UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

Commission File Number 001-38052

FORTE BIOSCIENCES, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**26-1243872**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3060 Pegasus Park Drive, Building 6 Dallas, Texas	**75247**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	FBRX	The Nasdaq Stock Market LLC

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark where the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Stock Market on June 30, 2025 was $157.0 million.

The number of shares of Registrant's Common Stock outstanding as of March 27, 2026 was 13,885,668.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, subsequent to the date hereof pursuant to Regulation 14A in connection with the Registrant's 2026 Annual Meeting of Stockholders will be incorporated by reference into Part III of this Annual Report on Form 10-K assuming such proxy statement is filed with the SEC not later than 120 days after the conclusion of the registrant's fiscal year ended December 31, 2025. If such proxy statement is not filed on or before such date, the information called for by Part III will be filed as part of an amendment to this Annual Report on Form 10-K on or before such date.

Auditor Firm ID: 185	Auditor Name: KPMG LLP	Auditor Location: San Diego, California

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PART I

FORWARD-LOOKING STATEMENTS

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

- any statements of the plans, strategies and objectives of management for future operations;
- any statements concerning proposed new products, services or developments;
- any statements regarding future economic conditions or performance;
- any statements regarding future regulatory approvals;
- our expectations regarding the timing of product launches, as well as product features and specifications, including target indications for FB102;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the timing, scope and likelihood of regulatory filings and approvals for future product candidates;
- our estimates regarding the sufficiency of our cash resources and our need for additional funding;
- our expectations regarding the market size, market growth and growth potential for our business, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our ability to grow our business;
- our internal control environment; and
- our intended use of the net proceeds from offerings of our securities or other financings we may complete from time to time.

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

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

Item 1. Business

Overview

Forte Biosciences, Inc. and its subsidiaries (www.fortebiorx.com) ("Forte", "we", "our") is a clinical-stage biopharmaceutical company whose current lead product candidate is FB102. FB102 is a proprietary anti-CD122 monoclonal antibody therapeutic candidate with potentially broad autoimmune and autoimmune-related indications.

Our FB102 program aims to address key pathways implicated in these indications with a CD122 antagonist. CD122 is a subunit of IL-2/IL-15 receptors which are key regulators of NK cells and certain T cell subsets.

In FB102 mechanistic in-vitro studies, human donor T and NK cells were stimulated with either IL2 or IL15 in the presence or absence of FB102. FB102 significantly inhibited proliferation (4-5x inhibition in the proliferation of T cells and 6-8 fold inhibition in the proliferation of NK cells) and also inhibited activation of T cells. The level of FB102 inhibition of proliferation and activation was at levels comparable to unstimulated cells. Human donor regulatory T cell (Treg) studies stimulated with IL2 demonstrated comparable proliferation both in the presence and absence of FB102. Additionally, in-vitro assays demonstrated superiority of FB102 compared to competing antibodies.

In 4- and 13-week non-human primate (NHP) studies, after a single dose, FB102 demonstrated significant reductions in the NK cell pharmacodynamic marker (up to approximately 80%-90%). Additionally, after multiple doses at exposures comparable to human therapeutic doses, Treg levels in the FB102 dosing arm were similar to vehicle supporting the in-vitro data and mechanism of action of FB102.

Three cohorts of single and two cohorts of multiple ascending doses in a Phase 1 trial of healthy volunteers were completed in which FB102 demonstrated a good safety profile. The primary objective of the Phase 1 trial was to assess the safety, tolerability and pharmacokinetics of single and multiple ascending doses of FB102. No dose limiting toxicities were observed. FB102 demonstrated significant reductions in the NK cell pharmacodynamic marker (greater than approximately 70%). Based on the successful completion of the Phase 1 healthy volunteer cohorts, we initiated a patient-based Phase 1b trial in celiac disease in the third quarter of 2024 and a patient-based Phase 1b trial for non-segmental vitiligo in the first quarter of 2025.

In June 2025, we announced positive data in our celiac disease Phase 1b study. The study enrolled 32 subjects 3:1 randomized (24 on FB102 and 8 on placebo). Subjects received 4 doses of FB102 (10 mg/kg) and underwent a 16-day gluten challenge. In addition to safety and tolerability, the study assessed morphologic and inflammatory endpoints along with gluten challenge induced symptoms.

FB102 demonstrated a statistically significant benefit on the composite histological VCIEL endpoint (change from baseline). The mean VCIEL change from baseline was -1.849 for placebo subjects compared to 0.079 for FB102 treated subjects (p=0.0099).

The change in the density of CD3-positive T cells, or IELs, from baseline was an increase of 13.3 for placebo subjects compared to a decline of 1.5 for FB102 treated subjects (p=0.0035). Baseline IEL density was 25.6 for the placebo subjects and 23.5 for the FB102 treated subjects.

The mean change in the Vh:Cd ratio from baseline was -0.173 (0.21) for placebo subjects compared to -0.046 (0.09), a 73% improvement for FB102 treated subjects compared to placebo.

Gluten challenge induced GI symptoms (nausea, vomiting, diarrhea, abdominal pain and abdominal bloating) reported during the 16-day gluten challenge from patient diaries/AE collection demonstrated a 42% benefit for FB102 treated subject (4.0 events per subject) compared to placebo (6.9 events per subject).

There were no dropouts in the study. Treatment emergent adverse events were primarily mild (grade 1) with no grade 3 or higher SAEs reported in the FB102 arm.

Based on the successful completion of our patient-based Phase 1b celiac disease study, we initiated a Phase 2 celiac study in July 2025 with the topline readout expected in 2026. In November 2025, the US FDA approved our IND application for a US arm of our Phase 2 celiac study. Our Phase 1b non-segmental vitiligo trial is expecting topline data in the first half of 2026 and we have also initiated a Phase 1b alopecia areata study with topline data expected in 2026.

Celiac disease is an autoimmune disease that is triggered by consuming gluten and results in damage to the small intestine. Symptoms include diarrhea, fatigue, headaches, anemia, nausea and dermatitis herpetiformis (an itchy skin rash). A significant patient population of celiac disease patients do not respond to gluten free diet. The health consequences for not treating include malnourishment, cancer, other autoimmune conditions. It is estimated that 1:133 in U.S. (2.5 million people) have celiac disease (Fasano, Arch Intern Med. 2003 PMID: 12578508) and that 0.3% to 0.5% of celiac disease patients are non-responsive (Malamut Gastroenterology. 2024

38556189). It has been estimated by various U.S. advocacy and epidemiology sources that up to 80% of people in the U.S. with celiac disease are undiagnosed. There are no approved treatment options for celiac disease.

Vitiligo is a disease of the skin mediated primarily by NK and CD8+ T cells that attack melanocytes leading to patchy depigmentation of the skin. It is estimated that vitiligo affects 2 million people in the U.S (NIH). The global vitiligo treatment market size was estimated at $1.6-1.8 billion in 2024-2025 and is projected to reach approximately $2.3-2.7 billion by 2032-2034 (Fortune Business Insights).

Alopecia areata is a disease in which immune cells attack and damage hair follicles and is mediated primarily by CD8+ T cells and NK cells. The global alopecia treatment market has been valued at around $3-3.5 billion in 2024 with some forecasts pointing to the potential to reach $6 billion in 2032-2034 (DataM Intelligence).

Further we believe FB102 has potentially other autoimmune and autoimmune-related applications including in type 1 diabetes ("T1D") which is caused by autoreactive T Cells destroying insulin-producing pancreatic β- cells. CD8+ T cells with receptors recognizing β-cell specific peptides are enriched in pancreatic islets of T1D patients. Environmental stress causes β-cells to upregulate MHC and to express IL-15 and IL-15RA. (Herold 2024 Nat Rev Immunol. PMID 38308004). It is estimated that 64,000 people in the U.S. are diagnosed with T1D annually (https://beyondtype1.org/type-1-diabetes-statistics/).

We had approximately $77.0 million in cash and cash equivalents as of December 31, 2025. Our common stock is publicly traded on the Nasdaq Capital Market under the ticker symbol FBRX. Prior to our merger with Tocagen, Inc., a publicly traded biotechnology company, Forte was a privately held company incorporated in Delaware on May 3, 2017.

Since our inception, we have funded our operations primarily through private placements and public offerings of our equity securities. In fiscal year 2025, 2024 and 2023, we raised approximately $75.0 million, $53.0 million and $25.0 million respectively, through a combination of private placements and public offerings as discussed in more detail in Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

Manufacturing and Supply

Forte has outsourced the manufacturing of FB102 to facilities at third party contract manufacturing organizations (CMOs) and the preclinical testing and clinical development to clinical research organizations (CROs). These facilities and associated equipment are designed and operated to be consistent with all applicable laws and regulations. However, from time to time, we source critical raw materials and services from one or a limited number of suppliers with potentially long lead times or limited manufacturing and testing slot availability. There is a risk that if such supplies or services were interrupted, it could materially harm the manufacturing and development of FB102.

Competition

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

We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize similar products that are safer, more effective, have fewer side effects or are less expensive than any products that we and/or our collaborators may develop.

Intellectual Property

We own one US patent for administering a combination of Gram-positive and Gram-negative bacteria along with metabolites for treatment of a wide variety of skin conditions. The patent’s estimated expiration date is 2039. This patent is not material to Forte’s FB102 program. We also own one pending PCT application, six pending US applications and eighteen pending foreign applications in Europe, Australia, Canada, China, Eurasia, Hong Kong, Israel, Japan, South Korea, Mexico, New Zealand, Singapore, Brazil, India, South Africa, Taiwan and Argentina related to the FB102 program. The estimated expiration dates of these patents are 2043-2046. We also own one pending US application and one pending application in Europe that is not material to Forte's FB102 program.

Government Regulation

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

United States Biological Product Development

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

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

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

Preclinical Studies and IND

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

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

Clinical Trials

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

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

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

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

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

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

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

FDA Review Process

Following completion of the clinical trials, data are analyzed to assess whether the investigational product is safe and effective for the proposed indicated use or uses. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling, chemistry and manufacturing information to ensure product quality and other relevant data. The BLA is

a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity and potency for the biologic. The application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from several alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

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

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

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

In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine in *Loper Bright Enterprises v. Raimondo*, which historically has provided deference to regulatory agencies' statutory interpretations in litigation against the government where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA and other federal agencies to challenge longstanding decisions and policies which could lead to uncertainties in the industry. Further, changes in the leadership of the FDA and other federal agencies under the current administration may lead to new policies, changes in the regulations, or disruptions to the operations of federal agencies, any of which may impact our clinical development plans.

Pediatric Information

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

PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

Post-marketing Requirements

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

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

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

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

Other Regulatory Matters

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

Other Healthcare Laws

Biopharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, anti-self-referral, false claims, transparency, including the federal Physician Payments Sunshine Act, consumer fraud, pricing reporting, data privacy, data protection, and security laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the biopharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which

require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of biopharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), thus complicating compliance efforts.

