufacture of FB-401 for clinical testing, as well as for commercial manufacture if FB-401 or any of its product candidates obtain marketing approval. Forte believes this strategy allows it to maintain a more efficient infrastructure by eliminating the need for Forte to invest capital resources in its own manufacturing facilities, equipment and personnel, while also enabling Forte to focus its expertise and resources on the clinical development of FB-401. To date, Forte has obtained FB-401 from a single-source third-party contract manufacturer. While any reduction or halt in supply from this contract manufacturer could limit Forte’s ability to develop FB-401 until a replacement contract manufacturer is found and qualified, Forte believes that it has sufficient access to supply of FB-401 to support its planned clinical trial programs. Forte also believes it has multiple potential additional sources for the manufacture of FB-401.

### **Intellectual Property**

Forte strives to protect and enhance the proprietary technology, inventions and improvements that are commercially important to Forte’s business, including seeking, maintaining and defending Forte’s patent rights. Forte owns or has an exclusive license to issued patents and patent applications relating to Forte’s lead product candidate FB-401, as well as Forte’s other product candidates. Forte’s policy is to seek to protect its proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States directed to Forte’s proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of Forte’s business. Forte also relies on trade secrets and know-how relating to Forte’s proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain Forte’s proprietary position in the field of oncology. Forte also plans to rely on data exclusivity, market exclusivity and patent term extensions when available. Forte’s commercial success will depend in part on its ability to obtain and maintain patent and other proprietary protection for its technology, inventions and improvements; to preserve the confidentiality of its trade secrets; to defend and enforce its proprietary rights, including any patents that Forte may own or license in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

Forte’s intellectual property portfolio for its core technology was initially built through licenses from the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality and the NIH. Forte subsequently expanded its intellectual property portfolio by filing patent applications worldwide and negotiating additional licenses.

### **In-Licensed IP**

In December 2017, Forte entered into an exclusive license agreement with DHHS. Under the agreement, the DHHS granted Forte an exclusive, sublicensable, worldwide license to certain patent rights under which Forte 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, Forte is obligated to meet certain development benchmarks within certain time periods. If Forte is unable to meet any of these development benchmarks, the DHHS could terminate the license. In addition, the DHHS may terminate or modify the DHHS License in the event of a material breach or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such material breach or insolvency event. The DHHS also has the right to require Forte to grant mandatory sublicenses to the 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 Forte is not reasonably satisfying or if necessary to meet requirements for public use specified by federal regulations, which Forte is not reasonably satisfying. Any required sublicense of the DHHS License could result in the loss of significant rights and could harm Forte’s ability to commercialize licensed products.

With respect to the financial obligations under the DHHS License, Forte is obligated to pay the DHHS a minimum annual payment of \$20,000 and is required to reimburse the DHHS for certain patent-related expenses. In addition, Forte may also be obligated to make “benchmark” payments to the DHHS aggregating up to \$105.5 million based on achieving specified development, regulatory and commercial milestones for the first licensed product and additional benchmark payments for each additional licensed product. In addition, to the extent licensed products are approved for commercial sale, Forte is also obligated to pay the DHHS a royalty within the range of 10% to 15% based on net sales of licensed products sold by Forte and its sublicensees until 2036. As of December 31, 2019, Forte had made aggregate payments of \$0.07 million to the DHHS under the license.

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

### ***Forte Owned IP***

More specifically with respect to FB-401, Forte’s seven U.S. patents in its exclusively licensed portfolio described above have claims directed to Forte’s lead product candidate FB-401 as a pharmaceutical composition comprising FB-401, as well as claims directed to a method of treatment of atopic dermatitis comprising administering FB-401. These U.S. patents are expected to expire in March 2037, absent any patent term extensions for regulatory delay.

As of March 1, 2020, Forte owned pending patent applications related to its FB-401 product candidate. Specifically, Forte owned two pending U.S. patent applications, two pending U.S. provisional patent applications and two pending foreign patent applications, both of which are international patent applications filed under the Patent Cooperation Treaty.

Forte’s owned portfolio described above also includes other pending patent applications related to FB-401. These applications include claims directed to FB-401 formulations, their manufacture, and their use for treatment of atopic disorders, including psoriasis, rosacea, and acne. Any patents that may issue from Forte’s pending patent applications related to FB-401 are expected to expire between 2039 and 2041, absent any patent term adjustments or extensions.

Forte also possess substantial know-how and trade secrets relating to the development and commercialization of Forte’s product candidates, including related manufacturing processes and technology.

With respect to Forte’s product candidates and processes Forte intends to develop and commercialize in the normal course of business, Forte intends to pursue patent protection covering, when possible, microbial consortia, methods of use, dosing and formulations. Microorganisms in FB-401 are naturally occurring Gram-negative bacteria. As such, pure composition of matter claims may not be possible in certain countries.

Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for

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20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

The patent positions of companies like Forte's are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of oncology has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish Forte's ability to protect Forte's technology or product candidates and could affect the value of such intellectual property. In particular, Forte's ability to stop third parties from making, using, selling, offering to sell or importing products that infringe Forte's intellectual property will depend in part on Forte's success in obtaining and enforcing patent claims that cover Forte's technology, inventions and improvements. Forte cannot guarantee that patents will be granted with respect to any of Forte's pending patent applications or with respect to any patent applications Forte may file in the future, nor can Forte be sure that any patents that may be granted to it in the future will be commercially useful in protecting Forte's products, the methods of use or manufacture of those products. Moreover, even Forte's issued patents may not guarantee it the right to practice Forte's technology in relation to the commercialization of Forte's products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent Forte from commercializing its product candidates and practicing its proprietary technology, and Forte's issued patents may be challenged, invalidated or circumvented, which could limit Forte's ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for Forte's product candidates. In addition, the scope of the rights granted under any issued patents may not provide Forte with protection or competitive advantages against competitors with similar technology. Furthermore, Forte's competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, Forte may face competition with respect to its product candidates. 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 patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

## **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 and 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 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 IND, application, which must become effective before human clinical trials may begin;
- Approval by an 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, 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.

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## 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

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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, the extent and length of which is uncertain, Forte will be required to develop and implement additional clinical study policies and procedures designed to help protect study participants from the COVID-19 virus, which may include using telemedicine visits and remote monitoring of patients and clinical sites. Forte will also need to ensure data from its clinical studies that may be disrupted as a result of the pandemic is collected pursuant to the study protocol and is consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. Patients who may miss scheduled appointments, any interruption in study drug supply, or other consequence that may result in incomplete data being generated during a study as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, FDA issued a guidance on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical study report (or as a separate document) contingency measures implemented to manage the study, and any disruption of the study as a result of COVID-19; a list of all study participants affected by COVID-19-related study disruption by unique subject identifier and by investigational site, and a description of how the individual's participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the study.

### ***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.

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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 and adequate 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

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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***

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which Forte may obtain marketing approval. Forte’s future arrangements with third-party payors, healthcare providers and physicians may expose Forte to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which Forte market, sell and distribute any drugs for which Forte obtain marketing



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approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below. Forte's business operations, including its research, marketing, and activities relating to the reporting of wholesaler or estimated retail prices for Forte's products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for Forte's products, and the sale and marketing of Forte's product and any future product candidates, are subject to scrutiny under these laws.

- The Anti-Kickback Statute ("AKS"), makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it.
- The federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, which impose penalties against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims that include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act.
- The federal anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- HIPAA imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. 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 Physician Payments Sunshine Act, enacted as part of the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists,

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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, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

- Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply regardless of payor. These laws are enforced by various state agencies and through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures. In addition, certain state and local laws require the registration of pharmaceutical sales representatives.

State and foreign laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. California recently enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General will commence enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact Forte's business activities. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact Forte's business activities if they are adopted. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of Forte's business to the evolving regulatory environment related to personal data and protected health information.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially considering the lack of applicable precedent and regulations. Federal and state enforcement bodies have continued to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that Forte's business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If Forte's operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to it, Forte may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if Forte becomes subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of Forte's operations. If any of the physicians or other healthcare providers or entities with whom Forte expects to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

#### ***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

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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.

There remain judicial, administrative, executive, and legislative 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, various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court, and the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. Forte cannot predict what affect further changes to the ACA would have on Forte's business.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2029, 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. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-

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controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. For example, the United States government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. At the federal level, the U.S. Presidential administration's budget proposal for the fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Further, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs, and the current administration previously released a "Blueprint", or plan, to reduce the cost of drugs. The U.S. Department of Health and Human Services ("HHS"), has solicited feedback on some of these measures and has implemented others under its existing authority. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Action of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require the HHS to directly negotiate drug prices with manufacturers. The Lower Drug Costs Now Act of 2019 has passed out of the House and was delivered to the Senate in December 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on Forte's business. 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.

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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 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

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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,

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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.

### ***Reimbursement***

Sales of Forte's products will depend, in part, on the extent to which Forte's products, if approved, 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 which Forte's products are used. 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 products 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 and clinical support for the use of Forte's products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, creating a new method by which rebates owed by are calculated for drugs that are inhaled, infused, instilled, implanted or injected, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits. Pricing and rebate programs must also comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. While all Medicare drug plans must give at least a standard level of coverage set by Medicare, Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not

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necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for products for which Forte receives marketing approval. However, any negotiated prices for Forte's products covered by a Part D prescription drug plan likely will be lower than the prices Forte might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer's price ("AMP"), and Medicaid rebate amounts reported by the manufacturer. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. The 340B program imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. It is unclear how this decision could affect covered hospitals who might purchase Forte's products in the future and affect the rates Forte may charge such facilities for its approved products. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

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.

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 frequency with which any such product candidate is prescribed or used.

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 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.



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## **Corporate History**

Forte was incorporated under the laws of the State of Delaware in August 2007. Forte Subsidiary was incorporated under the laws of the state of Delaware in May 2017.

## **Competition**

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, strong competition and an emphasis on proprietary products. While Forte believes that its technology, knowledge, experience and scientific resources provide it with competitive advantages, Forte faces substantial competition from many different sources, including larger pharmaceutical companies with more resources. Specialty biotechnology companies, academic research institutions, governmental agencies, as well as public and private institutions are also potential sources of competitive products and technologies. Forte believes that the key competitive factors affecting the success of any of its product candidates will include efficacy, safety profile, method of administration, cost, level of promotional activity and intellectual property protection.

Although there are currently many bacterial product candidates in development by companies that target the microbiome (e.g., Seres Therapeutics, Inc., Synlogic, Inc. and Evelo Biosciences, Inc.), Forte believes that it has a differentiated approach and does not consider itself to be in competition with these bacterial microbiome approaches.

Although Forte's novel chemistry approach is unique from most other existing or investigational therapies across the disease areas where its development is focused, Forte will need to compete with all currently or imminently available therapies in these areas. Forte is aware of several marketed and investigational products in its leading disease areas, including but not limited to:

- Dupixent (Regeneron/Sanofi)
- Eucrisa (Pfizer Inc.)
- JAK inhibitors (various)

## **Employees**

As of December 31, 2019, Forte had one employee, who was a full-time employee and 11 consultants. Forte has recruited additional employees since December 31, 2019, including the conversion of existing consultants to full-time employees. 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.

## **Facilities**

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

## **Legal proceedings**

As of the date hereof, Forte is not subject to any material legal proceedings.

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**Item 9.01 Financial Statements and Exhibits**

(a)

Attached here as Exhibit 99.1 are the audited financial statements of Forte Subsidiary, as previously filed with our prospectus dated May 14, 2020, filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to the Registration Statement on Form S-4, as amended (File No. 333-237371), which includes a proxy statement filed pursuant to Section 14 of the Securities Exchange Act of 1934.

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
5.1	<a href="#">Opinion of Wilson Sonsini Goodrich &amp; Rosati, PC</a>
10.1	<a href="#">At Market Issuance Sales Agreement between the Company and Ladenburg Thalmann &amp; Co. Inc.</a>
23.1	<a href="#">Consent of Mayer Hoffman McCann P.C., Independent Registered Public Accounting Firm</a>
23.2	<a href="#">Consent of Wilson Sonsini Goodrich &amp; Rosati, Professional Corporation (contained in Exhibit 5.1 hereto)</a>
99.1	<a href="#">Audited Financial Statements of Forte Subsidiary, Inc. (formerly known as Forte Biosciences, Inc.) for the years ended December 31, 2019 and December 31, 2018</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 4, 2020

**Forte Biosciences, Inc.**

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

September 4, 2020

Ladenburg Thalmann & Co.  
277 Park Avenue  
New York, New York 10172

Re: Common Stock Issued by Forte Biosciences, Inc.

Ladies and Gentlemen:

Reference is made to the At Market Issuance Sales Agreement, dated September 4, 2020 (the "**Sales Agreement**"), by and between Forte Biosciences, Inc., a Delaware corporation (the "**Company**"), and Ladenburg Thalmann & Co. ("**Ladenburg**"), relating to the issuance and sale by the Company of up to approximately \$30,000,000 of shares (the "**Shares**") of its common stock, par value \$0.001 per share (the "**Common Stock**"), from time to time, through an "at-the-market" equity offering program under which Ladenburg will act as sales agent. This opinion letter is delivered to you pursuant to Section 7(m)(i) of the Sales Agreement, and all terms used herein have the meanings defined for them in the Sales Agreement unless otherwise defined herein.

We have acted as counsel for the Company in connection with the negotiation of the Sales Agreement and the issuance of the Shares. As such counsel, we have made such legal and factual examinations and inquiries as we have deemed necessary or advisable for the purpose of rendering the opinions and statements set forth below.

In rendering the opinions and statements expressed below, we have examined originals or copies of the following:

- (i) the certificate of incorporation, as amended to date, of the Company (the "**Certificate of Incorporation**");
- (ii) the bylaws of the Company, as amended to date (the "**Bylaws**");
- (iii) the minutes of the meetings of, or actions by written consent of, the Board of Directors and the ATM Committee of the Board of Directors, with respect to the transactions covered by the opinions set forth below;
- (iv) the registration statement on Form S-3 (File No. 333-224880) filed by the Company under the Securities Act of 1933, as amended (the "**Securities Act**"), with the Securities and Exchange Commission (the "**Commission**") on May 11, 2018, together with the exhibits thereto and the documents or portions thereof incorporated by reference therein, as modified or superseded or as described therein (such registration statement, as amended at the time it became effective, including the information deemed to be a part of the registration statement pursuant to Rule 430B of the General Rules and Regulations under the Securities Act (the "**Rules and Regulations**"), being hereinafter referred to as the "**Registration Statement**");
- (v) the base prospectus, dated May 23, 2018, together with the documents incorporated by reference therein, as modified or superseded or as described therein which forms a part of the Registration Statement, in the form filed with the Registration Statement (the "**Base Prospectus**");

- (vi) the prospectus supplement, dated September 4, 2020, in the form in which it was filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations, together with the documents or portion thereof incorporated by reference therein, as modified or superseded as described therein (the “*Prospectus Supplement*”, together with the Base Prospectus, the “*Prospectus*”);
- (vii) the notice of effectiveness filed on May 23, 2018 on the Electronic Data Gathering, Analysis and Retrieval System (“*EDGAR*”) as to the effective time and date of the Registration Statement being on May 23, 2018;
- (viii) a specimen certificate for shares of the Common Stock;
- (ix) executed counterparts of the Sales Agreement, including the amendments thereto;
- (x) the officer’s certificate dated as of the date hereof delivered to you pursuant to Section 7(l) of the Sales Agreement;
- (xi) the certificate of the secretary of the Company dated as of the date hereof delivered to you pursuant to Section 7(l) of the Sales Agreement;
- (xii) (i) a certificate of the Secretary of State of Delaware, dated September 3, 2020, with respect to the good standing of the Company as a corporation incorporated under the laws of the State of Delaware, and (ii) a certificate of the Secretary of State of California, dated September 3, 2020, with respect to the good standing of the Company as a foreign corporation qualified to do business in the State of California;
- (xiii) the Reviewed Agreements (as defined below);
- (xiv) the Reviewed Judgments (as defined below); and
- (xv) the other documents delivered by the Company, the transfer agent and registrar and Ladenburg on the date hereof.

In addition, we have reviewed originals or copies of such corporate records of the Company, certificates of public officials, a certificate of an officer of the Company as to factual matters (the “*Officer’s Certificate*”) and such other documents which we consider necessary or advisable for the purpose of rendering the opinions set forth below. We have not independently established the facts stated therein.

In such examination we have assumed the genuineness of all signatures, the authenticity and completeness of all documents submitted to us as originals and the conformity to original documents of all copies submitted to us. In making our examination of documents, we have assumed that each party to any such document (other than the Company in connection with the Sales Agreement) has satisfied those

requirements that are applicable to it to the extent necessary to make such document a valid and binding obligation of such party, enforceable against such party in accordance with its terms. We have also assumed the conformity of the documents filed with the Commission via EDGAR, except for required EDGAR formatting changes, to physical copies submitted for our examination and the absence of any evidence extrinsic to the provisions of the written agreements between the parties that the parties intended a meaning contrary to that expressed by those provisions.

As used in the opinions or statements set forth below, the expressions “to our knowledge,” “known to us” or similar language with reference to matters of fact refer to the current actual knowledge of the attorneys of this firm who have rendered substantive legal services to the Company. Except to the extent expressly set forth herein, we have not undertaken any independent investigation to determine the existence or absence of any fact, and no inference as to our knowledge of the existence or absence of any fact should be drawn from our representation of the Company or the rendering of the opinions or statements set forth below.

We express no opinion as to any matter relating to the laws of any jurisdiction other than the federal laws of the United States of America, the General Corporation Law of the State of Delaware (“**Delaware General Corporation Law**”) and the laws of the States of California and New York. Other than as expressly set forth in this paragraph, we have made no inquiry into, and express no opinion as to, the statutes, regulations, treaties or common laws of any other nation, state or jurisdiction. This opinion letter should be interpreted in accordance with customary practice in the preparation and understanding of legal opinions in the United States as set forth in the Legal Opinion Principles issued by the Committee on Legal Opinions of the American Bar Association’s Section of Business Law as published in 53 *Business Lawyer* 831 (1998) and the “Statement on the Role of Customary Practice in the Preparation and Understanding of Third Party Legal Opinions” as published in 63 *Business Lawyer* 1277 (2008).

As used in this opinion letter, the “**Reviewed Agreements**” means only those contracts, agreements, or instruments filed or incorporated by reference as an exhibit to the Registration Statement pursuant to Item 601(b)(2), (4) or (10) of Regulation S-K. In rendering the opinions set forth in paragraphs 5 and 6 below, we have relied solely upon an examination of the Reviewed Agreements in the forms filed as exhibits to the Company’s filings with the Commission. The opinion in paragraph 6 below concerning violations or events of default under Reviewed Agreements is based on the result that would be obtained if a California court were to apply the internal laws of the State of California (excluding conflicts of law principles) to the interpretation and enforcement of the Reviewed Agreements, except in the case of Reviewed Agreements governed by New York law.

As used in this opinion letter, the “**Reviewed Judgments**” means only those judgments and decrees that are expressly identified on Schedule A hereto, if any. The Company has represented to us that the Reviewed Judgments are the only material judgments or decrees applicable to the Company, and nothing has come to our attention that has caused us to believe that we are not justified in relying on such representation.

The opinions and statements hereinafter expressed are subject to the following additional exceptions, qualifications, limitations and assumptions:

- (a) We have assumed that the representations and warranties as to factual matters made by the Company in the Sales Agreement and pursuant thereto are true, correct and complete.
- (b) In rendering the opinion set forth in paragraph 1 below as to due incorporation, valid existence, and good standing, we have relied solely upon the documents and certificates referenced in paragraphs (i) and (xii) above.
- (c) We express no opinion as to compliance with the anti-fraud provisions of applicable securities laws.
- (d) With regard to paragraph 6 below, we express no opinion with respect to any consents, approvals, authorizations, orders, filings, registrations or qualifications required by the Financial Industry Regulatory Authority, Inc. and the Blue Sky laws of the various states and other jurisdictions within the United States or the securities laws of any jurisdiction outside the United States for the issue and sales of the Shares and compliance by the Company with the provisions of the Sales Agreement.
- (e) In rendering the opinion set forth in paragraph 7 below, we (i) have been advised by the Company that the values used to form the basis of that opinion were determined by its management in accordance with Securities and Exchange Commission guidance regarding fair value methodologies and that we can treat those values as though they are fair values determined by the Company's Board of Directors; and (ii) have relied as to certain factual matters solely and exclusively upon the representations and information provided to us by an authorized representative of the Company as set forth in the Certificate Concerning the Status of the Company under the Investment Company Act of 1940, dated as of September 4, 2020.
- (f) Regarding our statement set forth below as to the effectiveness of the Registration Statement and the filing of the Prospectus, we have relied solely upon information contained on the Commission's EDGAR website. Regarding our statement set forth below as to no stop orders, we have relied solely upon information contained on the Commission's website.
- (g) We further advise you that (i) we have not been engaged by the Company or its subsidiaries as advisors on applicable laws governing FDA and regulatory issues, and (ii) we are not giving any opinion below in the capacity as advisors on FDA and regulatory issues.

Based upon and subject to the foregoing, we are of the opinion that:

1. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware. The Company has the corporate power and authority to own, lease and operate its properties and assets and to carry on its business as described in the Registration Statement and the Prospectus. The Company is qualified to do business and is in good standing as a foreign corporation in the State of California.
  2. Forte Subsidiary, Inc. ("**Forte Sub**") has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Delaware. Forte Sub has the corporate power and authority to own, lease and operate its properties and assets and to carry on its business as described in the Registration Statement and the Prospectus. Forte Sub is qualified to do business and is in good standing as a foreign corporation in the State of California.
  3. The Company has the corporate power and authority to (i) execute and deliver the Sales Agreement, (ii) issue and sell the Shares pursuant to the Sales Agreement and (iii) carry out and perform its obligations under the Sales Agreement.
  4. The Sales Agreement has been duly authorized, executed and delivered by the Company.
  5. The Shares have been duly authorized and, when issued in accordance with the provisions of the applicable Placement Notice and paid for in accordance with the Sales Agreement, will be validly issued, fully paid and nonassessable and free of any preemptive or similar rights arising by operation of the Certificate of Incorporation, Bylaws or the Delaware General Corporation Law or, to our knowledge, registration rights, rights of first refusal or other similar rights to subscribe for the Shares pursuant to any Reviewed Agreement.
  6. The execution and delivery by the Company of the Sales Agreement, and the performance by the Company of its obligations under the Sales Agreement, and the issuance and sale of the Shares pursuant to the Sales Agreement do not violate any provision of (i) any U.S. federal, California, or New York state law, rule or regulation known to us to be customarily applicable to transactions of the nature contemplated by the Sales Agreement; (ii) the Delaware General Corporation Law; or (iii) the Certificate of Incorporation or Bylaws. The execution and delivery by the Company of, and the performance by the Company of its obligations under, the Sales Agreement do not violate or constitute a default under any Reviewed Agreement or violate any Reviewed Judgment. No consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the valid execution and delivery of the Sales Agreement or the performance by the Company of its obligations thereunder, or the offer, sale or issuance of the Shares, except such as have been obtained or made under the Securities Act or the Securities Exchange Act of 1934, as amended.
  7. The Company is not and, immediately after giving effect to the offering and sale of Shares and the application of the proceeds thereof as described in the Prospectus, will not be required to register as an "investment company" as such term is defined in the Investment Company Act.
  8. The information included in the Registration Statement and the Prospectus under the caption "Description of Capital Stock," to the extent that it constitutes matters of law, summaries of legal matters, documents referred to therein or legal conclusions, has been reviewed by us and fairly summarizes the matters set forth therein in all material respects.
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The Registration Statement was declared effective under the Securities Act. The Prospectus was filed with the Commission in the manner and within the time required by Rule 424(b). No stop order suspending the effectiveness of the Registration Statement or any part thereof has been issued, and, to our knowledge, no proceedings for that purpose have been instituted or are pending under the Securities Act.

To our knowledge, there are (i) no lawsuits pending or threatened in writing against the Company that are required to be described in the Registration Statement or the Prospectus and that are not described in all material respects therein as required, and (ii) no indentures, contracts, leases, mortgages, deeds of trust, note agreements, loans or other agreements or instruments of a character required to be filed as exhibits to the Registration Statement, which are not filed as required by the Securities Act and the rules and regulations thereunder.. We note that we have not conducted a docket search in any jurisdiction with respect to lawsuits that may be pending against the Company.

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This opinion letter is furnished to you solely for your benefit in connection with the Sales Agreement, and may not be relied upon by any other person or for any other purpose without our prior written consent. We assume no obligation to inform you of any facts, circumstances, events or changes in the law that may arise or be brought to our attention after the date of this opinion letter that may alter, affect or modify the opinions or statements expressed herein.

Very truly yours,

**/s/ WILSON SONSINI GOODRICH & ROSATI**  
Professional Corporation

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**EXHIBIT A**

**Reviewed Judgments**

None.

## Forte Biosciences, Inc.

Common Stock  
(par value \$0.001 per share)

## At Market Issuance Sales Agreement

September 4, 2020

Ladenburg Thalmann & Co. Inc.  
277 Park Avenue, 26th Floor  
New York, NY 10172

Ladies and Gentlemen:

Forte Biosciences, Inc., a Delaware corporation (the "Company"), confirms its agreement (this "Agreement") with Ladenburg Thalmann & Co. Inc. (the "Agent") as follows:

1. Issuance and Sale of Shares. The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent, shares (the "Placement Shares") of the Company's common stock, par value \$0.001 per share (the "Common Stock"), *provided however*, that in no event shall the Company issue or sell through the Agent such number of Placement Shares that (a) exceeds the number of shares of Common Stock registered on the effective Registration Statement (as defined below) pursuant to which the offering is being made, or (b) exceeds the number of shares or dollar amount registered on the Prospectus (as defined below), or (c) exceeds the number of authorized but unissued shares of Common Stock or (d) exceeds the number or dollar amount of shares of Common Stock permitted to be sold under Form S-3 (the lesser of (a), (b), (c) and (d), the "Maximum Amount"). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 1 on the number of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that the Agent shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through the Agent will be effected pursuant to the Registration Statement (as defined below), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue any Placement Shares.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (the "Securities Act"), with the Securities and Exchange Commission (the "Commission"), a registration statement on Form S-3 (the "Current Registration Statement"), including a prospectus relating to the Placement Shares to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (the "Exchange Act"). The Company will prepare a prospectus supplement to the prospectus included as part of such registration statement specifically relating to the Placement Shares (the "Prospectus").