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

Current and Future Healthcare Reform Legislation

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

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

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and Forte expects there will be additional challenges and amendments to the ACA in the future. For example, in November 2020, the United States Supreme Court held oral arguments on the ACA case from the U.S. Court of Appeals for the 5th Circuit, which upheld the District Court ruling that the individual mandate is unconstitutional. In June 2021, the Supreme Court of the United States held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. Accordingly, the ACA remains in effect in its current form. In January 2021, President Trump issued an executive order to initiate a special enrollment period to allow people to obtain health insurance coverage through the ACA marketplace, and instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, among others. We cannot predict how the Supreme Court ruling, other litigation, or the healthcare reform measures of the Trump administration will impact our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will remain in effect through 2032, unless Congress takes additional action. 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. 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. Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates

that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022, or IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Additionally, the current administration also issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other government measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or that increase generic drug and biosimilar entry sooner than expected, could materially harm the Company's business, including with respect to its ability to set adequate pricing for new drugs to recover its research and development costs. The impact of future judicial challenges, legislative, executive, and administrative actions implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

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. For example, a number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase Forte's compliance burdens and expose it to greater liability under such state laws once it begins commercialization after obtaining regulatory approval for any of its products. For example, FDA has authorized the state of Florida to develop a program to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Packaging and Distribution in the United States

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

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

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

Changes in regulations, statutes or the interpretation of existing regulations could impact Forte's business in the future by requiring, for example: (i) changes to Forte's manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the

recall or discontinuation of Forte's approved products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of Forte's business.

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

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

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

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

U.S. Patent-Term Restoration and Marketing Exclusivity

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

An abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of 2009 ("BPCI Act"). This amendment to the PHSA, in part, attempts to minimize duplicative testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, that the product and the reference product may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biological product without such alternation or switch.

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

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

Rest of the World Regulation

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

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

Additional Laws and Regulations Governing International Operations

If Forte further expands its operations outside of the United States, Forte must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which it plans to operate. The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from offering, paying, promising to pay, or authorizing payment of money or anything of value, to any person, while knowing that all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any foreign official, political party or candidate to influence the foreign official in his or her official capacity, induce the foreign official to do or omit to do an act in violation of his or her lawful duty, or to secure any improper advantage in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls.

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

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

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

Coverage and Reimbursement

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

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

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

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

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

Employees and Human Capital

As of December 31, 2025, we had 19 full-time employees, primarily engaged in research and development, manufacturing and administration. None of Forte's employees are represented by labor unions or covered by collective bargaining agreements. Forte considers its relationship with its employees to be good.

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

Corporate Information and History

On June 15, 2020, Forte completed a business combination (the "Merger") with Tocagen, Inc. ("Tocagen"), a publicly traded biotechnology company, with Forte being the surviving business. Prior to the Merger, Forte was a privately held company incorporated in Delaware on May 3, 2017. Forte's legal predecessor, Tocagen, was incorporated in Delaware in August 2007.

Our principal executive office is located at 3060 Pegasus Park Drive, Building 6, Dallas TX 75247 and our telephone number is (310) 618-6994. Our corporate website is located at www.fortebiorx.com. We make available on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). Our SEC reports can be accessed through the investor relations page of our website located at https://www.fortebiorx.com/investor-relations/sec-filings/default.aspx. The SEC also maintains a website that contains our SEC filings. The address of that site is www.sec.gov.

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

Item 1A. Risk Factors.

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

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

- Forte will require significant additional capital to fund its operations and if Forte fails to obtain necessary financing, Forte will not be able to continue to advance or complete the clinical development and commercialization of its current lead product candidate, FB102, or any future product candidates.
- Forte's business is almost entirely dependent on the success of developing FB102, which may not be successful.
- Results from early preclinical studies and clinical trials may not necessarily be predictive of results from later stage studies or clinical trials.
- Forte has no approved products and has a limited operating history, which may make it difficult to evaluate its technology and product development capabilities and predict its future performance.
- Forte has incurred net losses in every year since its inception and anticipates that it will continue to incur net losses in the future.
- Forte's ability to successfully develop any product candidate is highly uncertain.
- Clinical development is a lengthy and expensive process, with an uncertain outcome. Forte may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidate.
- Forte's planned preclinical studies, clinical trials or future clinical trials or those of its future collaborators may reveal significant adverse events and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidates.
- Positive results from early preclinical studies and clinical trials may not necessarily be predictive of the results of any future clinical trials of product candidates. Forte may be unable to successfully develop, obtain regulatory approval for and commercialize any product candidates.
- Interim top-line and preliminary data from prior, current or future clinical trials that Forte announces or publishes from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The market opportunities for FB102 may be limited and Forte's estimates of the incidence and prevalence of its target patient populations may be inaccurate.
- Forte is early in its development efforts. FB102 will require significant additional clinical development before Forte seeks regulatory approval of any product candidate. If Forte is unable to advance FB102 to clinical development, obtain regulatory approval and ultimately commercialize a product candidate or experiences significant delays in doing so, its business will be materially harmed.
- If Forte is unable to obtain and maintain patent protection for any product candidate Forte develops, its competitors could develop and commercialize products or technology similar or identical to Forte's, and its ability to successfully commercialize any product candidate Forte may develop, and its technology, may be adversely affected.
- Forte expects to rely on third parties to conduct its preclinical studies and clinical trials and to manufacture its product candidates.
- The market price of Forte's common stock is expected to be volatile. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Litigation has previously arisen in connection with the 2023 Private Placement or the 2024 Private Placement, and more

could arise in the future in connection with volatility in trading and/or future securities offerings, which could be costly, divert management's attention and otherwise materially harm our business.

- If Forte experiences material weaknesses in or otherwise fails to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Risks related to Forte's business, technology and industry

Forte will require additional capital to fund its operations and if Forte fails to obtain necessary financing, Forte will not be able to complete the development and commercialization of its current lead product candidate, FB102, or any future product candidates.

Forte's operations have consumed substantial amounts of cash since inception. Forte expects to continue to spend substantial amounts to conduct preclinical studies and clinical trials of its current and future programs, to validate the manufacturing process and specifications for its product candidate, to seek regulatory approvals for its product candidate and to launch and commercialize any products for which Forte receives regulatory approval, including potentially building its own commercial organization. As of December 31, 2025, Forte had approximately $77.0 million of cash and cash equivalents on hand. Based on its current operating plan, Forte believes that its current cash and cash equivalents available will enable it to fund its operating expenses and capital expenditure requirements through at least twelve months from the issuance date of this Form 10-K. However, its future capital requirements and the period for which its existing resources will support its operations may vary significantly from what Forte currently expects, and Forte will in any event require additional capital in order to complete the clinical development of FB102. Forte's monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of FB102 and any future product candidates is highly uncertain, Forte is unable to estimate the actual funds it will require for development and any approved marketing and commercialization activities. Forte's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of additional preclinical studies and clinical trials for FB102 and any future product candidates and any need to conduct additional such studies as may be required by a regulator;
- the clinical development plans Forte establishes for FB102 and any future product candidates;
- the terms of any collaboration agreements Forte may choose to initiate or conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration ("FDA"), and other comparable foreign regulatory authorities;
- delay or failure in obtaining the necessary approvals from regulators or institutional review boards ("IRBs") in order to commence a clinical trial at a prospective trial site, or their suspension or termination of a clinical trial once commenced;
- failure of third-party contractors, such as contract research organizations ("CROs"), or investigators to comply with regulatory requirements, including Good Clinical Practice ("GCP");
- governmental or regulatory delays and changes in regulation or policy relating to the development and commercialization of its product candidate by the FDA or other comparable foreign regulatory authorities;
- undertaking and completing additional preclinical studies to generate data required to support the continued clinical development of a product candidate;
- inability to enroll sufficient patients to complete a protocol;
- difficulty in having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- problems with biopharmaceutical product candidate storage, stability and distribution;
- its inability to add new or additional clinical trial sites;
- varying interpretations of the data generated from its preclinical or clinical trials;
- Forte's inability to manufacture, or obtain from third parties, adequate supply of biopharmaceutical product candidate sufficient to complete its preclinical studies and clinical trials;

- the costs of establishing, maintaining, and overseeing a quality system compliant with current good manufacturing practice requirements ("cGMPs") and a supply chain for the development and manufacture of its product candidate;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against Forte, FB102;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- the effect of potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the military conflicts in Eastern Europe and the Middle East, trade policies, potential trade wars, and actions or inactions of the U.S. or other major national governments (including the imposition of tariffs and retaliatory measures), and any potential future financial institution failures, and otherwise;
- the effect of inflationary pressure on the United States capital markets and our ability to raise capital, including any impact of adverse developments affecting the financial services industry, such as those based on liquidity constraints or concerns;
- the cost of establishing sales, marketing and distribution capabilities for any product candidate for which Forte may receive regulatory approval in regions where Forte chooses to commercialize its products on its own; and
- potential unforeseen business disruptions or market fluctuations that delay its product development or clinical trials and increase its costs or expenses, such as business or operational disruptions, delays, or system failures due to malware, unauthorized access, terrorism, war, natural disasters, strikes, geopolitical conflicts, restrictions on trade, import or export restrictions, or public health crises.

In March 2025, the Company filed a shelf registration statement on Form S-3 that went effective in April 2025 to register the issuance of up to $300.0 million in securities.

In June 2025, the Company closed a public offering (the "Offering") pursuant to which it sold 5,630,450 shares of common stock at a price to the public of $12.00 per share and pre-funded warrants to purchase 619,606 shares of common stock at a price to the public of $11.999 per pre-funded warrant, which represents the per share public offering price for the shares less the exercise price for each pre-funded warrant. The Company also granted the underwriters an option (the "Option"), exercisable for a period of 30 days, to purchase up to an additional 937,508 shares of common stock. The pre-funded warrants have an exercise price of $0.001 per share, are immediately exercisable and remain exercisable until exercised in full. The holders of the pre-funded warrants will not be entitled to exercise any portion of any pre-funded warrant that, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by any such holder, together with its affiliates, to exceed 9.9%. However, the holder of the pre-funded warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to the Company. The gross proceeds from the Offering were $75.0 million and the Company incurred approximately $5.1 million in underwriting discounts, commissions and offering expenses. In July 2025 the underwriters of the Offering exercised the Option and purchased 148,258 shares of common stock for gross proceeds of $1.8 million and incurred issuance costs of $0.1 million.

In November 2024, the Company issued 4,931,389 shares of our common stock at a purchase price of $5.5520 per share, and 4,615,555 pre-funded warrants to purchase shares of common stock at a purchase price of $5.5510 per pre-funded warrant ("2024 Private Placement"). The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The gross proceeds of the 2024 Private Placement were $53.0 million and the Company incurred $3.4 million in issuance costs. Certain executive officers and senior management of the Company participated in this 2024 Private Placement, purchasing $475 thousand in shares of common stock at a purchase price of $5.552 per share. In connection with the 2024 Private Placement, the Company filed a registration statement on Form S-3 that was declared effective on December 20, 2024.

In July 2023, the Company completed the 2023 Private Placement financing pursuant to which the Company sold (i) 606,678 shares of common stock, and (ii) 387,566 pre-funded warrants to purchase common stock at a purchase price of $25.13 per pre-funded warrant. The pre-funded warrants have an exercise price of $0.025 per share of common stock, were immediately exercisable and remain exercisable until exercised in full. The gross proceeds of the 2023 Private Placement were approximately $25.0 million, before deducting offering expenses payable by the Company. While the proceeds from the Offering and the Private Placements provided further funding for the Company's operations, the Company will still require additional capital to fund its operations and complete the development and commercialization of FB102 or any future product candidates.

Forte does not have any committed external source of funds or other support for its development efforts, and Forte cannot be certain that additional funding will be available on acceptable terms, or at all. Until Forte can generate sufficient product or royalty

revenue to finance its cash requirements, which Forte may never do, Forte expects to finance its future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If Forte raises additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect its stockholders' rights. Further, to the extent that Forte raises additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, each existing investors' ownership interest will be diluted. If Forte raises additional capital through debt financing, Forte would be subject to fixed payment obligations and may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights. If Forte raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, Forte may have to relinquish certain valuable rights to its product candidate, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to it. Forte also could be required to seek collaborators for one or more of its current or future product candidates at an earlier stage than otherwise would be desirable or relinquish its rights to product candidates or technologies that Forte otherwise would seek to develop or commercialize itself. In addition, our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from trade policies, potential trade wars, and actions or inactions of the U.S. or other major national governments (including the imposition of tariffs and retaliatory measures), the military conflicts in Eastern Europe and the Middle East, the effect of inflationary pressure on the United States capital markets, adverse developments affecting the financial services industry (such as the collapse of Silicon Valley Bank in March 2023 and any similar bank collapses or closures) and otherwise. If Forte is unable to raise additional capital in sufficient amounts or on terms acceptable to it, Forte may have to significantly delay, scale back or discontinue the development or commercialization of its current product candidate, FB102, or one or more of its other current or future research and development initiatives. Any of the above events could significantly harm its business, prospects, financial condition and results of operations and cause the price of its common stock to decline.

Forte's business through 2021 had been almost entirely focused on the success of FB-401 and Forte subsequently decided to discontinue the advancement of FB-401. In 2022, Forte decided to devote significant time and resources to developing FB102, which may not be successful.

Through August 2021, Forte invested substantially all of its efforts and financial resources into the research and development of FB-401, which was its only product candidate to enter into clinical trials at that time. In September 2021, following the release of the FB-401 trial results, Forte announced that it would discontinue the advancement of FB-401 and conducted an extensive process to evaluate strategic alternatives. In 2022, the Company decided to focus on developing its FB102 program, and since has completed a Phase 1b trial of FB102 for patients with celiac disease in 2025. The Company is currently undertaking a Phase 2 trial in celiac's disease and Phase 1b trials for patients with non-segmental vitiligo and alopecia areata. We will be required to devote significant time and resources to developing FB102, which may not be successful.

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

We are still early in our testing of FB102, and it is our only product candidate in clinical development. While initial preclinical and Phase 1b clinical data demonstrated positive results, additional clinical studies may produce negative or inconclusive results. The FDA or a non-US regulatory authority may require us to conduct additional testing. Success of FB102 in early preclinical studies and clinical trials does not mean that future clinical trials will be successful. In addition, preclinical data are often susceptible to various interpretations and analyses, and many companies whose product candidates performed satisfactorily in preclinical studies have nonetheless failed to obtain marketing approval. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after obtaining promising results in preclinical studies and early clinical trials. Any of these events could limit the commercial potential of our product candidate and have a material adverse effect on our business, prospects, financial condition and results of operations.

Forte's prospects are highly dependent on a single product candidate, FB102. If we are unable to complete further development of, obtain approval for and commercialize FB102 for one or more indications in a timely manner, our business will be harmed.

Forte's long-term prospects are highly dependent on future acceptance and revenues from a single product, FB102. FB102 is our only product candidate at this time. Forte recently completed a Phase 1b trial for patients with celiac disease. We are currently undertaking Phase 1b trials in non-segmental vitiligo and alopecia areata, and a Phase 2 celiac study with the topline readouts for each clinical trial expected in 2026. Any further development of FB102 would require substantial capital and time to complete and there is no guarantee that the current or any future clinical trial, if pursued, would be timely or successful, or that FB102 will be approved or, if approved, that commercialization would be successful.

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

Prior to the closing of the Merger, Forte's predecessor company was formed in 2017 as a privately held company. We are early in our development efforts of FB102 and, prior to discontinuing the advancement of FB-401, were early in our clinical development efforts of FB-401.

Forte has no products approved for commercial sale and has not generated any revenue from product sales. Forte's ability to generate product revenue or profits is dependent on the successful development and eventual commercialization of FB102. Given the early stage of FB102, which recently completed a Phase 1b trial for celiac disease, and the highly uncertain nature of early-stage drug development, Forte may never be able to develop or commercialize a marketable product.

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

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

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

Forte is a clinical-stage life sciences company with a limited operating history. Investment in product development in the life sciences industry, including of biopharmaceutical products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. Forte's current lead product candidate, FB102, is currently in clinical development. Forte has no products approved for commercial sale and has not generated any revenue from product sales to date, and Forte will continue to incur significant research and development and other expenses related to its ongoing operations. As a result, Forte is not profitable and has incurred losses in each year since its inception in 2017. For the twelve months ended December 31, 2025, Forte reported a net loss of $69.4 million. As of December 31, 2025, Forte had an accumulated deficit of $223.4 million. Forte expects to continue to incur significant losses for the foreseeable future, and Forte expects these losses to increase as Forte continues its research and development of, and seeks regulatory approvals for, its current lead product candidate, FB102, and any future product candidates Forte may seek to develop. Forte anticipates that its expenses will increase substantially if, and as, it:

- conducts additional preclinical studies and clinical trials for FB102 and any future product candidates;
- continues to discover and develop additional applications for FB102 and any future product candidates;
- maintains, expands and protects its intellectual property portfolio;
- hires or contracts additional clinical, scientific, manufacturing and commercial personnel to support its product development and commercialization efforts;
- validates a manufacturing process and specifications for FB102 and any future product candidates;
- establishes in-house manufacturing capabilities;
- establishes a commercial manufacturing source and secures supply chain capacity sufficient to provide clinical trial material and commercial quantities of any product candidate for which Forte may obtain regulatory approval;
- acquires or in-licenses other product candidates and technologies;
- seeks various regulatory approvals;
- establishes a sales, marketing and distribution infrastructure to commercialize any product candidate for which Forte may obtain regulatory approval; and
- adds operational, compliance, financial and management information systems and personnel to support being a public company.

To become and remain profitable, Forte or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require Forte to be successful in a range of challenging activities, including completing additional preclinical studies and clinical trials, obtaining marketing approval for FB102 or any future product candidates, manufacturing, marketing and selling products for which Forte may obtain marketing approval and satisfying any post-marketing requirements. Forte may never succeed in any or all of these activities and, even if Forte does, Forte may never generate revenue that is significant enough to achieve profitability. If Forte does achieve profitability, it may not be able to sustain or increase profitability on a quarterly or annual basis. Forte's failure to become and remain profitable would decrease the value of the company and could impair its ability to raise capital, maintain its research and development efforts, expand its business or continue its operations.

Even if Forte succeeds in obtaining regulatory approval and commercializing its current product candidate, FB102, Forte may continue to incur substantial research and development and other expenditures to develop and market additional applications for its current product candidate or any future product candidates. Forte may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect its business. The size of its future net losses will depend, in part, on the rate of future growth of its expenses and its ability to generate revenue. Forte's prior losses and expected future losses have had and will continue to have an adverse effect on its stockholders' equity and working capital.

Forte's ability to successfully develop any product candidate is highly uncertain.

Forte's ability to successfully develop FB102 or any other future product candidate is highly uncertain and is dependent on numerous factors, many of which are beyond Forte's control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical study or clinical trial results may show the product candidate to be less effective than desired or to have harmful or problematic side effects or toxicities;
- clinical trial results may show the product candidate to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to execute the clinical trials caused by slow enrollment in clinical trials, patients dropping out of clinical trials, length of time to achieve clinical trial endpoints, additional time requirements for data analysis, inability to validate the manufacturing process or to achieve cGMP compliance for the product candidate or inability to identify a suitable bioanalytical assay method agreeable to applicable regulators;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, delays in preparation responding to an FDA request for additional clinical data or unexpected safety or manufacturing issues;
- manufacturing costs, formulation issues, manufacturing deficiencies or other factors that make FB102 or any future product candidate uneconomical; and
- proprietary rights of others and their competing products and technologies that may prevent FB102 or any future product candidate from being commercialized.

The length of time necessary to complete clinical trials and to submit an application for marketing approval of a drug product candidate for a final decision by a regulatory authority may be difficult to predict for FB102 or any future product candidate, in large part because of its limited regulatory history.

Even if Forte is successful in obtaining market approval for a drug product, commercial success of any approved products will also depend in large part on marketing acceptance, the availability of insurance coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. For example, in August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. For 2026, CMS selected 10 high-cost Medicare Part D drugs in 2023 and the negotiated maximum fair price for each drug has been announced. CMS has selected 15 additional Medicare Part D drugs for negotiated maximum fair pricing in 2027. For 2028, up to an additional 15 drugs, which may be covered under either Medicare Part B or Part D, will be selected, and for 2029 and subsequent years, up to 20 additional Part B or Part D drugs will be selected. Various industry stakeholders, including pharmaceutical companies and the

Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. Government agreements with pharmaceutical companies and other government measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increases generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear.

Individual states in the United States have also become increasingly active in implementing 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. For example, FDA has authorized the state of Florida to develop a program to import certain prescription drugs from Canada for a limited period to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We expect that additional state and federal healthcare reform measures will be adopted in the future. Any reduction in reimbursement from Medicare or other government programs may result in a reduction in payments from private payors. Third-party payors could require Forte to conduct additional studies, including post-marketing studies related to the cost-effectiveness of the product, to qualify for reimbursement, which could be costly and divert its resources. If government and other healthcare payors were not to provide adequate insurance coverage and reimbursement levels for any of its drug products once approved, market acceptance and commercial success would be reduced.

In addition, if any of Forte's drug product candidates, including FB102, are approved for marketing, Forte will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration. If approved, any of its drug products would be subject to restrictions on its products' labels and other conditions of regulatory approval that may limit its ability to market its products. Forte will also need to comply (and ensure that its third-party contractors comply) with cGMPs, and Good Clinical Practice ("GCP"), as Forte (and its third-party contractors) will be required to comply with these requirements for the products or product candidates used in its clinical trials or post-approval studies. In addition, Forte will need to comply with GCPs for any clinical trial conducted for any therapeutic indications Forte may develop for approval. In addition, there is always the risk that Forte or a regulatory authority might identify previously unknown problems with a drug product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements and other regulatory requirements is costly and any failure to comply or other issues with its product post-approval could have a material adverse effect on its business, financial condition and results of operations.

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

To obtain the requisite regulatory approvals to commercialize any product candidate, Forte must demonstrate through extensive clinical trials that its product candidate is safe and effective in humans for its intended use. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. As seen with the FB-401 trial, Forte may be unable to establish clinical endpoints, dose levels and regimens or bioanalytical assay methods that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. The outcome of preclinical studies and early clinical trials may not necessarily be predictive of the success of later clinical trials, and interim results of these studies or trials do not necessarily predict final results. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidate performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidate.

Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, and similar marketing applications to comparable foreign regulatory authorities, for each product candidate, and, consequently, the ultimate approval and commercial marketing of any product candidate.

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

- regulators or IRBs, or ethics committees may not authorize Forte or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- Forte may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of any product candidate may fail to show safety, purity or potency, or produce negative or inconclusive results and Forte may decide, or regulators may require it, to conduct additional preclinical studies or clinical trials or Forte may decide to abandon product development programs;
- the number of patients required for clinical trials of any product candidate may be larger than Forte anticipates, enrollment in these clinical trials may be slower than Forte anticipates, or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than Forte anticipates;
- clinical trials of its product candidates may produce negative or inconclusive results, and Forte may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- regulators may require Forte to perform additional or unanticipated clinical trials to obtain approval or Forte may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving its product candidates, or such requirements may not be as Forte anticipates;
- Forte's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to it in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that Forte add new clinical trial sites or investigators;
- the cost of clinical trials of its product candidates may be more than Forte anticipates or more than its available financial resources, and Forte may need to delay or suspend one or more trials until Forte completes additional financing transactions or otherwise receives adequate funding;
- the supply or quality of Forte's product candidates or other materials necessary to conduct clinical trials of its product candidate may be insufficient or inadequate and may not achieve compliance with applicable cGMPs;
- Forte's product candidates may have undesirable side effects or other unexpected characteristics, causing it or its investigators, regulators or IRBs or ethics committees to suspend or terminate clinical trials, or reports may arise from clinical testing of its product candidate that raise safety or efficacy concerns about its product candidate;
- clinical trials of Forte's product candidates may produce negative or inconclusive results, which may result in it deciding, or regulators requiring it, to conduct additional clinical trials or suspend or terminate its clinical trials;
- the FDA or other regulatory authorities may disagree with the design, implementation or results of its clinical trials, or require Forte to submit additional data such as long-term toxicology studies or impose other requirements before permitting it to initiate a clinical trial;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- Forte's limited experience in filing and pursuing a BLA necessary to gain regulatory approval;
- any failure to develop substantial evidence of clinical efficacy and safety, and to develop quality standards and manufacturing processes to demonstrate consistent safety, purity, identity, and/or potency standards;
- a decision by Forte, IRBs, or regulators to suspend or terminate its clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulatory inspections of its clinical trials, clinical trial sites or manufacturing facilities, which may, among other things, require Forte to undertake corrective action or suspend or terminate its clinical trials if regulators find it not to be in compliance with applicable regulatory requirements;

- Forte's ability to produce sufficient quantities of the product candidate to complete its clinical trials;
- varying interpretations of the data generated from its clinical trials; and
- changes in governmental regulations or administrative action.

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

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

Forte's planned additional preclinical studies or current and future clinical trials or those of its future collaborators may reveal significant adverse events and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of its product candidates.

Before obtaining regulatory approvals for the commercial sale of any products, Forte must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that FB102 is both safe and effective for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The results of preclinical studies as well as early clinical trials of a product candidate may not necessarily be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such clinical trials are completed. There is typically an extremely high rate of attrition from the failure of product candidate proceeding through clinical trials.

While we announced positive data from our Phase 1b trial in celiac disease for FB102 in June 2025, Forte's FB102 may fail to show the desired safety and efficacy profile in subsequent clinical trials. A number of companies in the life sciences industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy and/or unacceptable safety issues, notwithstanding promising results in earlier preclinical studies or clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of its future clinical trials would be successful or support further clinical development of any product candidates.

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

Positive results from early preclinical studies and clinical trials may not necessarily be predictive of the results of any current or future clinical trials of product candidates. Forte may be unable to successfully develop, obtain regulatory approval for and commercialize any product candidates.

While we announced positive data from our Phase 1b trial in celiac disease for FB102 in June 2025, any positive results from our preclinical studies and clinical trials of any product candidates may not necessarily be predictive of results from later stage studies or required clinical trials. Similarly, even if Forte is able to complete future clinical trials of FB102 or any other product candidates according to its current development timeline, the positive results from such future clinical trials may not be replicated in subsequent clinical trial results.

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

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

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

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

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

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

The market opportunities for FB102 may be limited and Forte's estimates of the incidence and prevalence of its target patient populations may be inaccurate.

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

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

The life sciences industry is characterized by intense competition and rapid innovation. Forte's competitors may be able to develop other compounds or products that are able to achieve similar or better results. Forte's potential competitors include major multinational pharmaceutical, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of its competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make any product candidate that Forte develops obsolete. Mergers and acquisitions in the life sciences industry may result in even more resources being concentrated amongst its competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Forte's competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing therapies that are more effective, safer, more easily commercialized or less costly than FB102 or may develop proprietary technologies or secure patent protection that Forte may need for the development of potential technologies and products. Forte believes the key competitive factors that will affect the development and commercial success of its product candidate are efficacy, safety, tolerability, reliability, convenience of use, compliance with regulatory requirements, acceptance by patients or prescribers, competitive pricing and reimbursement.

Forte anticipates competing with the largest life sciences companies in the world, many of which have greater financial, human, and manufacturing resources than Forte currently has. In addition to these fully integrated life sciences companies, Forte will also compete with those companies whose products target the same indications as FB102 or any future product candidate Forte develops. They include pharmaceutical companies, biotechnology companies, academic institutions and other research organizations. Any treatments developed by its competitors could be superior to any product candidates Forte develops. It is possible that these competitors will succeed in developing technologies that are more effective than Forte's potential products or that would render any of Forte's product candidate obsolete or noncompetitive. Forte anticipates that it will face increased competition in the future as additional companies enter its market and scientific developments surrounding competing therapies continue to accelerate.

Even if FB102 or any other product candidate that Forte develops receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, consumers and others in the medical or life sciences community necessary for commercial success.

If FB102 or any other future product candidate Forte develops receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, consumers and others in the medical community. If any such product candidate Forte develops does not achieve an adequate level of acceptance, Forte may not generate significant product revenues and Forte may not become profitable. The degree of market acceptance of any of Forte's product candidates, if approved for commercial sale, will depend on a number of factors, including:

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

Forte's operations and financial results could be adversely impacted by the public health emergencies or other disruptions to the industry.

While the extent of the impact of public health outbreaks on Forte's business and financial results is uncertain, including indirect impact via third parties Forte contracts with, a continued and prolonged public health crisis could have a negative impact on its business, financial condition and operating results. To the extent any global pandemic, such as the COVID-19 pandemic, impacts operations in the United States, its clinical studies could be slowed or delayed, or in a more severe scenario, its business, financial condition and operating results could be more severely affected.

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

As of March 27, 2026, Forte had 23 full-time employees. As its research, development, manufacturing and commercialization plans and strategies continue to focus on the development of FB102, including for additional indications, and any other future product candidates, Forte expects to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

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

Forte's future financial performance and its ability to commercialize FB102 or any future product candidate will depend, in part, on its ability to effectively manage any future growth, and its management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

Forte currently relies, and for the foreseeable future will continue to rely, in substantial part on certain organizations, advisors and consultants to provide certain services, including many aspects of regulatory affairs, clinical management and manufacturing. There can be no assurance that the services of these organizations, advisors and consultants will continue to be available to Forte on a timely basis when needed or that Forte can find qualified replacements. In addition, if Forte is unable to effectively manage its outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, its preclinical studies and clinical trials may be extended, delayed or terminated, and Forte may not be able to obtain regulatory approval of FB102 or any other future product candidate or otherwise advance its business. There can be no assurance that Forte will be able to manage its existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

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

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

Forte's current operations are located in Texas. Any unplanned event, such as flood, fire, tornado, explosion, earthquake, extreme weather condition, medical epidemics, such as the COVID-19 outbreak, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in it being unable to fully utilize its facilities, or the manufacturing facilities of its third-party contract manufacturers, may have a material and adverse effect on its ability to operate its business, particularly on a daily basis, and have significant negative consequences on its financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of its product candidate or interruption of its business operations. Any natural disasters could further disrupt its operations and have a material and adverse effect on its business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented it from using all or a significant portion of its headquarters, that damaged critical infrastructure, such as its research facilities or the manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for Forte to continue its business for a substantial period of time. As part of its risk management policy, Forte maintains insurance coverage at levels that Forte believes are appropriate for its business. However, in the event of an accident or incident at these facilities, Forte cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If its facilities, or the manufacturing facilities of its third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of its research and development programs may be harmed. Any business interruption may have a material and adverse effect on its business, financial condition, results of operations and prospects.

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

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

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

Forte's internal computer systems, or those used by its Clinical Research Organizations ("CROs"), Contract Manufacturing Organizations ("CMOs") or other contractors or consultants, may fail or suffer security breaches.

We are dependent upon information technology systems, infrastructure and data. In the ordinary course of our business, we directly or indirectly collect, use, generate, transfer, disclose, maintain, dispose of, or otherwise process (collectively, "Process" or "Processing") sensitive data, including intellectual property, confidential information, preclinical and clinical trial data, proprietary business information, personal data and personally identifiable health information of our clinical trial subjects and employees, in our data centers and on our networks, or on those of third-party service providers. The secure Processing of this information is critical to our operations. Our obligations under applicable laws, regulations, contracts, industry standards, and other documentation may include maintaining the confidentiality, integrity, and availability of such data in our possession or control, maintaining reasonable and appropriate security safeguards as part of an information security program, and restrictions on the use and disclosure of such data. These obligations create potential liability to regulators, business partners, personnel, and other relevant stakeholders. The multitude and complexity of our computer systems and those of our CROs, CMOs, clinical sites or other contractors or consultants make them inherently vulnerable to service interruption or destruction, malicious intrusion attempts and other attacks, and random attacks. Security breaches or incidents, whether resulting from inadvertent or intentional acts or omissions by third-party service providers, employees, contractors or others pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, business partners, or others could have been and may be exposed to unauthorized persons or to the public or otherwise lost, destroyed, altered, disclosed, disseminated, damaged, made unavailable or otherwise Processed without authorization.