Supplement”). The Company will furnish to the Agent, for use by the Agent, copies of the prospectus relating to the Placement Shares included as part of such registration statement, as supplemented by the Prospectus Supplement. Except where the context otherwise requires, such registration statement, and any post-effective amendment thereto, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act or any subsequent registration statement on Form S-3 filed pursuant to Rule 415(a)(6) under the Securities Act by the Company to cover any securities registered pursuant to the Current Registration Statement, including any Placement Shares, as a result of the end of the three-year period described in Rule 415(a)(5) of the Securities Act, is herein called the “Registration Statement.” The prospectus specifically relating to the Placement Shares, including all documents incorporated or deemed incorporated therein by reference to the extent such information has not been superseded or modified in accordance with Rule 412 under the Securities Act (as qualified by Rule 430B(g) of the Securities Act), included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, is herein called the “Prospectus.” Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated or deemed incorporated by reference therein, and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein (the “Incorporated Documents”).

For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval system, or if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, “EDGAR”).

2. Placements. Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a “Placement”), it will notify the Agent by email notice (or other method mutually agreed to in writing by the parties) of the number of Placement Shares, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales may not be made (a “Placement Notice”), the form of which is attached hereto as Schedule 1. The receipt of each such Placement Notice shall be promptly acknowledged by the Agent by email confirmation to the Company. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 2 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 2, as such Schedule 2 may be amended from time to time. Provided that the Company is otherwise in compliance with the terms of this Agreement, the Placement Notice shall be effective immediately upon receipt by the Agent unless and until (i) the Agent declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company suspends or

terminates the Placement Notice, or (iv) this Agreement has been terminated under the provisions of Section 13. The amount of any discount, commission or other compensation to be paid by the Company to the Agent in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 3. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of Sections 2 or 3 of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by the Agent.

a. Subject to the terms and conditions of this Agreement, for the period specified in a Placement Notice, the Agent will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market LLC (the "Exchange"), to sell the Placement Shares up to the amount specified in, and otherwise in accordance with the terms of, such Placement Notice. The Agent will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to the Agent pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Agent (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of a Placement Notice, the Agent agrees that all sales of the Placement Shares by the Agent will be made only by methods permitted by law and deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act. Subject to the terms of a Placement Notice, the Agent may also sell Placement Shares by any other method permitted by law, including but not limited to privately negotiated transactions, with the Company's consent. "Trading Day" means any day on which Common Stock is purchased and sold on the Exchange.

b. For such time as the Agent is actively offering Placement Shares pursuant to this Agreement, the Agent shall not for its own account engage in (i) any short sale of any security of the Company, (ii) any sale of any security of the Company that the Agent does not own for the account of the Agent or any sale which is consummated by the delivery of a security of the Company borrowed by, or for the account of, the Agent, or (iii) any market making, bidding, purchasing, stabilization or other trading activity with regard to the Common Stock or related derivative securities, or attempting to induce another person to do any of the foregoing, if such activity would be prohibited under Regulation M or other anti-manipulation rules under the Securities Act. Neither the Agent nor any of its affiliates or subsidiaries shall engage in any proprietary trading or trading for the Agent's (or its affiliates' or subsidiaries') own account. For the avoidance of doubt, this restriction shall not apply to transactions by or on behalf of any customer of the Agent or transactions by the Agent to facilitate any such transactions by or on behalf of any customer of the Agent.

4. Suspension of Sales. The Company or the Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 2), suspend any sale of Placement Shares (a “Suspension”); *provided, however*, that such Suspension shall not affect or impair any party’s obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a Suspension is in effect, any obligation under Sections 7(l), 7(m), and 7(n) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 2 hereto and acknowledged in accordance with this Section 4, as such Schedule may be amended from time to time.

5. Sale and Delivery to the Agent; Settlement.

a. Sale of Placement Shares. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, upon the Agent’s acceptance of the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Exchange to sell such Placement Shares up to the amount specified in, and otherwise in accordance with the terms of, such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that the Agent will be successful in selling Placement Shares, (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations and the rules of the Exchange to sell such Placement Shares as required under this Agreement and (iii) the Agent shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement, except as otherwise agreed by the Agent and the Company.

b. Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2<sup>nd</sup>) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “Settlement Date”). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the “Net Proceeds”) will be equal to the aggregate sales price received by the Agent, after deduction for (i) the Agent’s commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

c. Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting the Agent's or its designee's account (provided that the Agent shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System ("DWAC") or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Agent will be responsible for providing DWAC instructions or instructions for delivery by other means with respect to the transfer of the Placement Shares being sold. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Shares on a Settlement Date through no fault of the Agent, then in addition to and in no way limiting the rights and obligations set forth in Section 11(a) hereto, it will (i) hold the Agent harmless against any loss, claim, damage, or reasonable, documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to the Agent (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

d. Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate number of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Agent in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Agent in writing. Further, under no circumstances shall the Company cause or permit the aggregate offering amount of Placement Shares sold pursuant to this Agreement to exceed the Maximum Amount.

e. Sales Through Agent. The Company agrees that any offer to sell, any solicitation of an offer to buy, or any sales of Common Stock or any other equity security of the Company shall only be effected by or through the Agent, and only the Agent, on any single given date; provided however that (i) the foregoing limitation shall not apply to (A) exercise of any option, warrant, right or any conversion privilege set forth in the instruction governing such securities, (B) sales solely to employees, directors or security holders of the Company or its Subsidiaries, or to a trustee or other person acquiring such securities for the accounts of such person and (ii) such limitation shall not apply (A) on any day during which no sales are made pursuant to this Agreement or (B) during a period in which the Company has notified the Agent that it will not sell Common Stock under this Agreement and (1) no Placement Notice is pending or (2) after a Placement Notice has been withdrawn.

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6. Representations and Warranties of the Company.<sup>1</sup> Except as disclosed in the Registration Statement or Prospectus (including the Incorporated Documents), the Company represents and warrants to, and agrees with the Agent that as of the date of this Agreement and as of each Applicable Time (as defined below), unless such representation, warranty or agreement specifies a different date or time:

a. Registration Statement and Prospectus. The Company and, assuming no act or omission on the part of the Agent that would make such statement untrue, the transactions contemplated by this Agreement meet the requirements for and comply with the conditions for the use of Form S-3 under the Securities Act. The Registration Statement has been filed with the Commission and has been declared effective under the Securities Act. The Prospectus Supplement will name Ladenburg Thalmann & Co. Inc. as the Agent in the section entitled "Plan of Distribution." The Company has not received, and has no notice of, any order of the Commission preventing or suspending the use of the Registration Statement, or threatening or instituting proceedings for that purpose. The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule. Any statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement have been so described or filed. Copies of the Registration Statement, the Prospectus, and any such amendments or supplements and all documents incorporated by reference therein that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to the Agent and its counsel. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute, any offering material in connection with the offering or sale of the Placement Shares, other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus (as defined below) to which the Agent has consented, any such consent not to be unreasonably withheld, conditioned or delayed. The Common Stock is currently quoted on the Exchange. The Company has not, in the 12 months preceding the date hereof, received notice from the Exchange to the effect that the Company is not in compliance with the listing or maintenance requirements of the Exchange. The Company has no reason to believe that it will not in the foreseeable future continue to be in compliance with all such listing and maintenance requirements.

b. No Misstatement or Omission. At each Settlement Date, the Registration Statement and the Prospectus, as of such date, will conform in all material respects with the requirements of the Securities Act. The Registration Statement, when it became or becomes effective, did not, and will not, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus and any amendment and supplement thereto, on the date thereof and at each Applicable Time (defined below), did not or will not include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The documents incorporated by reference in the Prospectus or any Prospectus Supplement did not, and any further documents filed and incorporated by reference therein will not, when filed with the Commission, contain an

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<sup>1</sup> Note: reps and warrants remain subject to review by Mintz IP and regulatory specialists.



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untrue statement of a material fact or omit to state a material fact required to be stated in such document or necessary to make the statements in such document, in light of the circumstances under which they were made, not misleading. The foregoing shall not apply to statements in, or omissions from, any such document made in reliance upon, and in conformity with, the Agent's Information.

c. Conformity with Securities Act and Exchange Act. The Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or any amendment or supplement thereto, and the Incorporated Documents, when such documents were or are filed with the Commission under the Securities Act or the Exchange Act or became or become effective under the Securities Act, as the case may be, conformed or will conform in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable.

d. Financial Information. The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified and have been prepared in compliance in all material respects with the requirements of the Securities Act and Exchange Act, as applicable, as in effect as of the time of filing and in conformity with generally accepted accounting principles in the United States as in effect as of the time of filing ("GAAP") applied on a consistent basis (except (i) for such adjustments to accounting standards and practices as are noted therein and (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes or may be condensed or summary statements) during the periods involved; the other financial and statistical data with respect to the Company contained or incorporated by reference in the Registration Statement and the Prospectus, are accurately and fairly presented in all material respects and prepared on a basis materially consistent with the financial statements and books and records of the Company; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement, or the Prospectus that are not included or incorporated by reference as required; the Company does not have any material liabilities or obligations, direct or contingent (including any off balance sheet obligations), not described in the Registration Statement (including the exhibits thereto and documents incorporated by reference thereto) and the Prospectus, which are required to be described in the Registration Statement or Prospectus (including the exhibits thereto and documents incorporated by reference thereto); and all disclosures contained or incorporated by reference in the Registration Statement and the Prospectus, if any, regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable.

e. Conformity with EDGAR Filing. The Prospectus delivered to the Agent for use in connection with the sale of the Placement Shares pursuant to this Agreement will be identical to the versions of the Prospectus created to be transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

f. Organization. The Company is and will be, duly organized, validly existing as a corporation and in good standing under the laws of its jurisdiction of organization. The Company is, and will be, duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which its ownership or lease of property or the conduct of its business requires such license or qualification, and has all corporate power and authority necessary to own or hold its properties and to conduct its businesses as described in the Registration Statement and the Prospectus (including the exhibits thereto and documents incorporated by reference thereto), except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect or would reasonably be expected to have a material adverse effect on the assets, business, operations, earnings, properties, condition (financial or otherwise), prospects, stockholders' equity or results of operations of the Company taken as a whole, or prevent the consummation of the transactions contemplated hereby (a "Material Adverse Effect").

g. Subsidiaries. The subsidiaries set forth on Schedule 4 hereto (each, a "Subsidiary" and collectively, the "Subsidiaries") are the Company's only significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission). Each Subsidiary is duly organized and validly existing as a corporation or other entity under the laws of its respective jurisdictions of organization and is in good standing under such laws. Each of the Subsidiaries has requisite corporate or other organizational power to carry on its business as described in the Prospectus. Each of the Subsidiaries is duly qualified to transact business and is in good standing in all jurisdictions in which the conduct of its business requires such qualification; except where the failure to be so qualified or to be in good standing would not result in a Material Adverse Effect.

h. No Violation or Default. Neither the Company nor any of its Subsidiaries are (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company is a party or by which the Company is bound or to which any of the property or assets of the Company is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority having jurisdiction over the Company, except, in the case of each of clauses (ii) and (iii) above, for any such violation or default that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, no other party under any material contract or other agreement to which it or any of its Subsidiaries is a party is in default in any respect thereunder where such default would reasonably be expected to have a Material Adverse Effect.

i. No Material Adverse Effect. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement and Prospectus, other than the transactions contemplated by the Agreement and Plan of Merger and Reorganization by and among Forte Biosciences, Inc., Forte Subsidiary, Inc., Tocagen Inc. and Telluride Merger Sub, Inc., dated February 19, 2020, as amended, there has not been (i) any Material Adverse Effect, or any development involving a prospective Material Adverse Effect, in

or affecting the business, properties, management, condition (financial or otherwise), results of operations, or prospects of the Company or its Subsidiaries, (ii) other than the transactions contemplated by this Agreement, any transaction which is material to the Company or its Subsidiaries, (iii) any obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or its Subsidiaries, which is material to the Company or its Subsidiaries, (iv) any material change in the capital stock (other than (A) the grant of additional options or other equity awards under the Company's existing stock option plans, (B) changes in the number of outstanding Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, Common Stock outstanding on the date hereof, (C) as a result of the issuance of Placement Shares, (D) any repurchases of capital stock of the Company, (E) as described in a proxy statement filed on Schedule 14A or a Registration Statement on Form S-4, or (F) otherwise publicly announced) or outstanding long-term indebtedness of the Company or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company, other than in each case above (A) in the ordinary course of business or, (B) as otherwise disclosed in the Registration Statement or Prospectus (including any document incorporated by reference therein).

j. Capitalization. The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and non-assessable and, other than as disclosed in the Registration Statement or the Prospectus, are not subject to any preemptive rights, rights of first refusal or similar rights. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than (i) the grant of additional options or other equity awards under the Company's existing stock option plans, (ii) changes in the number of outstanding shares of Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, Common Stock outstanding on the date hereof, (iii) as a result of the issuance of Placement Shares, or (iv) any repurchases of capital stock of the Company), and such authorized capital stock conforms in all material respects to the description thereof set forth in the Registration Statement and the Prospectus. The description of the Common Stock in the Registration Statement and the Prospectus is complete and accurate in all material respects.

k. S-3 Eligibility. (i) At the time of filing the Registration Statement and (ii) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the Securities Act (whether such amendment was by post-effective amendment, incorporated report filed pursuant to Section 13 or 15(d) of the Exchange Act or form of prospectus), the Company met the then applicable requirements for use of Form S-3 under the Securities Act.

l. Authorization; Enforceability. The Company has full legal right, power and authority to enter into this Agreement and perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification and contribution provisions of Section 11 hereof may be limited by federal or state securities laws and public policy considerations in respect thereof.