Although we take measures designed to protect such information from unauthorized Processing, our internal computer systems and those of our CROs, CMOs, clinical sites and other contractors and consultants are vulnerable to cyberattacks, computer viruses, bugs or worms, and other attacks by computer hackers, cracking, application security attacks, social engineering, supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), extortion, and intentional disruptions of service; computer and network vulnerabilities or the negligence and malfeasance of individuals with authorized access to our information, failure or damage from natural disasters, terrorism, war, fire and telecommunication and electrical failures. Ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Third parties may also attempt to fraudulently induce our employees, contractors, consultants, or third-party service providers into disclosing sensitive information such as usernames, passwords, or other information or otherwise compromise the security of our computer systems, networks, and/or physical facilities in order to gain access to our data. Cyberattacks are increasing in their frequency, sophistication and intensity. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups, such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Geopolitical tensions or conflicts have in the past led to, and may in the future lead to, increased risk of cybersecurity attacks. Moreover, advancements in technology, such as artificial intelligence and machine learning, are changing and may continue to change the way companies are subjected to attempts to gain unauthorized access and disrupt systems, thereby increasing the risks of security threats and attacks. Additionally, some of our employees work remotely, which may pose additional data security risks. While we have invested, and continue to invest, in the protection of our data and information

technology infrastructure, there can be no assurance that our efforts, or the efforts of our partners, vendors, CROs, CMOs, clinical sites and other contractors and consultants will prevent service interruptions, or identify breaches or incidents in our or their systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. Furthermore, we may not have adequate insurance coverage to protect us from, or adequately mitigate, liabilities or costs resulting from security breaches and incidents. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

If any such event were to occur and cause interruptions in our operations, it could result in a disruption of our development of product candidates. For example, the loss or unauthorized modification or unavailability of clinical trial data from completed or ongoing clinical trials for FB102 could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required. We expect to incur significant costs in an effort to detect and prevent security breaches and incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident. To the extent that any disruption or security breach or incident were to result in a loss of or damage to our data or applications, or the loss, destruction, alteration, prevention of access to, disclosure, or dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal, confidential, or proprietary information) processed or maintained on our behalf, or any of these is perceived or believed to have occurred, we could incur liability and the further development of any product candidates could be delayed. Any such event or the perception that it has occurred, could also result in legal claims, demands, litigation or other proceedings by private actors, regulatory investigations or other proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, injunctive relief, mandatory corrective action, and other remedies, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

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

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

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

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, import or export controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act ("FCPA"), or comparable foreign regulations;
- challenges enforcing its contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, terrorism and public health crises, such as COVID-19 and its variants.

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

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

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

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

Tax reform legislation could adversely affect Forte's business and financial condition.

Recent changes to U.S. tax laws, as well as changes to U.S. or international tax laws that may be enacted in the future, could impact the tax treatment of Forte's business and financial condition. For example, in July 2025, the United States enacted federal tax legislation commonly referred to as the One Big Beautiful Bill (the "OBBB Act"). The new tax law did not have a material impact on our effective income tax rate and net deferred federal income tax assets, as we continue to maintain a full valuation allowance, similar legislation passed in the future could adversely affect our financial condition and results of operations. In addition, many countries in Europe, as well as a number of other countries and organizations, have recently considered changes to existing tax law that could adversely affect Forte's financial condition and results of operations.

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

As of December 31, 2025, Forte has U.S. federal and state net operating loss ("NOL") carryforwards of $59.8 million and $11.6 million, respectively. Under current law, the federal NOL carryforwards have an indefinite life but the deductibility of such federal NOL carryforwards will be limited to 80% of Forte's current year taxable income and generally may not be carried back to prior taxable years. All of Forte's state NOL carryforwards expire beginning in 2037. These NOL carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future federal taxable income or taxes. For these purposes, an ownership change generally

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

Unstable market and economic conditions, including adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, may have serious adverse consequences on Forte's business, financial condition, results of operations, and stock price.

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

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

In addition, actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all.

Changes in United States trade policy, with regard to tariffs, could have a material adverse impact on our business, financial condition, and results of operations.

Changes in United States trade policy, including with regard to tariffs, could have a material adverse impact on our business, financial condition, and results of operations. The imposition of retaliatory or new tariffs or increases in existing tariffs on goods imported from countries where we source study or trial material or supplies from third party suppliers could result in increased material costs for us. If we are unable to mitigate these risks through supply chain adjustments, such as changing third party suppliers, the development, testing and clinical trials of our drug candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

If we, or our wholly-owned subsidiary, lose our ability to operate in Australia, or if our subsidiary is unable to benefit from the past or future R&D tax rebates available under current Australian regulations, our business and results of operations could be harmed.

Through our wholly-owned subsidiary in Australia, we conduct certain R&D activities, including some of our clinical trials. Current Australian tax regulations provide for a R&D cash rebate on qualified R&D activities incurred in the country. The Australian R&D tax incentive program is a self-assessment program, and as such, the Australian Taxation Office (ATO) has the right to review our program and our related expenditures for a period of four years following the tax return filing date. If we are ineligible or unable to receive the anticipated cash rebate, if past rebates are determined to be ineligible upon an audit by the ATO, or if the Australian government significantly reduces or eliminates the rebate, our business and results of operations would be adversely affected.

Due to the geographic distance from our headquarters, we may not be able to successfully monitor or conduct our clinical trials and R&D activities in Australia. We can provide no assurance that the results of any clinical trials that we conduct in Australia will be accepted by the FDA or other foreign authority. Furthermore, if we lose our ability to operate our subsidiary in Australia, our business and results of operations may be adversely affected.

Risks related to government regulation

Forte is early in its development efforts. FB102 will require significant additional clinical development before Forte seeks regulatory approval of any product candidate. If Forte is unable to continue or advance the clinical development of FB102, obtain regulatory approval and ultimately commercialize a product candidate or experiences significant delays in doing so, its business will be materially harmed.

Forte is early in its development efforts and will invest substantially all of its efforts and financial resources in the development of FB102. Its ability to generate product revenues, which Forte does not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of a product candidate, which may never occur. Forte currently generates no revenue from sales of any products, and Forte may never be able to develop or commercialize a marketable product. The success of FB102 will depend on several factors, including the following:

- successful completion of additional preclinical studies and clinical trials;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for FB102;
- establishing cGMP-compliant clinical supply and commercial manufacturing operations or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for FB102;
- launching commercial sales of FB102, if and when approved or allowed for marketing, whether alone or in collaboration with others;
- acceptance of FB102, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims;
- the marketing of FB102; and
- maintaining a continued acceptable safety profile of FB102 following approval or commercialization.

If Forte does not achieve one or more of these factors in a timely manner or at all, Forte could experience significant delays or an inability to successfully commercialize FB102, which would materially harm its business. If Forte does not receive regulatory approvals for FB102, it may not be able to continue its operations.

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

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

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

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

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

Further, under the current administration, mass layoffs due to the reduction in force initiative and other measures implemented by the Department of Government Efficiency may impact the normal operations of the FDA as well as other federal agencies. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. In January 2025, an executive order entitled "Unleashing Prosperity Through Deregulation", was issued which calls for at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. Recent developments at the FDA include implementation of Elsa, a generative AI tool, across all centers at the agency, announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, and the announcement of a new Commissioner's National Priority Voucher program to companies supporting certain U.S. national health priorities and interests. FDA has also increased its scrutiny of foreign drug manufacturing facilities and other contractors based in China, especially with respect to the transfer of biological materials, genetic data, and other sensitive data of American patients to parties located in China. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our competitive advantage and intellectual property. It is unclear how our industry and our clinical programs will be impacted by policies and regulations implemented under the current administration and FDA commissioner, or other executive orders. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent agency changes and new policies lead to disruptions in FDA's operations, our correspondence and regulatory review processes with the FDA may be materially delayed.

Inadequate funding, layoffs, changes in agency leadership, and other policies and executive orders impacting the normal operations of the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the approval of Forte's product candidates rely, which would negatively impact its business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. Changes in the leadership of the FDA and other federal agencies under the current administration, including return-to-office policy, hiring freeze, layoffs, and other measures implemented by the Department of Government Efficiency, may also lead to changes in the operations of the FDA and other federal agencies, which may have a material impact on our business operations and the industry as a whole. In addition, government funding of the SEC and other government agencies on which its operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

If a prolonged government shutdown or other disruption occurs, including due to government shutdowns, furloughs, budget constraints, travel restrictions, staffing shortages, or if global health or other concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process its regulatory submissions, which could have a material adverse effect on our business, including our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute can constitute a false or fraudulent claim under the False Claims Act ("FCA"). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and a referral source on the other, including prescribers, purchasers, and formulary managers. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;

- federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil

actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare professionals (such as physician assistants and nurse practitioners, among others), and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- General Data Protection Regulation and other ex-U.S. protections.

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

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

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

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

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

Obtaining and maintaining regulatory approval does not guarantee that Forte will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the

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

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

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

To proceed with its development plans and ultimately commercialization of FB102, Forte will be required to conduct additional preclinical studies and clinical trials. Forte cannot be certain of the timely completion or outcome of its preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept its proposed clinical programs, including the design, dose level, and dose regimen, or if the outcome of its preclinical testing and studies will ultimately support the development of its clinical programs.

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

Any product candidate Forte may develop and the activities associated with the development and commercialization of such product candidate, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before Forte can commercialize any product candidate, Forte must obtain marketing approval. Forte has never received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that no product candidates will ever obtain regulatory approval. Forte, as a company, has no experience in filing and supporting the applications necessary to gain regulatory approvals and expects to rely on third-party CROs and/or regulatory consultants to assist it in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety, efficacy, purity, and potency.

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

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

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

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

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

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

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

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

Forte's product candidate, FB102, or any future product candidate Forte develops, may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

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

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

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

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

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

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

If FB102 or any other product candidate Forte develops is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, Forte will be subject to continued compliance with cGMP and GCP requirements for any clinical trials that Forte conducts post-approval.

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

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

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

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

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

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any product candidate Forte develops. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine in the *Loper Bright* decision, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA to challenge longstanding decisions and policies of the FDA, including FDA's statutory interpretations of market exclusivities and the "substantial evidence" requirements for drug approvals, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. Further, under the current administration, agency reorganization, departure of high-profile regulators at the FDA, layoffs due to the reduction in force initiative, government shutdown, and a lapse of U.S. government appropriations may impact the normal operations at the FDA as well as other federal agencies. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. In January 2025, the federal government issued an executive order entitled "Unleashing Prosperity Through Deregulation", which calls for at least 10 existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. Fewer agency guidance documents could interfere with FDA programs or lead to more Complete Response Letters or refusals to approve products. It is unclear how our industry and our clinical programs will be impacted by policies and regulations implemented under the current administration. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent the agency reorganization and other agency changes lead to disruptions in FDA's operations, including changes resulting from executive orders; freeze on hiring, federal funding for research, and external communications; layoffs; government shutdowns; return-to-office policies; and changes in funding for certain programs at the FDA, correspondence and regulatory review processes with the FDA may be materially delayed. Forte cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. To the extent any legislative, administrative, or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if Forte is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if Forte is not able to maintain regulatory compliance, Forte may lose any marketing approval that Forte may have obtained, and Forte may not achieve or sustain profitability.

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

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

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

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by

the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

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

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

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

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

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Risks related to Forte's intellectual property

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

Forte's success depends in large part on its ability to obtain and maintain patent protection in the United States and other countries with respect to any product candidate and other technologies Forte may develop. Given that the development of its technology is at an early stage, its intellectual property portfolio with respect to certain aspects of its technology and any product candidates is also at an early stage. Forte has filed and intends to file patent applications on these aspects of its technology and any product candidates; however, there can be no assurance that any such patent applications will issue as granted patents.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. Forte

cannot be certain, however, that the claims in its future patent applications covering the composition of matter of any product candidates will be considered patentable by the United States Patent and Trademark Office ("USPTO"), or by patent offices in foreign countries, or that the claims in any of its issued patents will be considered valid and enforceable by courts in the United States or foreign countries.

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

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

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

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

Any patents that Forte may own in the future may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, Forte does not know whether any product candidate or other technologies it develops will be protectable or remain protected by valid and enforceable patents. Forte's competitors or other third parties may be able to circumvent Forte's future patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect its business, financial condition, results of operations and prospects.

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

challenge its priority of invention or other features of patentability with respect to any future owned patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit its ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of any product candidates Forte develops. Such proceedings also may result in substantial cost and require significant time from its scientists and management, even if the eventual outcome is favorable to us.

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

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

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

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

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

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

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

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

- the scope of the option or license rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the collaborator that is not subject to the option or license rights granted under the agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- Forte's diligence obligations under the agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our collaborators and us and our other partners; and
- the priority of invention of patented technology.

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

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

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

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

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

In Europe, beginning June 1, 2023, European applications and patents may be subjected to the jurisdiction of the Unified Patent Court ("UPC") unless those are explicitly opted out. Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for United States-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-United States manufacturers.

Although we do not currently own issued patents or pending patent applications that have been generated through the use of United States government funding, we may obtain intellectual property rights in future on patents and patent applications that have been generated through the use of United States government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the United States government has certain rights in inventions developed with government funding. On December 8, 2023, the National Institute of Standards and Technology ("NIST") released the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights ("Guidance") to the public for comment. The Guidance represents the first federal framework specifying that price can be a factor in considering whether the government may exercise its march-in authority pursuant to 35 U.S.C. 200 et seq. (Bayh-Dole). These United States government march-in rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the United States government has the right, under certain limited circumstances, to require us to

grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations, also referred to as march-in rights. If the United States government exercised its march-in rights in our future intellectual property rights that are generated through the use of United States government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the United States government for the exercise of such rights. The United States government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the United States government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for United States industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for United States industry may limit our ability to contract with non-United States product manufacturers for products covered by such intellectual property.

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

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

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

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

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

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent

protection available in certain circumstances or weakening the rights of patent owners in certain situations. It is unpredictable how decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of Forte's patent rights. For example, the Supreme Court of the United States held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit issued a decision involving the interaction of patent term adjustment ("PTA"), terminal disclaimers, and obvious-type double patenting. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on Forte's future patent portfolio and its ability to protect and enforce its intellectual property in the future.

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

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

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

Patents have a limited lifespan. In the United States and abroad, if all maintenance fees/annuity fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date. The protection a patent affords is limited. Even if patents covering Forte's products are obtained, once the patent life has expired, Forte may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, Forte's future owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

Forte may be subject to claims that former employees, collaborators or other third parties have an interest in its owned patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. For example, Forte may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing its product candidate or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or its ownership of its owned patent rights, trade secrets or other intellectual property. If Forte fails in defending any such claims, in addition to paying

monetary damages, Forte may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to its product candidate and other technologies. Even if Forte is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on Forte's business, financial condition, results of operations and prospects.

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

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

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

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

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

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

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

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

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

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

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to autoimmune technologies and in the fields in which Forte is developing its product candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that its product candidate and other technologies may give rise to claims of infringement of the patent rights of others. Forte cannot assure you that its product candidate and other technologies that Forte has developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. Forte may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which Forte is developing its product candidate and other technologies, might assert infringement by future Forte product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover future Forte product candidates or other technologies. It is also possible that patents owned by third parties of which Forte is aware, but which Forte does not believe Forte infringes or that Forte believes Forte has valid defenses to any claims of patent infringement, could be found to be infringed by Forte. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to Forte's product candidates. As such, we monitor third-party patents in the fields in which Forte is developing its product candidate. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that future Forte product candidates or other technologies may infringe. Generative artificial intelligence (AI) resources that are publicly available also present a risk that Forte may inadvertently obtain, incorporate, or use a third party's intellectual property. Forte cannot provide any assurances that third-party patents do not exist which might be enforced against its current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting its manufacture or future sales, or, with respect to its future sales, an obligation on its part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Forte may identify third-party patents in which it will determine that the best course of action is to challenge the validity of such third-party patents in a post-grant proceeding at the USPTO, such as in a reexamination, or a post-grant and inter partes review. Such third-party patents may have claims broadly covering autoimmune technologies in which Forte is developing its product candidate. Forte recently identified U.S. Patent No. 11,278,505, owned by the University of Massachusetts, which claims broad field of autoimmune technologies. Forte filed a petition for post grant review of U.S. Patent No. 11,278,505 (the "'505 Patent"), owned by the University of Massachusetts, at the Patent Trial and Appeal Board ("PTAB") on December 22, 2022. On July 3, 2023, the PTAB issued a decision to institute review. On June 24, 2024, the PTAB issued a final written decision, finding all claims of the '505 Patent unpatentable. The University of Massachusetts filed a request for rehearing on July 24, 2024. The PTAB denied the request for rehearing on October 30, 2024. The University of Massachusetts filed a notice of appeal on December 30, 2024. The outcome of such post-grant proceedings is uncertain and if the USPTO upholds the validity of a third-party patent, it could have an adverse impact on Forte's ability to commercialize its future products, including either an injunction prohibiting its manufacture or future sales, or, with respect to its future sales, an obligation on its part to pay royalties and/or other forms of compensation to third parties, which could be significant. Regardless of outcome, challenging the validity of third-party patents can have an adverse impact on us due to legal fees and expenses, diversion of management resources, negative publicity, reputational harm and other factors.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of Forte's product candidates or other technologies infringes upon these patents. In the event that any third-party claims that Forte infringes their patents or that Forte is otherwise employing their proprietary technology without authorization and initiates litigation against us, even if Forte believes such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by Forte's product candidates or other technologies. In this case, the holders of such patents may be able to block Forte's ability to commercialize the applicable product candidate or technology unless Forte obtains a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if Forte is able to obtain a license, the license would likely obligate Forte to pay license fees or royalties

or both, and the rights granted to Forte might be non-exclusive, which could result in its competitors gaining access to the same intellectual property. If Forte is unable to obtain a necessary license to a third-party patent on commercially reasonable terms, Forte may be unable to commercialize its product candidates or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm Forte's business.

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

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

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

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

- it is possible that Forte's future pending owned patent applications will not lead to issued patents;
- future issued patents that Forte holds rights to may be held invalid or unenforceable, including as a result of legal challenges by its competitors or other third parties;
- Forte's competitors or other third parties might conduct research and development activities in countries where Forte does not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- Forte may not develop additional proprietary technologies that are patentable;
- the patents of others may harm Forte's business; and
- Forte may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks related to Forte's reliance on third parties

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

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

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

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

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, or if these third parties need to be replaced, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our

efforts to, successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

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

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

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

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

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

- third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- current and future third parties may not perform their obligations as expected;
- current and future third parties may not pursue development and commercialization of any product candidate that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic merger that may divert resources or create competing priorities;
- third parties may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- current and future third parties could independently develop, or develop with third parties, products that compete directly or indirectly with Forte's products and product candidate if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with Forte may be viewed by its current or future third parties as competitive with their own product candidate or products, which may cause such third parties to cease to devote resources to the commercialization of its product candidate;
- current and future third parties may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- current and future third parties with marketing and distribution rights to one or more of Forte's product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with current or future third parties, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidate, might lead to additional responsibilities for Forte with respect to product candidate, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- current and future third parties may not properly maintain or defend its intellectual property rights or may use its proprietary information in such a way as to invite litigation that could jeopardize or invalidate its intellectual property or proprietary information or expose Forte to potential litigation;
- current and future third parties may infringe the intellectual property rights of third parties, which may expose Forte to litigation and potential liability;
- if a current or future third parties of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by Forte; and
- current and future relationships may be terminated by the collaborator, and, if terminated, Forte could be required to raise additional capital to pursue further development or commercialization of the applicable product candidate.

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

of the risks relating to product development, regulatory approval and commercialization described in this prospectus also apply to the activities of its collaborators.

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

Relationships are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Forte faces significant competition in seeking appropriate collaborators. Forte's ability to reach a definitive agreement for a collaboration will depend, among other things, upon its assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If Forte is unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, Forte may have to curtail the development of a product candidate, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense. If Forte elects to increase its expenditures to fund development or commercialization activities on its own, Forte may need to obtain additional expertise and additional capital, which may not be available to it on acceptable terms, or at all. If Forte fails to enter into relationships or does not have sufficient funds or expertise to undertake the necessary development and commercialization activities, Forte may not be able to further develop its product candidates, bring them to market and generate revenue from sales of drugs or continue to develop its technology, and its business may be materially and adversely affected.

General Risks

The market price of Forte's common stock is expected to be volatile. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies.

The market price of Forte's common stock could be subject to significant fluctuations. For example, Forte's announcement in September 2021 that the clinical trial of FB-401 for the treatment of AD failed to meet statistical significance for its primary endpoint of EASI-50 (the proportion of patients with at least a 50% improvement in atopic dermatitis disease severity as measured by EASI) resulted in a significant decline in the market price of Forte's common stock. Following the announcement on September 2, 2021, the price of Forte's common stock dropped $588.25 per share, or approximately 82%, from $714.75 per share as of the close of business on September 2, 2021 to $126.50 per share as of the close of business on September 3, 2021. The closing price of Forte's common stock on March 27, 2026, was $25.50 per share. Some of the factors that may cause the market price of Forte's common stock to fluctuate include:

- any strategic decisions that Forte pursues or announces, including Forte's decision to focus on the development of FB102;
- Forte's ability to obtain regulatory approvals for any product candidates it develops, and delays or failures to obtain such approvals;
- failure of any of Forte's product candidates, if approved, to achieve commercial success;
- Forte's failure to maintain its existing third-party license and supply agreements;
- failure by Forte or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to product candidates Forte develops;
- any inability to obtain adequate supply of any product candidates Forte develops or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services or technologies by Forte's competitors;
- failure to meet or exceed financial and development projections Forte may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by Forte or its competitors;

- disputes or other developments relating to proprietary rights, including patents, litigation matters, and Forte's ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- claims or litigation related to the Rights Plan;
- if securities or industry analysts do not publish research or reports about Forte's business, or if they issue an adverse or misleading opinion regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- the ability for Forte's common stock to continue to be listed on Nasdaq;
- sales of Forte's common stock by Forte or its stockholders in the future;
- trading volume of Forte's common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of Forte;
- changes in the structure of health care payment systems; and
- period-to-period fluctuations in Forte's financial results.

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

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the company's profitability and reputation and negatively impact our business.

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

The global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts in Ukraine and the Middle East, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such military conflicts, including in Eastern Europe and the Middle East, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Forte has previously been and may in the future be noncompliant with Nasdaq's minimum bid price requirement, which could result in the delisting of our common stock, negatively affect the price of our common stock and limit investors' ability to trade in our common stock.

Our common stock is listed on Nasdaq. Nasdaq rules impose certain continued listing requirements, including the minimum $1 bid price, corporate governance standards and number of public stockholders. On September 14, 2023, we were notified by Nasdaq that we are not compliant with its minimum bid price requirement because the closing bid price of our common stock was below $1.00 per share for 30 consecutive trading days. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial compliance period of 180 calendar days, or until March 12, 2024 to become compliant. On March 13, 2024, we received an extension of 180 calendar days, or until September 9, 2024 (the "Deadline Date"), to regain compliance with the minimum bid price requirement for a minimum of ten consecutive business days.