m. Authorization of Placement Shares. The Placement Shares, when issued and delivered pursuant to the terms approved by the board of directors of the Company or a duly authorized committee thereof, or a duly authorized executive committee, against payment therefor as provided herein, will be duly and validly authorized and issued and fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim (other than any pledge, lien, encumbrance, security interest or other claim arising from an act or omission of the Agent or a purchaser), including any statutory or contractual preemptive rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Placement Shares, when issued, will conform in all material respects to the description thereof set forth in or incorporated into the Prospectus.

n. No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or any governmental or regulatory authority having jurisdiction over the Company is required for the execution, delivery and performance by the Company of this Agreement, and the issuance and sale by the Company of the Placement Shares as contemplated hereby, except for the registration of the Placement Shares under the Securities Act and pursuant to the Registration Statement which has been completed that, and such consents, approvals, authorizations, orders and registrations or qualifications as may be required under applicable state securities laws or by the by-laws and rules of the Financial Industry Regulatory Authority (“FINRA”) or the Exchange, including any notices that may be required by Exchange, in connection with the sale of the Placement Shares by the Agent.

o. No Preferential Rights. (i) No person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a “Person”), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any Common Stock or shares of any other capital stock or other securities of the Company (other than upon the exercise of options or warrants to purchase Common Stock or upon the exercise of options that may be granted from time to time under the Company’s stock option plans), (ii) no Person has any preemptive rights, rights of first refusal, or any other rights (whether pursuant to a “poison pill” provision or otherwise) to purchase any Common Stock or shares of any other capital stock or other securities of the Company from the Company which have not been duly waived with respect to the offering contemplated hereby, (iii) no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Common Stock, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act any Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated thereby or otherwise, except in each case for such rights as have been waived on or prior to the date hereof.

p. Independent Public Accountant. The Company’s accountants whose report on the consolidated financial statements of the Company is filed with or incorporated into the Commission as part of the Company’s most recent Annual Report on Form 10-K filed with the Commission and incorporated into the Registration Statement, are and, during the periods

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covered by their report, were independent public accountants within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company's knowledge, following due inquiry, the Company's accountants are not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") with respect to the Company.

q. Enforceability of Agreements. All agreements between the Company and third parties expressly referenced in the Prospectus, other than such agreements that have expired by their terms or whose termination is disclosed in documents filed by the Company on EDGAR, are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, against the Company and, to the Company's knowledge, the other parties thereto, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification provisions of certain agreements may be limited by federal or state securities laws or public policy considerations in respect thereof, and except for any unenforceability that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect.

r. No Litigation. There are no legal, governmental or regulatory actions, suits or proceedings pending, nor, to the Company's knowledge, any legal, governmental or regulatory investigations, to which the Company or its Subsidiaries is a party or to which any property of the Company or its Subsidiaries is the subject that, individually or in the aggregate, if determined adversely to the Company or its Subsidiaries, would reasonably be expected to have a Material Adverse Effect or materially and adversely affect the ability of the Company to perform its obligations under this Agreement; to the Company's knowledge, no such actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others that, individually or in the aggregate, if determined adversely to the Company, would reasonably be expected to have a Material Adverse Effect; and (i) there are no current or pending legal, governmental or regulatory actions, suits or proceedings, or, to the Company's knowledge, investigations, that are required under the Securities Act to be described in the Prospectus that are not described in the Prospectus including any Incorporated Document; and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement that are not so filed.

s. Licenses and Permits. The Company and its Subsidiaries possess and have obtained all licenses, certificates, consents, orders, approvals, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in the Registration Statement and the Prospectus (the "Permits"), except where the failure to possess, obtain or make the same would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company and its Subsidiaries have not received written notice of any proceeding relating to revocation or modification of any such Permit or has any reason to believe that such Permit will not be renewed in the ordinary course, except where the failure to obtain any such renewal would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

t. No Material Defaults. The Company and its Subsidiaries have not defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. The Company has not filed a report pursuant to Section 13(a) or 15(d) of the Exchange Act since the filing of its last Annual Report on Form 10-K, indicating that it (i) has failed to pay any dividend or sinking fund installment on preferred stock or (ii) has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

u. Certain Market Activities. Neither the Company, nor any of its directors, officers or controlling persons has taken, directly or indirectly, any action designed, or that has constituted or would reasonably be expected to cause or result in, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

v. Broker/Dealer Relationships. Neither the Company nor its Subsidiaries nor any related entities (i) are required to register as a “broker” or “dealer” in accordance with the provisions of the Exchange Act or (ii) directly or indirectly through one or more intermediaries, controls or is a “person associated with a member” or “associated person of a member” (within the meaning set forth in the FINRA Manual).

w. Reliance. The Company has not relied upon the Agent or legal counsel for the Agent for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

x. Taxes. The Company and its Subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to do so would not reasonably be expected to have a Material Adverse Effect. Except as otherwise disclosed in or contemplated by the Registration Statement or the Prospectus, no tax deficiency has been determined adversely to the Company or its Subsidiaries which has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment which has been asserted or threatened against it which would have a Material Adverse Effect.

y. Title to Real and Personal Property. The Company and its Subsidiaries have good and valid title in fee simple to all items of real property and good and valid title to all personal property described in the Registration Statement or Prospectus as being owned by them that are material to the businesses of the Company and its Subsidiaries, in each case, free and clear of all liens, encumbrances and claims, except those that would reasonably be expected to not, individually or in the aggregate, have a Material Adverse Effect. Any real property described in the Registration Statement or Prospectus as being leased by the Company or its Subsidiaries is held by them under valid, existing and enforceable leases, except those that would not be reasonably be expected, individually or in the aggregate, have a Material Adverse Effect.

z. Intellectual Property. To the Company's knowledge, the Company and its Subsidiaries own or possess adequate enforceable rights to use all patents, patent applications, trademarks (both registered and unregistered), service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) (collectively, the "Intellectual Property"), necessary for the conduct of their respective businesses as conducted as of the date hereof; the Company and its Subsidiaries have not received any written notice of any claim of infringement or conflict which asserted Intellectual Property rights of others, which infringement or conflict, if the subject of an unfavorable decision, would result in a Material Adverse Effect; there are no pending, or to the Company's knowledge, threatened judicial proceedings or interference proceedings against the Company or its Subsidiaries challenging the Company's rights in or to or the validity of the scope of any of the Company's patents, patent applications or proprietary information; to the Company's knowledge, no other entity or individual has any right or claim in any of the Company's or its Subsidiaries' patents, patent applications or any patent to be issued therefrom by virtue of any contract, license or other agreement entered into between such entity or individual and the Company or by any non-contractual obligation, other than by written licenses granted by the Company, except for such right or claim that would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect; the Company and its Subsidiaries have not received any written notice of any claim challenging the rights of the Company in or to any Intellectual Property owned, licensed or optioned by the Company or its Subsidiaries which claim, if the subject of an unfavorable decision would result in a Material Adverse Effect.

aa. Environmental Laws. The Company (i) is in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"); (ii) has received and is in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as described in the Registration Statement and the Prospectus; and (iii) has not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except, in the case of any of clauses (i), (ii) or (iii) above, for any such failure to comply or failure to receive required permits, licenses, other approvals or liability as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

bb. Disclosure Controls. The Company maintains systems of internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company is not aware of any material weaknesses in its internal control over financial reporting (other than as set forth in the Registration Statement or the Prospectus). Since the date of the latest audited financial statements of the Company included in

the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting (other than as set forth in the Registration Statement or the Prospectus). The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company is made known to the certifying officers by others within those entities, particularly during the period in which the Company's Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the most recent Evaluation Date. Since the filing date of the Form 10-K for the fiscal year most recently ended (such date, the "Evaluation Date"), there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly affect the Company's internal controls. To the knowledge of the Company, the Company's "internal controls over financial reporting" and "disclosure controls and procedures" are effective.

cc. Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or, to the knowledge of the Company, any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission during the past 12 months. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Exchange Act Rules 13a-15 and 15d-15.

dd. Finder's Fees. The Company has not incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to the Agent pursuant to this Agreement.

ee. Labor Disputes. No labor disturbance by or dispute with employees of the Company or its Subsidiaries exists or, to the knowledge of the Company, is threatened which would reasonably be expected to result in a Material Adverse Effect.

ff. Investment Company Act. Neither the Company or its Subsidiaries is or, after giving effect to the offering and sale of the Placement Shares, will be, an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "Investment Company Act").

gg. Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance in all material respects with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting



Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company and its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency having jurisdiction over the Company and its Subsidiaries (collectively, the “Money Laundering Laws”), except as would not reasonably be expected to result in a Material Adverse Effect; and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

hh. Off-Balance Sheet Arrangements. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity (each, an “Off Balance Sheet Transaction”) that would reasonably be expected to affect materially the Company’s liquidity or the availability of or requirements for its capital resources, including those Off Balance Sheet Transactions described in the Commission’s Statement about Management’s Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), required to be described in the Registration Statement or the Prospectus which have not been described as required.

ii. Underwriter Agreements. The Company is not a party to any agreement with an agent or underwriter for any other “at the market” or continuous equity transaction.

jj. ERISA. To the knowledge of the Company, each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (“ERISA”), that is maintained, administered or contributed to by the Company or any of its affiliates for employees or former employees of the Company has been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Internal Revenue Code of 1986, as amended (the “Code”); no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred which would result in a material liability to the Company with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no “accumulated funding deficiency” as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions, other than, in the case of (i), (ii) and (iii) above, as would not reasonably be expected to have a Material Adverse Effect.

kk. Forward-Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) (a “Forward-Looking Statement”) contained in the Registration Statement and the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith. The Forward-Looking Statements incorporated by reference in the Registration Statement and the Prospectus from the Company’s Annual Report on Form 10-K for the fiscal year most recently ended (i) except for any Forward-Looking Statement included in any financial

statements and notes thereto, are, to the Company's knowledge, within the coverage of the safe harbor for forward looking statements set forth in Section 27A of the Securities Act, Rule 175(b) under the Securities Act or Rule 3b-6 under the Exchange Act, as applicable, (ii) were made by the Company with a reasonable basis and in good faith and reflect the Company's good faith commercially reasonable best estimate of the matters described therein as of the respective dates on which such statements were made, and (iii) have been prepared in accordance with Item 10 of Regulation S-K under the Securities Act.

ll. Margin Rules. Neither the issuance, sale and delivery of the Placement Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System.

mm. Insurance. The Company and its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company and its Subsidiaries, as applicable, reasonably believes are adequate for the conduct of their business and as is customary for companies of similar size engaged in similar businesses in similar industries.

nn. No Improper Practices. (i) Neither the Company nor to the Company's knowledge, any of their respective executive officers has, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of law) or made any contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any law or of the character required to be disclosed in the Prospectus; (ii) no relationship, direct or indirect, exists between or among the Company or, to the Company's knowledge, or any affiliate of any of the Company, on the one hand, and the directors, officers and stockholders of the Company or, on the other hand, that is required by the Securities Act to be described in the Registration Statement and the Prospectus that is not so described; (iii) no relationship, direct or indirect, exists between or among the Company or any affiliate of them, on the one hand, and the directors, officers, stockholders or directors of the Company or, on the other hand, that is required by the rules of FINRA to be described in the Registration Statement and the Prospectus that is not so described; (iv) there are no material outstanding loans or advances or material guarantees of indebtedness by the Company to or for the benefit of any of its officers or directors or any of the members of the families of any of them; and (v) the Company has not offered, or caused any placement agent to offer, Common Stock to any person with the intent to influence unlawfully (A) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company or (B) a trade journalist or publication to write or publish favorable information about the Company or any of its products or services, and, (vi) neither the Company nor, to the Company's knowledge, any employee or agent of the Company has made any payment of funds of the Company or received or retained any funds in violation of any law, rule or regulation (including, without limitation, the Foreign Corrupt Practices Act of 1977), which payment, receipt or retention of funds is of a character required to be disclosed in the Registration Statement or the Prospectus.

oo. Status Under the Securities Act. The Company was not and is not an ineligible issuer as defined in Rule 405 at the times specified in Rules 164 and 433 under the Securities Act in connection with the offering of the Placement Shares.

pp. No Misstatement or Omission in an Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time (as defined in Section 25 below), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any incorporated document deemed to be a part thereof that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Agent specifically for use therein.

qq. No Conflicts. Neither the execution of this Agreement, nor the issuance, offering or sale of the Placement Shares, nor the consummation of any of the transactions contemplated herein and therein, nor the compliance by the Company with the terms and provisions hereof and thereof will conflict with, or will result in a breach of, any of the terms and provisions of, or has constituted or will constitute a default under, or has resulted in or will result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any contract or other agreement to which the Company is a party to or to which any of the property or assets of the Company is subject, except such conflicts, breaches, defaults, liens, charges or encumbrances as may have been waived; nor will such action result (x) in any violation of the provisions of the organizational or governing documents of the Company, or (y) in any material violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any court or of any federal, state or other regulatory authority or other government body having jurisdiction over the Company, except where such violation would not reasonably be expected to have a Material Adverse Effect.

rr. Compliance with Applicable Laws. The Company and its Subsidiaries: (A) are and at all times have been in material compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company ("Applicable Laws"), except for such non-compliance as would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect, (B) have not received any Form 483 from the Food and Drug Administration of the U.S. Department of Health and Human Services (the "FDA"), notice of adverse finding, warning letter, or other written correspondence or notice from the FDA, the European Medicines Agency (the "EMA"), or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, consents, approvals, clearances, authorizations, permits, orders and supplements or amendments thereto required by any such Applicable Laws ("Authorizations"), which would, individually or in the aggregate, result in a Material Adverse Effect; (C) possess all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (D) have not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA, the EMA, or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any Company product, operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA, the EMA, or any other federal, state, local or foreign governmental or regulatory authority or third party is considering

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any such claim, litigation, arbitration, action, suit, investigation or proceeding against the Company or its Subsidiaries, except as would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect; (E) have not received notice that the FDA, EMA, or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA, EMA, or any other federal, state, local or foreign governmental or regulatory authority is considering such action, except as would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Effect; and (F) have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations except where the failure to file such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments would not result in a Material Adverse Effect, and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission).

ss. Clinical Studies. All animal and other preclinical studies and clinical trials conducted by the Company or on behalf of the Company were, and, if still pending are, to the Company's knowledge, being conducted in all material respects in compliance with all Applicable Laws and in accordance with experimental protocols, procedures and controls generally used by qualified experts in the preclinical study and clinical trials of new drugs and biologics as applied to comparable products to those being developed by the Company, except in each case where failure to comply would not reasonably be expected to have a Material Adverse Effect; the descriptions of the results of such preclinical studies and clinical trials contained in the Registration Statement and the Prospectus are accurate in all material respects, and, except as set forth in the Registration Statement and the Prospectus, the Company has no knowledge of any other clinical trials or preclinical studies, the results of which reasonably call into question the clinical trial or preclinical study results described or referred to in the Registration Statement and the Prospectus when viewed in the context in which such results are described; and the Company has not received any written notices or correspondence from the FDA, the EMA, or any other domestic or foreign governmental agency requiring the termination or suspension of any preclinical studies or clinical trials conducted by or on behalf of the Company that are described in the Registration Statement and the Prospectus or the results of which are referred to in the Registration Statement and the Prospectus.

tt. Compliance Program. The Company and its Subsidiaries have taken such steps as are reasonable and appropriate to comply in all material respects with applicable regulatory guidelines (including, without limitation, those administered by the FDA, the EMA, and any other foreign, federal, state or local governmental or regulatory authority having jurisdiction over the Company and its Subsidiaries and performing functions similar to those performed by the FDA or EMA); except where such noncompliance would not reasonably be expected to have a Material Adverse Effect.

uu. OFAC.

(i) To the Company's knowledge, neither the Company (the "Entity") nor, to the Company's knowledge, any director, officer, employee, agent, affiliate or representative of the Entity, is a government, individual, or entity (in this paragraph (ss), "Person") that is, or is owned or controlled by a Person that is:

(a) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council ("UNSC"), the European Union ("EU"), Her Majesty's Treasury ("HMT"), or other relevant sanctions authority (collectively, "Sanctions"), nor

(b) located, organized or resident in a country or territory that is the subject of Sanctions.

(ii) The Entity represents and covenants that it will not, directly or indirectly, knowingly use the proceeds of the offering, or knowingly lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(a) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(b) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) The Entity represents and covenants that, except as detailed in the Prospectus, for the past five years, it has not knowingly engaged in, is not now knowingly engaged in, and will not knowingly engage in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

vv. Stock Transfer Taxes. On each Settlement Date, all material stock transfer or other taxes (other than income taxes) which are required to be paid by the Company in connection with the sale and transfer of the Placement Shares to be sold hereunder will be, or will have been, fully paid or provided for by the Company and all laws imposing such taxes will be or will have been fully complied with by the Company in all material respects.

Any certificate signed by an officer of the Company and delivered to the Agent or to counsel for the Agent pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to the Agent as to the matters set forth therein.

7. Covenants of the Company. The Company covenants and agrees with the Agent that:

a. Registration Statement Amendments. After the date of this Agreement and during any period in which a prospectus relating to any Placement Shares is required to be delivered by the Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act) (the "Prospectus Delivery Period"), (i) the Company will notify the Agent promptly of the time when any

subsequent amendment to the Registration Statement, other than documents incorporated by reference or amendments not related to any Placement, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus related to the Placement or for additional information related to the Placement, (ii) the Company will prepare and file with the Commission, promptly upon the Agent's request, any amendments or supplements to the Registration Statement or Prospectus that, in the Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agent (*provided, however*, that the failure of the Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and provided, further, that the only remedy the Agent shall have with respect to the failure to make such filing shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus relating to the Placement Shares or a security convertible into the Placement Shares (other than an Incorporated Document) unless a copy thereof has been submitted to the Agent within a reasonable period of time before the filing and the Agent has not reasonably objected thereto within two (2) Business Days (as defined below) (*provided, however*, that (A) the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and (B) the Company has no obligation to provide the Agent any advance copy of such filing or to provide the Agent an opportunity to object to such filing if the filing does not name the Agent or is not related to the transaction herein provided; and provided, further, that the only remedy the Agent shall have with respect to the failure by the Company to obtain such consent shall be to cease making sales under this Agreement), and the Company will furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iii) the Company will cause each amendment or supplement to the Prospectus to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

b. Notice of Commission Stop Orders. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its reasonable best efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise the Agent promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus.

c. Delivery of Prospectus; Subsequent Changes. During the Prospectus Delivery Period, the Company will use its commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430A under the Securities Act, it will use its commercially reasonable efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430A and to notify the Agent promptly of all such filings. If during the Prospectus Delivery Period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such Prospectus Delivery Period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify the Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; *provided, however*, that the Company may delay the filing of any amendment or supplement, if in the judgment of the Company, it is in the best interest of the Company.

d. Listing of Placement Shares. During the Prospectus Delivery Period, the Company will use its reasonable best efforts to cause the Placement Shares to be listed on the Exchange and to qualify the Placement Shares for sale under the securities laws of such jurisdictions in the United States as the Agent reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

e. Delivery of Registration Statement and Prospectus. The Company will furnish to the Agent and its counsel (at the reasonable expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during the Prospectus Delivery Period (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as the Agent may from time to time reasonably request and, at the Agent's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to furnish any document to the Agent to the extent such document is available on EDGAR.

f. Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

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g. Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled “Use of Proceeds.”

h. Notice of Other Sales. Without the prior written consent of the Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the date on which any Placement Notice is delivered to the Agent hereunder and ending on the third (3rd) Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and will not directly or indirectly in any other “at the market” or continuous equity transaction offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the termination of this Agreement; *provided, however*, that such restrictions will not be required in connection with the Company’s issuance or sale of (i) Common Stock, options to purchase Common Stock or Common Stock issuable upon the exercise of options, pursuant to any employee or director stock option or benefits plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented; (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to the Agent; (iii) Common Stock, or securities convertible into or exercisable for Common Stock, offered and sold in a privately negotiated transaction to vendors, customers, strategic partners or potential strategic partners or other investors conducted in a manner so as not to be integrated with the offering of Common Stock hereby; and (iv) Common Stock in connection with any acquisition, strategic investment or other similar transaction (including any joint venture, strategic alliance or partnership).

i. Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice, advise the Agent promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document required to be provided to the Agent pursuant to this Agreement.

j. Due Diligence Cooperation. During the term of this Agreement, the Company will cooperate with any reasonable due diligence review conducted by the Agent or their representatives in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company’s principal offices, as the Agent may reasonably request.



k. Required Filings Relating to Placement of Placement Shares. To the extent that the filing of a prospectus supplement with the Commission with respect to a placement of Placement Shares becomes required under Rule 424(b) under the Securities Act, the Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a “Filing Date”), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through the Agent, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

l. Representation Dates: Certificate. Each time during the term of this Agreement that the Company:

(i) amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed Form 10-K);

(iii) files its quarterly reports on Form 10-Q under the Exchange Act; or

(iv) files a current report on Form 8-K containing amended financial information (other than information “furnished” pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act;

(Each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a “Representation Date.”):

the Company shall furnish the Agent (but in the case of clause (iv) above only if the Agent reasonably determines that the information contained in such Form 8-K is material) with a certificate, in the form attached hereto as Exhibit 7(l). The requirement to provide a certificate under this Section 7(l) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date on which the Company files its annual report on Form 10-K. Notwithstanding the foregoing, (i) upon the delivery of the first Placement Notice hereunder and (ii) if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver

and did not provide the Agent with a certificate under this Section 7(l), then before the Agent sells any Placement Shares, the Company shall provide the Agent with a certificate, in the form attached hereto as Exhibit 7(l), dated the date of the Placement Notice.

m. Legal Opinion.

(i) Company Counsel. On or prior to the date of the first Placement Notice given hereunder, the Company shall cause to be furnished to the Agent the written opinion and a negative assurance letter of Wilson, Sonsini, Goodrich & Rosati LLP ("Company Counsel"), or other counsel reasonably satisfactory to the Agent, in form and substance reasonably satisfactory to the Agent. Thereafter, within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in substantially the form attached hereto as Exhibit 7(l) for which no waiver is applicable, and not more than once per calendar quarter, the Company shall cause to be furnished to the Agent the written opinion and a negative assurance letter of Company Counsel in form and substance previously agreed, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided that*, in lieu of such opinion and negative assurance for subsequent periodic filings under the Exchange Act, Company Counsel may furnish the Agent with a letter (a "Reliance Letter") to the effect that the Agent may rely on the opinion and negative assurance letter previously delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

(ii) Intellectual Property Counsel. On or prior to the date of the first Placement Notice given hereunder, the Company shall cause to be furnished to the Agent the written opinion and a negative assurance letter of Wilson, Sonsini, Goodrich & Rosati LLP (collectively, "Intellectual Property Counsel"), or other counsel reasonably satisfactory to the Agent, in form and substance reasonably satisfactory to the Agent. Thereafter, within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in substantially the form attached hereto as Exhibit 7(l) for which no waiver is applicable, and not more than once per calendar quarter, the Company shall cause to be furnished to the Agent the written opinion and negative assurance letter of Intellectual Property Counsel in form and substance previously agreed, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided that*, in lieu of such opinion and negative assurance for subsequent periodic filings under the Exchange Act, Intellectual Property Counsel may furnish the Agent with a Reliance Letter to the effect that the Agent may rely on the opinion and negative assurance letter previously delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior letter shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

n. Comfort Letter. On or prior to the date of the first Placement Notice given hereunder and within five (5) Trading Days after each subsequent Representation Date, other than pursuant to Section 7(l)(iii), the Company shall cause its independent accountants to furnish the Agent letters (the "Comfort Letters"), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(n); provided, that if requested by the

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Agent, the Company shall cause a Comfort Letter to be furnished to the Agent within five (5) Trading Days of such request following the date of occurrence of any restatement of the Company's financial statements. The Comfort Letter from the Company's independent accountants shall be in a form and substance reasonably satisfactory to the Agent, (i) confirming that they are an independent public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings (the first such letter, the "Initial Comfort Letter") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

o. Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or would reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase Common Stock in violation of Regulation M, or pay anyone any compensation for soliciting purchases of the Placement Shares other than the Agent.

p. Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that it will not be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act.

q. No Offer to Sell. Other than an Issuer Free Writing Prospectus approved in advance by the Company and the Agent in their capacity as agent hereunder pursuant to Section 23, neither of the Agent nor the Company (including its agents and representatives, other than the Agent in their capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

r. Sarbanes-Oxley Act. The Company will maintain and keep accurate books and records reflecting its assets and maintain internal accounting controls in a manner designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company's consolidated financial statements in accordance with GAAP, (iii) that receipts and expenditures of the Company are being made only in accordance with management's and the Company's directors' authorization, and (iv) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements. The Company will use commercially reasonable efforts to maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that

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information required to be disclosed by the 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 Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the 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 officer and principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared.

8. Representations and Covenants of the Agent. The Agent represents and warrants that it is duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which the Agent is exempt from registration or such registration is not otherwise required. The Agent shall continue, for the term of this Agreement, to be duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which it is exempt from registration or such registration is not otherwise required, during the term of this Agreement. The Agent shall comply with all applicable law and regulations, including but not limited to Regulation M, in connection with the transactions contemplated by this Agreement, including the issuance and sale through the Agent of the Placement Shares.