On August 28, 2024, we implemented a 1-for-25 reverse stock split. On September 12, 2024, we received a letter from Nasdaq that, for the 10 consecutive business days, the closing bid price of our common stock had been at $1.00 per share or greater. Accordingly, we have regained compliance with Nasdaq Listing Rule 5550(a)(2) and Nasdaq considers the prior minimum bid price deficiency matter now closed.

If, in the future, we fail to satisfy the continued listing requirements of Nasdaq, such as the minimum bid price requirement, Nasdaq may take steps to delist our shares of common stock. Such a delisting would have a negative effect on the price of our shares of common stock, impair the ability to sell or purchase our shares of common stock when persons wish to do so, and any delisting would materially and adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from Nasdaq could also have other negative results, including the potential loss of institutional investor interest and fewer business development opportunities, as well as a limited amount of news and analyst coverage of Forte. Delisting could also result in a determination that our shares of common stock are a "penny stock," which would require brokers trading in our shares of common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary market for our shares of common stock. In the event of a delisting, we would attempt to take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our shares of common stock to become listed again, stabilize the market price or improve the liquidity of our securities, prevent our shares of common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

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

As a public company, Forte incurs and will continue to incur significant legal, accounting and other expenses including costs associated with public company reporting requirements. Forte incurs costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act, as well as any new requirements implemented by the SEC and Nasdaq. These rules and regulations have increased Forte's legal and financial compliance costs from when it was a private company and make some activities more time consuming and costly. These rules and regulations also may make it difficult and expensive for Forte to obtain and maintain directors' and officers' liability insurance. As a result, it may be more difficult for Forte to attract and retain qualified individuals to serve on its board of directors or as executive officers, which may adversely affect investor confidence in and could cause Forte's business or stock price to suffer.

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

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

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

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

employees, which may discourage such lawsuits against Forte and its directors, officers and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, Forte may incur additional costs associated with resolving such action in other jurisdictions.

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

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

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

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

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

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

The company will have broad discretion in the use of proceeds from any capital raising efforts, including the 2023 Private Placement, 2024 Private Placement, the Offering and any future private placement financings or public offerings, and may invest or spend the proceeds in ways with which its stockholders do not agree and in ways that may not increase the value of their investments.

Forte has and will continue to have broad discretion over the use of proceeds from any capital raising efforts, including private placement financings and public offerings completed in 2020, 2023, 2024 and 2025 and an "at the market" equity offering program commenced in 2022. Its stockholders may not agree with Forte's decisions, and its use of the proceeds may not yield any return on its stockholders' investments. Forte's failure to apply the net proceeds of such financings effectively could compromise its ability to pursue its growth strategy and Forte might not be able to yield a significant return, if any, on its investment of these net proceeds. Forte's stockholders will not have the opportunity to influence its decisions on how to use the net proceeds from such financings.

If Forte experiences material weaknesses in or otherwise fails to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Forte is subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that Forte maintain effective disclosure controls and procedures and internal control over financial reporting. Forte must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal control over financial reporting in its Annual Report on Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This requires that Forte incur substantial professional fees and internal costs to expand its accounting and finance functions and that it expends significant management efforts. Forte may experience difficulty in meeting these reporting requirements in a timely manner.

During the audit process related to Forte's fiscal year ended December 31, 2022, management identified a material weakness in Forte's controls related to the review of the annual income tax provision which had been prepared by a third-party accounting firm that has since been remediated. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

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

evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of error or fraud will be detected.

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

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

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

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

As of December 31, 2025, Forte's executive officers, directors, holders of 5% or more of its capital stock and their respective affiliates beneficially owned a significant percentage of its outstanding voting stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of Forte's organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for Forte's common stock that you may feel are in your best interest as one of Forte's stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for Forte's common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We have implemented and maintain processes designed to identify, assess and manage material risks from cybersecurity threats to our computer networks, third party hosted services, communications systems, hardware and software, and our data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and personal information of employees and others ("Information Systems and Data").

Our information technology consultants help identify, assess and manage the Company's cybersecurity threats and risks. Our information technology consultants identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example: manual and automated cybersecurity tools such as malware scans and; vulnerability testing.

Depending on the environment, we implement and maintain technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate risks from cybersecurity threats to our Information Systems and Data, including, for example: employee training; access controls; data encryption; systems monitoring; regular patching of operating systems and software; and a password policy.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, our information technology consultants work with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We use third-party service providers to perform a variety of functions throughout our business, such as electronic communications service providers, cloud-based file storage service providers, and contract manufacturing and research organizations. We evaluate the cybersecurity posture of such third-party service providers, including whether such providers maintain appropriate security measures and, where appropriate, require them to implement and maintain reasonable security measures in connection with their work with us.

Our Board, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives updates, as needed, on cybersecurity and information technology matters and related risk exposures from our Chief Financial Officer as well as other members of the senior leadership team. The Board also receives updates from management and the Audit Committee on cybersecurity risks. For additional information regarding whether any risks from cybersecurity threats are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Item 2. Properties.

We entered into lease agreements in December 2021 for office space in Dallas, Texas and in April 2023 for laboratory space in San Diego, California. These lease agreements are cancellable by the Company with a six-month notice. We believe that our existing facilities are adequate to meet our current business requirements and that if additional space is required, it will be available on commercially reasonable terms. In addition, we believe that our existing facilities are in good condition, adequate and suitable for their intended purposes.

Item 3. Legal Proceedings.

For discussion of legal proceedings, see Note 6 to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders of Record

As of March 27, 2026, there were 168 registered stockholders of record. We are unable to estimate the actual number of stockholders as our shares are also held by brokers and other institutions on behalf of our stockholders.

Dividend Policy

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

Stock Price Performance Graph

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

Securities Authorized for Issuance Under Equity Compensation Plan

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

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

There were no repurchases of shares of common stock made during the year ended December 31, 2025.

Sales of Unregistered Securities

During the year ended December 31, 2025, there have been no unregistered sales of securities.

Item 6. Reserved

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

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

Overview

Forte Biosciences, Inc. and its subsidiaries (www.fortebiorx.com) ("Forte", "we", "our") is a clinical-stage biopharmaceutical company whose current lead product candidate is FB102. FB102 is a proprietary anti-CD122 monoclonal antibody therapeutic candidate with potentially broad autoimmune and autoimmune-related indications.

Our FB102 program aims to address key pathways implicated in these indications with a CD122 antagonist. CD122 is a subunit of IL-2/IL-15 receptors which are key regulators of NK cells and certain T cell subsets.

In FB102 mechanistic in-vitro studies, human donor T and NK cells were stimulated with either IL2 or IL15 in the presence or absence of FB102. FB102 significantly inhibited proliferation (4-5x inhibition in the proliferation of T cells and 6-8 fold inhibition in the proliferation of NK cells) and also inhibited activation of T cells. The level of FB102 inhibition of proliferation and activation was at levels comparable to unstimulated cells. Human donor regulatory T cell (Treg) studies stimulated with IL2 demonstrated comparable proliferation both in the presence and absence of FB102. Additionally, *in-vitro* assays demonstrated superiority of FB102 compared to competing antibodies.

In 4- and 13-week non-human primate (NHP) studies, after a single dose, FB102 demonstrated significant reductions in the NK cell pharmacodynamic marker (up to approximately 80%-90%). Additionally, after multiple doses at exposures comparable to human therapeutic doses, Treg levels in the FB102 dosing arm were similar to vehicle supporting the *in-vitro* data and the mechanism of action of FB102.

Three cohorts of single and two cohorts of multiple ascending doses in a Phase 1 trial of healthy volunteers were completed in which FB102 demonstrated a good safety profile. The primary objective of the Phase 1 trial was to assess the safety, tolerability and pharmacokinetics of single and multiple ascending doses of FB102. No dose limiting toxicities were observed. FB102 demonstrated significant reductions in the NK cell pharmacodynamic marker (greater than approximately 70%). Based on the successful completion of the Phase 1 healthy volunteer cohorts, we initiated a patient-based Phase 1b trial in celiac disease in the third quarter of 2024 and a patient-based Phase 1b trial for non-segmental vitiligo in the first quarter of 2025.

In June 2025, we announced positive data in our celiac disease Phase 1b study. The study enrolled 32 subjects 3:1 randomized (24 on FB102 and 8 on placebo). Subjects received 4 doses of FB102 (10 mg/kg) and underwent a 16- day gluten challenge. In addition to safety and tolerability, the study assessed morphologic and inflammatory endpoints along with gluten challenge induced symptoms.

FB102 demonstrated a statistically significant benefit on the composite histological VCIEL endpoint (change from baseline). The mean VCIEL change from baseline was -1.849 for placebo subjects compared to 0.079 for FB102 treated subjects (p=0.0099).

The change in the density of CD3-positive T cells, or IELs, from baseline was an increase of 13.3 for placebo subjects compared to a decline of 1.5 for FB102 treated subjects (p=0.0035). Baseline IEL density was 25.6 for the placebo subjects and 23.5 for the FB102 treated subjects.

The mean change in the Vh:Cd ratio from baseline was -0.173 (0.21) for placebo subjects compared to -0.046 (0.09), a 73% improvement for FB102 treated subjects compared to placebo.

Gluten challenge induced GI symptoms (nausea, vomiting, diarrhea, abdominal pain and abdominal bloating) reported during the 16-day gluten challenge from patient diaries/AE collection demonstrated a 42% benefit for FB102 treated subject (4.0 events per subject) compared to placebo (6.9 events per subject).

There were no dropouts in the study. Treatment emergent adverse events were primarily mild (grade 1) with no grade 3 or higher SAEs reported in the FB102 arm.

Based on the successful completion of our patient-based Phase 1b celiac disease study, we initiated a Phase 2 celiac study in July 2025 with the topline readout expected in 2026. In November 2025, the US FDA approved our IND application for a United States arm of our Phase 2 celiac study. Our Phase 1b non-segmental vitiligo trial is expecting topline data in the first half of 2026 and we have initiated a Phase 1b alopecia areata study with topline data expected in 2026.

Celiac disease is an autoimmune disease that is triggered by consuming gluten and results in damage to the small intestine. Symptoms include diarrhea, fatigue, headaches, anemia, nausea and dermatitis herpetiformis (an itchy skin rash). A significant patient population of celiac disease patients do not respond to gluten free diet. The health consequences for not treating include malnourishment, cancer and other autoimmune conditions. It is estimated that 1:133 in U.S. (2.5 million people) have celiac disease (Fasano, Arch Intern Med. 2003 PMID: 12578508) and that 0.3% to 0.5% of celiac disease patients are non-responsive (Malamut Gastroenterology. 2024 38556189). It has been estimated by various U.S. advocacy and epidemiology sources that up to 80% of people in the U.S. with celiac disease are undiagnosed. There are no approved treatment options for celiac disease.

Vitiligo is a disease of the skin mediated primarily by NK and CD8+ T cells that attack melanocytes leading to patchy depigmentation of the skin. It is estimated that vitiligo affects 2 million people in the United States (NIH). The global vitiligo treatment market size was estimated at $1.6-1.8 billion in 2024-2025 and is projected to reach approximately $2.3-2.7 billion by 2032-2034 (Fortune Business Insights).