9. Payment of Expenses. The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, filing, including any fees required by the Commission, and printing of the Registration Statement (including financial statements and exhibits) as originally filed and of each amendment and supplement thereto and each Free Writing Prospectus, in such number as the Agent shall deem reasonably necessary, (ii) the printing and delivery to the Agent of this Agreement and such other documents as may be reasonably required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to the Agent, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to the Agent, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the fees and disbursements of counsel to the Agent up to \$40,000 payable upon execution of this Agreement and up to \$4,000 for each calendar quarter for expenses associated with ongoing due diligence; (vi) the fees and expenses of the transfer agent and registrar for the Common Stock, (vii) the filing fees incident to any review by FINRA of the terms of the sale of the Placement Shares, and (viii) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

10. Conditions to the Agent's Obligations. The obligations of the Agent hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein (other than those representations and warranties made as of a specific date or time), to the due performance in all material respects by the Company of its obligations hereunder, to the completion by the Agent of a due diligence

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review satisfactory to it in its reasonable judgment, and to the continuing reasonable satisfaction (or waiver the Agent in its sole discretion) of the following additional conditions:

a. Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the sale of all Placement Shares contemplated to be issued by any Placement Notice.

b. No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus which have not, as of the time of such Placement, been so made; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, which changes shall not as of the time of such Placement have been so made.

c. No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

d. Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any Material Adverse Effect, or any development that would reasonably be expected to cause a Material Adverse Effect, or a downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of the Agent (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus..

e. Legal Opinions. The Agent shall have received the opinions and negative assurances of Company Counsel and Intellectual Property Counsel required to be delivered pursuant Section 7(m) on or before the date on which such delivery of such opinions are required pursuant to Section 7(m).

f. Comfort Letter. The Agent shall have received the Comfort Letter required to be delivered pursuant Section 7(n) on or before the date on which such delivery of such letter is required pursuant to Section 7(n).

g. Representation Certificate. The Agent shall have received the certificate required to be delivered pursuant to Section 7(l) on or before the date on which delivery of such certificate is required pursuant to Section 7(l).

h. Secretary's Certificate. On or prior to the first Representation Date, the Agent shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to the Agent and its counsel.

i. No Suspension. Trading in the Common Stock shall not have been suspended on the Exchange and the Common Stock shall not have been delisted from the Exchange.

j. Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to the Agent such appropriate further information, certificates and documents as the Agent may reasonably request and which are usually and customarily furnished by an issuer of securities in connection with a securities offering of the type contemplated hereby.

k. Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

l. Approval for Listing. The Placement Shares shall either have been approved for listing on the Exchange, subject only to notice of issuance, or the Company shall have filed an application for listing of the Placement Shares on the Exchange at, or prior to, the issuance of any Placement Notice.

m. No Termination Event; Insurance. There shall not have occurred any event that would permit the Agent to terminate this Agreement pursuant to Section 13(a). The Company and its Subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business in which it is engaged.

n. FINRA. The Agent shall have received a letter from the Corporate Financing Department of FINRA confirming that such department has determined to raise no objection with respect to the fairness or reasonableness of the terms and arrangements related to the sale of the Placement Shares pursuant to this Agreement.

o. Termination of Equity Distribution Agreement. The Company shall have irrevocably terminated the Equity Distribution Agreement entered into by and between the Company and Citigroup Global Markets Inc. on November 21, 2018.

11. Indemnification and Contribution.

a. Company Indemnification. The Company agrees to indemnify and hold harmless the Agent, its partners, members, managers, directors, officers, employees and agents and each person, if any, who controls the Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or arising out of any untrue statement or alleged untrue statement of a material fact included in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 11(d) below) any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expense whatsoever, as incurred (including the reasonable and documented out-of-pocket fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above,

*provided, however*, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto) or in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto) solely in reliance upon and in conformity with the Agent's Information.

b. Indemnification by the Agent. The Agent agrees to indemnify and hold harmless the Company and its directors and each officer of the Company who signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability,

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claim, damage and expense described in the indemnity contained in Section 11(a), as incurred, but only with respect to untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.

c. Procedure. Any party that proposes to assert the right to be indemnified under this Section 11 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 11, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 11 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 11 unless, and only to the extent that, such omission results in the forfeiture or material impairment of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. Each indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict of interest exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable and documented out-of-pocket fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable and documented out-of-pocket fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for an indemnified party. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment



in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 11 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

d. Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 11 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or the Agent, the Company and the Agent will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Agent, such as persons who control the Company within the meaning of the Securities Act or the Exchange Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Agent may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other hand. The relative benefits received by the Company on the one hand and the Agent on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by the Agent (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this Section 11(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 11(d) shall be deemed to include, for the purpose of this Section 11(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 11(c) hereof. Notwithstanding the foregoing provisions of this Section 11(d), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 11(d), any person who controls a party to this Agreement within the

meaning of the Securities Act or the Exchange Act, and any officers, directors, partners, employees or agents of the Agent, will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 11(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 11(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 11(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 11(c) hereof.

12. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 11 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of the Agent, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

13. Termination.

a. The Agent may terminate this Agreement, by written notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any Material Adverse Effect, or any development that is reasonably likely to have a Material Adverse Effect or, in the reasonable judgment of the Agent, is material and adverse and makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the reasonable judgment of the Agent, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or (6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time);

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Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If the Agent elects to terminate this Agreement as provided in this Section 13(a), the Agent shall provide the required notice as specified in Section 14 (Notices).

b. The Company shall have the right, by giving written notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination.

c. The Agent shall have the right, by giving written notice as hereinafter specified, to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination.

d. Unless earlier terminated pursuant to this Section 13, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through the Agent on the terms and subject to the conditions set forth herein except that the provisions of Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination.

e. This Agreement shall remain in full force and effect unless terminated pursuant to Sections 13(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 9 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) shall remain in full force and effect. Upon termination of this Agreement, the Company shall not have any liability to the Agent for any discount, commission or other compensation with respect to any Placement Shares not otherwise sold by the Agent under this Agreement.

f. Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

14. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified, and if sent to the Agent, shall be delivered to:

Ladenburg Thalmann & Co. Inc.  
277 Park Avenue, 26th Floor  
New York, NY 10172  
Attention: Joseph Giovanniello, Counsel  
Tel: (212) 409-2544  
Email: jgiovanniello@ladenburg.com

with a copy to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.  
666 Third Avenue  
New York, NY 10017  
Attention: Ivan K. Blumenthal, Esq.  
Telephone: (212) 692-6784  
Email: ikblumenthal@mintz.com

and if to the Company, shall be delivered to:

1124 West Carson Street  
MRL Building 3-320  
Torrance, CA  
Attention: Paul A. Wagner, Ph.D., President and Chief Executive Officer  
Telephone: (310) 618-6994  
Email: pwagner@fortebiorx.com

with a copy to:

Wilson, Sonsini, Goodrich & Rosati LLP  
12235 El Camino Real  
San Diego, CA 92130  
Attention: Dan Koeppen, Esq.  
Telephone: (858) 350-2300  
Email: dkoeppen@wsgr.com

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally, by email, or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "Business Day" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

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An electronic communication ("Electronic Notice") shall be deemed written notice for purposes of this Section 14 if sent to the electronic mail address specified by the receiving party under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives confirmation of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form ("Nonelectronic Notice") which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

15. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Agent and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 11 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party.

16. Adjustments for Stock Splits. The parties acknowledge and agree that all share- related numbers contained in this Agreement shall be adjusted to take into account any share consolidation, stock split, stock dividend, corporate domestication or similar event effected with respect to the Placement Shares.

17. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agent. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

18. GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. EACH PARTY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

19. CONSENT TO JURISDICTION. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE NON-EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.

20. Use of Information. The Agent may not use any information gained in connection with this Agreement and the transactions contemplated by this Agreement, including due diligence, to advise any party with respect to transactions not expressly approved by the Company.

21. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile transmission.

22. Effect of Headings. The section and Exhibit headings herein are for convenience only and shall not affect the construction hereof.

23. Permitted Free Writing Prospectuses.

The Company represents, warrants and agrees that, unless it obtains the prior consent of the Agent, which shall not be unreasonably withheld, conditioned or delayed, and the Agent represents, warrants and agrees that, unless it obtains the prior consent of the Company, which shall not be unreasonably withheld, conditioned or delayed, it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by the Agent or by the Company, as the case may be, is hereinafter referred to as a “Permitted Free Writing Prospectus.” The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus,” as

defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 23 hereto are Permitted Free Writing Prospectuses.

24. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

a. The Agent is acting solely as agent in connection with the public offering of the Placement Shares and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and the Agent, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not the Agent has advised or is advising the Company on other matters, and the Agent has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

b. it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

c. No Agent has provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

d. it is aware that the Agent and its respective affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and the Agent has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

e. it waives, to the fullest extent permitted by law, any claims it may have against the Agent for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that the Agent shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, employees or creditors of Company, other than in respect of the Agent's obligations under this Agreement and to keep information provided by the Company to the Agent and its counsel confidential to the extent not otherwise publicly-available.

25. Definitions.

As used in this Agreement, the following terms have the respective meanings set forth below:

“Agent's Information” means such information provided by the Agent for inclusion in the Prospectus; provided, however, that the parties hereto acknowledge that no such information was provided by or on behalf of the Agent as of the date of this Agreement.

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“Applicable Time” means (i) each Representation Date and (ii) the time of each sale of any Placement Shares pursuant to this Agreement.

“Issuer Free Writing Prospectus” means any “issuer free writing prospectus,” as defined in Rule 433, relating to the Placement Shares that (1) is required to be filed with the Commission by the Company, (2) is a “road show” that is a “written communication” within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (3) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g) under the Securities Act.

“Rule 172,” “Rule 405,” “Rule 415,” “Rule 424,” “Rule 424(b),” “Rule 430B,” and “Rule 433” refer to such rules under the Securities Act.

All references in this Agreement to financial statements and schedules and other information that is “contained,” “included” or “stated” in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to “supplements” to the Prospectus shall include, without limitation, any supplements, “wrappers” or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by the Agent outside of the United States.

[Remainder of the page intentionally left blank]



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If the foregoing correctly sets forth the understanding between the Company and the Agent, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and the Agent.

Very truly yours,

**FORTE BIOSCIENCES, INC.**

By:           /s/ Paul Wagner          

Name: Paul Wagner, Ph.D.

Title: Chief Executive Officer

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**ACCEPTED as of the date first-above written:**

**LADENBURG THALMANN & CO. INC.**

By: /s/ David J. Strupp

Name: David J. Strupp Jr.

Title: Managing Director

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SCHEDULE 1

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FORM OF PLACEMENT NOTICE

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From: Forte Biosciences, Inc.  
To: [●]  
Attention: [●]  
Subject: At Market Issuance—Placement Notice  
Date: \_\_\_\_\_, 20\_\_

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the At Market Issuance Sales Agreement between Forte Biosciences, Inc., a Delaware corporation (the "Company"), Ladenburg Thalmann & Co. Inc. (the "Agent") dated September 4, 2020, the Company hereby requests that the Agent sell up to [ ] shares of the Company's Common Stock, \$0.001 par value per share, at a minimum market price of \$[ ] per share, during the time period beginning [month, day, time] and ending [month, day, time].

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**SCHEDULE 2**

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**Notice Parties**

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The Company

Paul Wagner

Tony Riley

The Agent

David Rosenberg – [dr@ladenburg.com](mailto:dr@ladenburg.com)

David Strupp – [dstrupp@ladenburg.com](mailto:dstrupp@ladenburg.com)

Vlad Ivanov – [vivanov@ladenburg.com](mailto:vivanov@ladenburg.com)

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**SCHEDULE 3**

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**Compensation**

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The Company shall pay to the Agent in cash, upon each sale of Placement Shares pursuant to this Agreement, an amount equal to up to 3.0% of the gross proceeds from each sale of Placement Shares.

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**SCHEDULE 4**

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**Subsidiaries**

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Forte Subsidiary, Inc.

**EXHIBIT 7(I)**

**Form of Representation Date Certificate**

\_\_\_\_\_, 20\_\_

This Representation Date Certificate (this "Certificate") is executed and delivered in connection with Section 7(l) of the At Market Issuance Sales Agreement (the "Agreement"), dated September 4, 2020 and entered into between Forte Biosciences, Inc. (the "Company"), Ladenburg Thalmann & Co. Inc. (the "Agent"). All capitalized terms used but not defined herein shall have the meanings given to such terms in the Agreement.

The Company hereby certifies as follows:

1. As of the date of this Certificate (i) the Registration Statement does not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading and (ii) neither the Registration Statement nor the Prospectus contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading and (iii) no event has occurred as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein not untrue or misleading for this paragraph 1 to be true.
2. Each of the representations and warranties of the Company contained in the Agreement were, when originally made, and are, as of the date of this Certificate, true and correct in all material respects.
3. Each of the covenants required to be performed by the Company in the Agreement on or prior to the date of the Agreement, this Representation Date, and each such other date prior to the date hereof as set forth in the Agreement, has been duly, timely and fully performed in all material respects and each condition required to be complied with by the Company on or prior to the date of the Agreement, this Representation Date, and each such other date prior to the date hereof as set forth in the Agreement has been duly, timely and fully complied with in all material respects.
4. Subsequent to the date of the most recent financial statements in the Prospectus, and except as described in the Prospectus, including Incorporated Documents, there has been no Material Adverse Effect.
5. No stop order suspending the effectiveness of the Registration Statement or of any part thereof has been issued, and to the Company's knowledge, no proceedings for that purpose have been instituted or are pending or threatened by any securities or other governmental authority (including, without limitation, the Commission).

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6. No order suspending the qualification or registration of the Placement Shares under the securities or Blue Sky laws of any jurisdiction are in effect and no proceeding for such purpose is pending before, or threatened, to the Company's knowledge or in writing by, any securities or other governmental authority (including, without limitation, the Commission).

The undersigned has executed this Representation Date Certificate as of the date first written above.

**FORTE BIOSCIENCES, INC.**

By: \_\_\_\_\_

Name:

Title:



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**EXHIBIT 23**

**Permitted Issuer Free Writing Prospectuses**

None.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the Registration Statement on Form S-3 (File No. 333-224880) and related Prospectus of Forte Biosciences, Inc., of our report dated March 24, 2020, relating to the financial statements of Forte Subsidiary, Inc. (formerly known as Forte Biosciences, Inc.) as of December 31, 2019 and 2018 and for the two years then ended appearing in the Form 8-K dated September 4, 2020 and in the Registration Statement on Form S-4, as amended (File No. 333-237371), and to the reference to us under the heading “Experts” in the Prospectus Supplement dated September 4, 2020 related to the Registration Statement on Form S-3 (File No. 333-224880).

/s/ Mayer Hoffman McCann P.C.

San Diego, California  
September 4, 2020

**FORTE BIOSCIENCES, INC.**

**Audited Financial Statements**

**For the years ended December 31, 2019 and December 31, 2018**

**FORTE BIOSCIENCES, INC.  
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FBRX-1

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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 balance sheets of **Forte Biosciences, Inc.** (the “Company”) as of December 31, 2019 and 2018, and the related statements of operations, convertible preferred stock and stockholders’ deficit, and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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 these 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 and in accordance with auditing standards generally accepted in the United States of America. 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 24, 2020

**FORTE BIOSCIENCES, INC.**  
**BALANCE SHEETS**

	<u>December 31,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
<b>Assets</b>		
Current assets:		
Cash	\$ 6,938,778	\$ 5,015,634
Prepaid expenses and other current assets	567,422	56,045
<b>Total current assets</b>	<u>7,506,200</u>	<u>5,071,679</u>
Property and equipment, net	150,601	—
<b>Total assets</b>	<u>\$ 7,656,801</u>	<u>\$ 5,071,679</u>
<b>Liabilities, convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,568,734	\$ 78,379
Accrued liabilities	343,216	71,251
<b>Total current liabilities</b>	<u>1,911,950</u>	<u>149,630</u>
Commitments and contingencies (Note 4)		
Series A Convertible Preferred Stock, \$0.0001 par value; 15,072,819 shares authorized as of December 31, 2019 and 2018; 15,072,814 and 8,247,354 shares issued and outstanding as of December 31, 2019 and 2018, respectively; aggregate liquidation preference of \$10,820,773 and \$5,920,775 as of December 31, 2019 and 2018, respectively	10,514,638	5,658,977
<b>Stockholders' deficit:</b>		
Common stock, \$0.0001 par value: 28,858,687 shares authorized as of December 31, 2019 and 2018; 10,000,000 shares issued and outstanding at December 31, 2019 and 2018	1,000	1,000
Additional paid-in capital	199,710	164,000
Accumulated deficit	(4,970,497)	(901,928)
<b>Stockholders' deficit:</b>	<u>(4,769,787)</u>	<u>(736,928)</u>
<b>Total liabilities, convertible preferred stock and stockholders' deficit</b>	<u>\$ 7,656,801</u>	<u>\$ 5,071,679</u>

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

**FORTE BIOSCIENCES, INC.**  
**STATEMENTS OF OPERATIONS**

	<u>Year Ended</u> <u>December 31, 2019</u>	<u>Year Ended</u> <u>December 31, 2018</u>
Operating expenses:		
Research and development	\$ 2,683,930	\$ 422,602
General and administrative	1,380,306	265,680
Total operating expenses	<u>4,064,236</u>	<u>688,282</u>
Loss from operations	(4,064,236)	(688,282)
Other income (expense):		
Interest income (expense)	2,520	(173,380)
Other expenses	(6,853)	—
Net loss	<u>\$ (4,068,569)</u>	<u>\$ (861,662)</u>
Per share information:		
Net loss per share — basic and diluted	\$ (0.41)	\$ (0.10)
Weighted average shares outstanding, basic and diluted	10,000,000	8,958,904

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

**FORTE BIOSCIENCES, INC.**  
**STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
<b>Balance — December 31, 2017</b>	—	\$ —	—	\$ —	\$ —	\$ (40,266)	\$ (40,266)
Issuance of common stock to founder	—	—	10,000,000	1,000	—	—	1,000
Issuance of Series A convertible preferred stock, conversion of notes payable	1,143,303	656,623	—	—	—	—	—
Issuance of Series A convertible preferred stock, net of issuance cost of \$ 97,645	7,104,051	5,002,354	—	—	—	—	—
Beneficial conversion feature on conversion of notes payable	—	—	—	—	164,000	—	164,000
Net loss	—	—	—	—	—	(861,662)	(861,662)
<b>Balance — December 31, 2018</b>	8,247,354	5,658,977	10,000,000	1,000	164,000	(901,928)	(736,928)
Issuance of Series A convertible preferred stock, net of issuance cost of \$ 44,337	6,825,460	4,855,661	—	—	—	—	—
Stock based compensation	—	—	—	—	35,710	—	35,710
Net loss	—	—	—	—	—	(4,068,569)	(4,068,569)
<b>Balance — December 31, 2019</b>	15,072,814	\$ 10,514,638	10,000,000	\$ 1,000	\$ 199,710	\$ (4,970,497)	\$ (4,769,787)

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

**FORTE BIOSCIENCES, INC.**

**STATEMENTS OF CASH FLOWS**

	<u>Year Ended</u> <u>December 31, 2019</u>	<u>Year Ended</u> <u>December 31, 2018</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (4,068,569)	\$ (861,662)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	10,996	—
Stock based compensation expense	35,710	—
Beneficial conversion feature on conversion of notes payable	—	164,000
Accrued interest converted to Series A preferred	—	6,623
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,873	(56,045)
Accounts payable	976,105	57,709
Accrued liabilities	271,965	71,251
Net cash used in operating activities	<u>(2,770,920)</u>	<u>(618,124)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(161,597)	—
Net cash used in investing activities	<u>(161,597)</u>	<u>—</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of notes payable	—	630,104
Proceeds from issuance of convertible preferred stock, net of issuance costs	4,855,661	5,002,354
Proceeds from issuance of common stock	—	1,000
Net cash provided by financing activities	<u>4,855,661</u>	<u>5,633,458</u>
Net increase in cash	1,923,144	5,015,334
Cash — beginning of period	5,015,634	300
Cash — end of period	<u>\$ 6,938,778</u>	<u>\$ 5,015,634</u>
<b>Non-cash investing and financing activities:</b>		
Issuance of preferred stock for conversion of notes payable and accrued interest	<u>\$ —</u>	<u>\$ 656,623</u>
Conversion of accounts payable into note payable	<u>\$ —</u>	<u>\$ 19,896</u>

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



NOTES TO FINANCIAL STATEMENTS

**1. Organization and Description of Business**

Forte Biosciences, Inc., or the “Company” is a Delaware Corporation, incorporated under the laws of the State of Delaware on May 3, 2017. The Company’s principal executive office is located in Torrance, California. The Company is developing a new topical therapeutic treatment for the treatment of atopic dermatitis.

***Liquidity and Capital Resources***

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern. Since inception, the Company has incurred losses and negative cash flows from operations. For the year ended December 31, 2019, the Company incurred a net loss of \$4,068,569, and used \$2,770,920 of cash for operating activities in the year ended December 31, 2019. As of December 31, 2019, the Company had cash on hand of \$6,938,778.

Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company’s research and development activities. However, the Company believes that its existing cash on hand as of December 31, 2019, will provide sufficient funds to enable it to meet its obligations for twelve months from the issuance of these financial statements. Future operations beyond 2020 will be reliant on additional equity or financing arrangements. There can be no assurances that, in the event that the Company requires additional financing, such financing will be available on terms which are favorable to the Company, or at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it will be forced to delay or reduce the scope of its research programs and/or limit or cease its operations.

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

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The Company prepares its financial statements in accordance with U.S. generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standards Codification and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (“FASB”).

***Use of Estimates***

The preparation of the Company’s financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in the Company’s financial statements and accompanying notes. Significant management estimates that affect the reported amounts of assets and liabilities include useful lives of property and equipment, stock-based compensation 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's chief executive officer is the chief operating decision maker (CODM). The CODM reviews financial information presented on a basis. Resource allocation decisions are made by the CODM based on results. There are no segment managers who are held accountable by the CODM for operations, operating results, and planning for levels or components below the unit level. As such, the Company has concluded that there is one operating and reportable segment.

### ***Cash***

Cash includes deposits with commercial banks.

### ***Property and Equipment***

Property and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. 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 lives for property and equipment are as follows:

	<u>Estimated Useful Lives</u>
Manufacturing equipment	3 years

### ***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 comparison of 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, 2019.

### ***Research and Development Costs***

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and benefits, contract services, and other outside costs. The value of goods and services received from contract research organizations and contract manufacturing organizations in the reporting period are estimated based on the level of services performed, and progress in the period in cases when the Company has not received an invoice from the supplier.

### ***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.

### ***Income (Loss) Per Share***

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated

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using the treasury stock method. Potential common shares comprise of the Company's outstanding but unexercised options.

The number of stock options excluded from the diluted loss per share calculation for the year ended December 31, 2019 and 2018 presented because their effect would be anti-dilutive was 2,450,000 and 2,450,000, respectively.

### ***Stock-Based Compensation***

The Company issues stock-based awards to employees and non-employees, generally in the form of stock options. The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* (ASC 718). As of January 1, 2019, the Company adopted the guidance in Accounting Standards Update (“ASU”) 2018-07, “Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting”. Subsequent to adoption of ASU 2018-07, non-employee awards are no longer required to be remeasured at each financial period; instead they are measured on the grant date and fair value of the awards are recognized on a straight-line basis over the requisite service period. The adoption of ASU 2018-07 did not have a material impact on the Company's financial statements. Prior to adoption of ASU 2018-07, the fair value of the non-employees' awards were subject to re-measurement at each reporting date until the vesting date in accordance with ASC 505-50, *Equity-Based Payments to Non-Employees*.

The Company measures compensation cost for all equity awards for 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, which requires management to make assumptions with respect to the fair value of the Company's common stock on the grant date, including the expected term of the award, the expected volatility of the Company's common stock, calculated based on a period of time generally commensurate with the expected term of the award, risk-free interest rates and expected dividend yields of the Company's common stock. The fair value of the shares of common stock underlying the Company's stock-based awards was determined on the grant date by the Company's Board of Directors based on a valuation estimate from management considering most recently available independent third-party valuation of the Company's common stock. The Company's Board of Directors also assessed and considered, with input from management, additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the grant date. Stock-based compensation expense for an award with a performance condition is recognized when the achievement of such performance condition is determined to be probable. If the outcome of such performance condition is not determined to be probable or is not 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 or in which the award recipient's service payments are classified.

### ***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 is classified as temporary equity and excluded from stockholders' equity as the potential redemption, in the event of a deemed liquidation event, is outside the Company's control.

### ***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.

### ***Comprehensive Loss***

Comprehensive loss includes net loss and other comprehensive income (loss) for the period. The Company did not have other comprehensive income (loss) items such as unrealized gains and losses. For the years ended December 31, 2019 and 2018, the comprehensive loss was equal to the net loss.

### ***Recently Adopted Accounting Standards***

In February 2016, the FASB issued ASU No. 2016-02, *Leases (“ASC 842”)*, which supersedes all existing lease guidance. This guidance offers specific accounting guidance for a lessee, a lessor and sale and leaseback transactions. The new standard requires lessees to recognize an operating lease with a term greater than one year on their balance sheets as a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments. Lessees are required to classify leases as either finance or operating leases. If the lease is effectively a financed-purchase by the lessee, it is classified as a financing lease, otherwise it is classified as an operating lease. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. ASC 842 provides accounting guidance for transactions that meet specific criteria for a leaseback transaction. If the criteria are not met, the transaction is considered a “failed sale” and the transaction must be accounted for as a financing arrangement. The new standard was effective for the Company as of January 1, 2019. Upon adoption, lessees must apply a modified retrospective transition approach for leases existing at, or entered after, the beginning of the earliest comparative period presented in the financial statements. Adoption of this new guidance did not have an impact on the Company’s financial position and results of operations.

In June 2018, the FASB issued ASU 2018-07, *“Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting”*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. The guidance is effective for the Company for fiscal years beginning after December 15, 2018. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606. The Company early adopted the guidance as of January 1, 2019, which did not have a material impact on the Company’s financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows Topic 230: Restricted Cash*, which requires the statement of cash flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. When cash, cash

equivalents, restricted cash and restricted cash equivalents are presented in more than one-line item on the balance sheet, the new guidance requires a reconciliation of the totals in the statement of cash flows to the related captions in the balance sheet. This reconciliation can be presented either on the face of the statement of cash flows or in the notes to the financial statements. The new standard was effective for the Company on January 1, 2019. The adoption of this standard did not have an impact on the Company's statement of cash flow presentation and disclosure.

### ***Recently Issued Accounting Standards***

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the 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 its financial position or results of operations.

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. This update is effective for the Company as of January 1, 2020. The Company believes the adoption will modify the way the Company analyzes financial instruments, but it does not anticipate a material impact on its financial position or results of operations.

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

In December 2019, the FASB issued ASU 2019-12, *Income Taxes ("ASC 740")*, which simplifies the accounting for income taxes by eliminating certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for calendar-year public business entities in 2021 and interim periods within that year. For all other calendar-year entities, it is effective for annual periods beginning in 2022 and interim periods in 2023. Early adoption is permitted. The Company does not expect adoption of this new guidance will have a material impact on its financial position or results of operations.

### **3. Balance Sheet Components**

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

Prepaid expenses and other current assets, as of December 31, 2019 and 2018 consist of the following:

	<b>As of December 31, 2019</b>	<b>As of December 31, 2018</b>
Prepaid manufacturing expenses	\$ 514,250	\$ —
Other	53,172	56,045
<b>Total Prepaid Expenses</b>	<b>\$ 567,422</b>	<b>\$ 56,045</b>

#### ***Prepaid Manufacturing Expenses***

Prepaid manufacturing expenses include raw materials, slot reservation fees and other amounts paid to contract manufacturing organizations.

## Accrued Liabilities

Accrued liabilities, as of December 31, 2019 and 2018 consists of the following:

	As of December 31, 2019	As of December 31, 2018
Legal and professional fees	\$ 140,688	\$ 43,414
Compensation	175,000	—
Professional fees	27,528	27,837
Total Accrued Liabilities	\$ 343,216	\$ 71,251

## 4. Commitments and Contingencies

### Concentrations of Credit Risk

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

### Indemnifications

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

### License to Patented Technology

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

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

No milestones have been achieved as of December 31, 2019. The Company paid \$20,000 and \$31,150 in minimum royalty payments for the year ended December 31, 2019 and December 31, 2018, respectively. In addition, the Company paid \$1,396 and \$19,069 in reimbursed patent prosecution costs pursuant to this license for the year ended December 31, 2019 and December 31, 2018, respectively.

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### ***Lease Agreement***

In April 2019, the Company entered into a lease agreement for certain office and laboratory space in Torrance, CA. The lease agreement is cancellable by the Company at any time with 30 day notice. The Company recorded total rent expenses of \$17,800 for the year ended December 31 2019.

### **5. Convertible Notes**

Between August 2018 and November 2018, the Company issued \$650,000 in convertible notes at five percent (5%) interest due in August 2020 (the "Notes") for cash proceeds of \$450,000 and \$200,000 in converted liabilities from the Company's chief executive officer (See Note 9). In the event of a qualified financing, as defined in the agreement, the outstanding principal amount of the notes and all accrued interest would automatically convert into shares of preferred stock issued in such financing at 80% of the price per share paid by the other investors. On November 27, 2018 in conjunction with the Series A financing (see Note 6), the qualified financing occurred and total principal and accrued interest of approximately \$657,000 was converted into 1,143,303 shares of Series A Convertible Preferred Stock. Additionally, the Company recorded interest expense of \$164,000 related to the beneficial conversion feature, which represents the discount realized by the holders of the convertible notes upon the conversion.

### **6. Equity**

On May 3, 2017, the Corporation was incorporated with 1,500 shares of common stock authorized. On November 27, 2018, the Board of Directors approved an amendment to the Company's Certificate of Incorporation resulting in 28,858,687 shares of common stock and 15,072,819 shares of Series A convertible preferred stock being authorized.

#### ***Series A Convertible Preferred Stock***

On November 27, 2018, the Company entered into a preferred stock purchase agreement which authorized the sale and issuance of up to 8,247,354 shares of preferred stock. The Company issued 7,104,051 shares at \$0.7179 per share for net proceeds of \$5,002,354 and 1,143,303 shares for the conversion of \$656,623 in convertible notes and interest. In addition, on January 2, 2019, the Company completed a second round of the Series A preferred stock financing and issued 6,825,460 shares at \$0.7179 per share for net proceeds of \$4,855,661.

The holders of the convertible preferred stock have the following rights:

#### ***Voting Rights***

The holders of convertible preferred stock are entitled to vote on all matters and have the number of votes equal to the number of shares of common stock into which the shares of convertible preferred stock are convertible. Certain directors comprising the Board of Directors shall be elected by majority vote of the holders of convertible preferred stock. A majority vote of the holders of convertible preferred stock is required to liquidate or dissolve the Company, amend the Certificate of Incorporation or Bylaws, reclassify common stock or establish another class of capital stock, create shares that would rank senior to or authorize additional shares of convertible preferred stock, declare a dividend or make a distribution, change the authorized number of directors constituting the Board of Directors, or establish a new employee stock option plan.

#### ***Dividends***

The holders of the outstanding shares of Series A convertible preferred stock are entitled to first receive, when and if declared by the Board of Directors, a non-cumulative dividend of eight percent (8%) of the Series A original issue price, prior to any dividends being paid to the common stockholders. No dividends have been declared as of December 31, 2019.

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### *Conversion*

Each share of Series A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, into such number of fully paid shares as determined by dividing the original Series A issue price of \$0.7179 by the Series A Conversion Price, which is initially \$0.7179, with certain possible adjustments as defined in the Company's revised Articles of Incorporation.

### *Liquidation Preference*

The holders of the Series A convertible preferred stock have preferences in the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, as defined in the Restated Certificate of Incorporation. The holders of Series A Preferred Stock shall be paid out of the assets of the Company available for distribution before any payment shall be made to the holders of common stock, in an amount per share equal to \$0.7179 plus any dividends declared but unpaid. In the event the assets of the Company are insufficient to pay the holders of Series A Preferred Stock the full amount to which they are due, the holders of Series A Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable.

In addition, the Series A Convertible Preferred Stock can be redeemed upon certain liquidation events that are outside of the Company's control.

### ***Common Stock***

The voting, dividend and liquidation rights of the holders of common stock are subject to and qualified by the rights, powers and preferences of the holders of convertible preferred stock as summarized above.

### *Voting*

The holders of common stock are entitled to one vote for each share of common stock held at the meeting of stockholders. Holders of common stock are not entitled to vote on any amendment of the Company's Certificate of Incorporation that relates to solely to the terms of preferred stock, either separately or as a class.

## **7. Stock-Based Compensation**

### ***Equity Plans***

In December 2018, the Company adopted the 2018 Equity Incentive Plan (the "2018 Incentive Plan"). The number of stock-based awards initially reserved for issuance under the 2018 Incentive Plan was 2,785,868. The terms and conditions of stock-based awards are defined at the sole discretion of the Company's Board of Directors. The Company issues service-based awards, vesting over a defined period of service, and performance-based awards, vesting upon achievement of defined conditions. Service-based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service and the remaining awards vesting monthly in equal installments over the following thirty-six months. Stock options granted under the 2018 Incentive Plan expire ten years from the date of grant and the exercise price must be at least equal to the fair market value of common stock on the grant date.

At December 31, 2019, there were 335,868 shares available for future issuance under the 2018 Incentive Plan.

### ***Options***

The risk-free interest rate assumption for options is based on the U.S. Treasury yield curve rate at the date of grant with a maturity approximating the expected term of the option. The expected term assumption for options granted to employees is determined using the simplified method that represents the average of the contractual



term of the option and the weighted average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term. For non-employee options, the contractual term of the option issued is used as the expected term prior to adoption of ASU 2018-07. Subsequent to the adoptions of ASU 2018-07, the Company elected to use the simplified method to determine the expected term of the options. Assumptions as to expected volatility for the Company's common stock are based on estimates from the historical volatility of a peer group of public companies that the Company believes are similar in nature to us. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future. The fair value per share is determined by the Company's Board of Directors, as of the date of each grant based on the independent third-party valuations, taking into consideration various objective and subjective factors.

The underlying weighted-average assumptions used to value employee and non-employee stock options granted during 2018 using the Black-Scholes option-pricing were as follows. The weighted average grant date fair value of:

	<b>For the year ended December 31, 2018</b>
Fair value of common stock	\$ 0.18
Risk-free interest rate	2.70%
Dividend yield	0.00%
Expected term of options (years)	6.08
Volatility	70.0%

There were no stock options granted during 2019.

#### ***Stock-Based Compensation Expense***

Stock-based compensation expenses included in the Company's statement of operations for the year ended December 31, 2019 were:

	<b>For the year ended December 31, 2019</b>
Research and development	\$ 6,770
General and administrative	28,940
	<u>\$ 35,710</u>

The Company did not recognize stock-based compensation expense in 2018 because it was immaterial.

As of December 31, 2019, there was unrecognized stock-based compensation expense of \$249,000, which is expected to be recognized over a weighted-average period of 2.3 years. The table below summarizes the stock option activity under the 2018 Incentive Plan:

	Number of Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances at December 31, 2017	—	\$ —	—	
Granted	2,450,000	0.18	9.9	
Exercised	—	—		
Cancelled/Forfeited	—	—		
Balances at December 31, 2018	<u>2,450,000</u>	\$ 0.18	9.9	
Granted	—	—		
Exercised	—	—		
Cancelled/Forfeited	—	—		
Balances at December 31, 2019	<u>2,450,000</u>	\$ 0.18	<u>9.0</u>	<u>\$ 175,750</u>
Vested and expected to vest at December 31, 2019	<u>2,450,000</u>	\$ 0.18	<u>9.0</u>	<u>\$ 175,750</u>
Exercisable at December 31, 2019	<u>259,895</u>	\$ 0.17	<u>9.0</u>	<u>\$ 19,875</u>

The aggregate intrinsic value of options at December 31, 2019 is based on the Company's estimated fair value of the stock price on that date of \$0.25 per share.

## 8. Income Taxes

The Company did not record a provision for or benefit from income taxes for the years ended December 31, 2019 and 2018.

The reconciliations of income tax attributable to loss before the provision for income taxes at the U.S. federal statutory tax rate to income tax expense for the year ended December 31, 2019 and 2018 are as follows:

	December 31, 2019		December 31, 2018	
Income tax expense (benefit) at federal statutory rate	\$ (854,399)	21%	\$ (177,084)	21%
Increase/(decrease) in tax resulting from:				
State income taxes	(283,839)	7%	(58,890)	7%
Change in valuation allowance	1,145,234	28%	232,188	28%
Tax rate change	—		3,786	0%
Other	(6,996)	0%	—	
Total	<u>\$ —</u>	<u>0%</u>	<u>\$ —</u>	<u>0%</u>

The primary components of temporary differences which give rise to the Company's net deferred tax assets and liabilities as of December 31, 2019 and 2018 are as follows:

	December 31, 2019	December 31, 2018
<i>Assets:</i>		
Accrual to cash adjustment	\$ 401,899	\$ —
Startup costs	478,886	—
Depreciation	3,281	—
Net operating loss	<u>597,100</u>	<u>243,786</u>
Total noncurrent deferred tax assets	1,481,166	243,786
<i>Liabilities:</i>		
State taxes	<u>(92,146)</u>	—
Total noncurrent deferred tax liabilities	(92,146)	—
Valuation allowance	<u>(1,389,020)</u>	<u>(243,786)</u>
Net deferred tax assets after valuation allowance	\$ —	\$ —

In determining the need for a valuation allowance, the Company considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Based on the review of all positive and negative evidence, including a historical cumulative pre-tax loss, the Company determined that a full valuation allowance should be recorded against all U.S. deferred tax assets at December 31, 2019 and 2018.

The gross federal and state net operating loss carryforwards of \$2,001,002 and \$2,001,002, respectively, begin to expire in 2038 and 2039, respectively. Of the \$2,001,002 of federal net operating loss carryforwards, \$11,151 was generated before January 1, 2018 and is subject to the 20-year carryforward period ("Pre-Tax Act losses"). The remaining \$1,989,851 ("Post-Tax Act losses") can be carried forward indefinitely but is subject to the 80% taxable income limitation. The Pre-Tax Act U.S. federal and state net operating loss carryforwards will expire in varying amounts through 2039. Utilization of the net operating loss and tax credit carryforwards may become subject to annual limitations due to ownership change limitations that could occur in the future as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), as well as similar state provisions. These ownership changes may limit the amount of the net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income.

Any uncertain tax positions would be related to tax years that remain open and subject to examination by the relevant tax authorities. The Company has no liabilities related to uncertain tax positions or unrecognized benefits as of the year end December 31, 2019 and 2018. The Company has not accrued for interest or penalties associated with unrecognized tax liabilities. The Company anticipates that there will be no material changes to the unrecognized tax benefit associated with uncertain tax positions over the next twelve months.

The Company is subject to U.S. federal income tax, as well as, income tax of multiple state tax jurisdictions. The Company is subject to U.S federal income tax and state income tax examination from 2017 onward.

## 9. Related Party Transactions

As discussed in Note 5, the Company issued \$650,000 in convertible notes in 2018. The Company's founder and chief executive officer, Dr. Paul Wagner, paid expenses on behalf of the Company in 2018 and 2017 in the amounts of \$69,202 and \$19,896, respectively. Dr. Wagner loaned an additional \$110,902 to the Company prior to the issuance of the Notes (Note 5) in August 2018. These amounts were treated as liabilities to Dr. Wagner and were converted into convertible notes payable in August 2018, with the same terms as the terms given to other noteholders. In November 2018, Dr. Wagner loaned the Company an additional \$100,000 which amount was

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recorded as an additional convertible note payable, with the same terms. Dr. Wagner's total loan to the Company of \$300,000 was converted to preferred stock in November 2018 in the Series A preferred stock financing. Dr. Paul Wagner received 526,864 shares of preferred stock in exchange for his \$300,000 notes and accrued interest.

## **10. Subsequent Events**

On February 19, 2020, the Company and Tocagen Inc. ("Tocagen"), a publicly traded biotechnology company entered into an Agreement and Plan of Merger and Reorganization ("Merger Agreement"), which included the proposed business combination ("Merger") of the Company and a wholly owned subsidiary of Tocagen, with the Company as the surviving company, subject to shareholder approval.

The proposed Merger is structured as a stock-for-stock transaction whereby all of the Company's outstanding shares of common stock and securities convertible into or exercisable for the Company's common stock will be converted into the right to receive Tocagen common stock and securities convertible into or exercisable for Tocagen common stock. Under the exchange ratio formula in the Merger Agreement, the former equityholders of the Company immediately before the Merger are expected to own approximately 76.7% of the outstanding capital stock of the combined company, and the equityholders of Tocagen immediately before the Merger are expected to own approximately 23.3% of the outstanding capital stock of the combined company, on a fully diluted basis using the treasury stock method subject to certain assumptions. The Company anticipates that the Merger will close in the second quarter of 2020.

On February 19, 2020, the Company entered into certain Share Purchase Agreements with certain investors pursuant to which the Company issued 13,055,999 shares of common stock and warrants to purchase 13,055,999 shares of common stock for gross proceeds of \$14.1 million at a price per share of \$1.08.

On March 18, 2020, the Company entered into certain Share Purchase Agreements with certain investors pursuant to which the Company issued 4,851,888 common stock for gross proceeds of \$5.2 million at a price per share of \$1.08.