Alopecia areata is a disease in which immune cells attack and damage hair follicles and is mediated primarily by CD8+ T cells and NK cells. The global alopecia treatment market has been valued at around $3-3.5 billion in 2024 with some forecasts pointing to the potential to reach $6 billion in 2032-2034 (DataM Intelligence).

Further, we believe FB102 has potentially other autoimmune and autoimmune-related applications including in type 1 diabetes ("T1D") which is caused by autoreactive T Cells destroying insulin-producing pancreatic β- cells. CD8+ T cells with receptors recognizing β-cell specific peptides are enriched in pancreatic islets of T1D patients. Environmental stress causes β-cells to upregulate MHC and to express IL-15 and IL-15RA. (Herold 2024 Nat Rev Immunol. PMID 38308004). It is estimated that 64,000 people are diagnosed with T1D annually (https://beyondtype1.org/type-1-diabetes-statistics/).

We had approximately $77.0 million in cash and cash equivalents as of December 31, 2025. Our common stock is publicly traded on the Nasdaq Capital Market under the ticker symbol FBRX. Prior to our merger with Tocagen, Inc., a publicly traded biotechnology company, Forte was a privately held company incorporated in Delaware on May 3, 2017.

In March 2025, the Company filed a new shelf registration statement on Form S-3 that was declared effective by the SEC in April 2025 for the issuance of up to $300.0 million in securities. On June 25, 2025, we closed a public offering (the “Offering”) pursuant to which we sold 5,630,450 shares of common stock at a price to the public of $12.00 per share and pre-funded warrants to purchase 619,606 shares of common stock at a price to the public of $11.999 per pre-funded warrant, which represents the per share public offering price for the shares less the exercise price for each pre-funded warrant. The gross proceeds from the Offering were $75.0 million and the Company incurred approximately $5.1 million in underwriting discounts, commissions and offering expenses. We also granted the underwriters an option, exercisable for a period of 30 days, to purchase up to an additional 937,508 shares of common stock. In July 2025, the underwriters of the Offering exercised their option and purchased 148,258 shares of common stock for gross proceeds of $1.8 million. The pre-funded warrants have an exercise price of $0.001 per share, are immediately exercisable and remain exercisable until exercised in full.

In November 2024, we issued 4,931,389 shares of our common stock at a purchase price of $5.5520 per share, and 4,615,555 pre-funded warrants to purchase shares of common stock at a purchase price of $5.5510 per pre-funded warrant ("2024 Private Placement"). The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The gross proceeds of the 2024 Private Placement were $53.0 million and we incurred $3.4 million in issuance costs. In connection with the 2024 Private Placement, we filed a registration statement on Form S-3 that was declared effective in December 2024.

Intellectual Property

We own one US patent for administering a combination of Gram-positive and Gram-negative bacteria along with metabolites for treatment of a wide variety of skin conditions. The patent’s estimated expiration date is 2039. This patent is not material to Forte’s FB102 program. We also own one pending PCT application, six pending US applications and eighteen pending foreign applications in Europe, Australia, Canada, China, Eurasia, Hong Kong, Israel, Japan, South Korea, Mexico, New Zealand, Singapore, Brazil, India, South Africa, Taiwan and Argentina related to the FB102 program. The estimated expiration dates of these patents are 2043-2046. We also own one pending US application and one pending application in Europe that is not material to Forte's FB102 program.

Macroeconomic Environment

Businesses throughout our industry have been and will continue to be impacted by a number of challenging and unexpected global and national events and circumstances that continue to evolve, including without limitation, the military conflicts in Ukraine and the Middle East, increased economic uncertainty, inflation, rising interest rates, recent and any potential future financial institution failures, trade policies, potential trade wars, and actions or inactions of the U.S. or other major national governments (including the

imposition of tariffs and retaliatory measures) and other geopolitical tensions. The extent of the impact of these events and circumstances on our business, operations and development timelines and plans remains uncertain, and will depend on certain developments, including the duration and scope of the events and their impact on our development activities, third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We have been and continue to actively monitor the potential impacts that these various events and circumstances may have on our business and we take steps, where warranted, to minimize any potential negative impacts on our business resulting from these events and circumstances.

In July 2025, the U.S. federal government enacted the One Big Beautiful Bill Act ("OBBBA"), a broad tax and spending bill that includes provisions impacting corporate taxpayers. The OBBBA's various provisions include, among other things, accelerated tax deductions for qualified property and research expenditures. The legislation has multiple effective dates, with certain provisions effective in 2025 and others to be implemented through 2027. The impact of the new tax law did not have a material effect on our effective income tax rate and net deferred federal income tax assets, as we continue to maintain a full valuation allowance.

Components of Operating Results

Revenue

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

Research and Development Expenses

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

Drug manufacturing and clinical trial costs are a component of research and development expenses. The Company expenses costs for its drug manufacturing activities performed by Contract Manufacturing Organizations ("CMOs"), costs for its preclinical and clinical trial activities performed by Contract Research Organizations ("CROs") and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual study in accordance with associated agreements. The Company uses information it receives from internal personnel and outside service providers to estimate the percentage of completion and therefore the expense to be incurred. Our research and development expenses may fluctuate due to fluctuations in the level of manufacturing and progression of clinical activity as we continue to develop FB102.

We anticipate research and development expenses to continue to increase in the future as we develop our current lead product candidate, FB102. Our research and development expenses may increase as we continue to advance FB102 through a celiac Phase 2 trial including a U.S. arm as a result of the FDA approving our IND, multiple Phase 1b clinical trials and if we pursue additional autoimmune indications.

General and Administrative Expenses

General and administrative expenses consist primarily of professional fees such as legal, auditing, tax and business consulting services, personnel expenses and travel costs, costs associated with being a publicly traded company such as Sarbanes-Oxley compliance, accounting fees, and directors' and officers' liability insurance premiums. Our general and administrative expenses may fluctuate due to fluctuations in professional and legal advisory fees and generally increase as we build out our infrastructure to further develop FB102.

Interest Income

Other income consists of interest income earned on our cash, cash equivalents and short-term investment balances.

Other expense, net

Other expense, net, consists of franchise taxes and foreign exchange gains and losses.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that may be readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

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

Research and Development Expenses

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

Stock-Based Compensation

We account for stock-based compensation arrangements with employees, directors and non-employees in accordance with Accounting Standards Codification ("ASC") 718, *Stock Compensation*. Stock-based awards issued by us have been primarily stock options and restricted stock units with time-based or performance-based vesting. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all stock-based awards. To determine the grant-date fair value of stock options, we utilize the Black-Scholes option pricing model, which is impacted by the fair value of our common stock as well as other variables including, but not limited to, the expected term that stock-based awards will remain outstanding, expected common stock price volatility over the expected term of the stock-based awards, risk-free interest rates and expected dividends.

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

Estimates of the fair value of stock-based awards as of the grant date using the Black-Scholes option pricing model are affected by assumptions regarding a number of variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. The volatility input is subjective and generally requires significant analysis and judgment to develop and involves inherent uncertainties and the application of significant judgment. If we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

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

Pre-Funded Warrants

We assessed the pre-funded warrants issued with equity financing for appropriate equity or liability classification and determined the pre-funded warrants were freestanding instruments that do not meet the definition of a liability in accordance with ASC 480 and do not meet the definition of a derivative in accordance with ASC 815.

The pre-funded warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, are not considered mandatorily redeemable, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the warrants do not provide any guarantee of value or return. Accordingly, the pre-funded warrants are classified as equity and accounted for as a component of additional paid-in capital at the time of issuance.

Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for purposes of computing net loss per share because the shares may be issued for little or no consideration and are exercisable after the original issuance date.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following tables summarize our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 58,247	$ 21,193	$ 37,054
General and administrative	12,410	15,409	(2,999)
Total operating expenses	70,657	36,602	34,055
Loss from operations	(70,657)	(36,602)	(34,055)
Interest income	2,715	1,314	1,401
Other expense, net	(396)	(190)	(206)
Total other income, net	2,319	1,124	1,195
Net loss before taxes	(68,338)	(35,478)	(32,860)
Income tax expense	1,037	-	1,037
Net loss	$ (69,375)	$ (35,478)	$ (33,897)

Research and Development Expenses

Research and development expenses were $58.2 million for the year ended December 31, 2025, compared to $21.2 million during the same period in 2024. The increase was primarily due to an increase of $36 million in manufacturing and clinical expenses related to FB102 for our Phase 2 clinical trial for celiac disease and Phase 1b clinical trials for vitiligo and alopecia areata, an increase of $0.4 million in discovery work, and an increase of $1.9 million in personnel-related expenses due to an increase in headcount, partially offset by a decrease of $1.5 million in preclinical expenses as a result of toxicology work performed in 2024.

Our research and development expenses may increase as we continue to advance FB102 through a celiac Phase 2 trial including a U.S. arm as a result of the FDA approving our IND, multiple Phase 1b clinical trials and if we pursue additional autoimmune indications.

General and Administrative Expenses

General and administrative expenses were $12.4 million for the year ended December 31, 2025 compared to $15.4 million for the same period in 2024. The decrease was primarily due to decreases in professional and legal advisory fees, including litigation and settlement expenses, of $6.1 million, partially offset by an increase of $3.0 million in personnel-related expenses, including additional non-cash stock-based compensation of $2.5 million.

Our general and administrative expenses may fluctuate in the future due to fluctuations in professional and advisory fees as we build out our infrastructure to advance FB102 through a Phase 2 trial, multiple Phase 1b clinical trials and if we pursue additional autoimmune indications.

Interest Income

The increase in interest income for the year ended December 31, 2025, compared with the same period in the prior year was primarily driven by higher interest income earned from higher average cash and cash equivalents balances.

Other Expense, net

The increase in other expense, net for the year ended December 31, 2025, compared with the same period in the prior year was primarily driven by foreign exchange losses.

Income Tax Expense

Income tax expense for the year ended December 31, 2025, was related to the Company's subsidiary in Australia.

Liquidity and Capital Resources

We have no products approved for commercial sale and have not generated any revenue from product sales or other sources. We have incurred operating losses in each year since inception. Our net loss was $69.4 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $223.4 million. We expect to incur operating losses in the foreseeable future as we further develop FB102.

In March 2025, the Company filed a new shelf registration statement on Form S-3 that was declared effective by the SEC in April 2025 for the issuance of up to $300.0 million in securities. On June 25, 2025, the Company closed a public offering (the “Offering”) pursuant to which it sold 5,630,450 shares of common stock at a price to the public of $12.00 per share and pre-funded warrants to purchase 619,606 shares of common stock at a price to the public of $11.999 per pre-funded warrant, which represents the per share public offering price for the shares less the exercise price for each pre-funded warrant. The Company also granted the underwriters an option (the "Option"), exercisable for a period of 30 days, to purchase up to an additional 937,508 shares of common stock. The pre-funded warrants have an exercise price of $0.001 per share, are immediately exercisable and remain exercisable until exercised in full. The gross proceeds from the Offering were $75.0 million and the Company incurred approximately $5.1 million in underwriting discounts, commissions and offering expenses.

In July 2025 the underwriters of the Offering exercised the Option and purchased 148,258 shares of common stock for gross proceeds of $1.8 million and incurred issuance costs of $0.1 million.

In November 2024, the Company issued 4,931,389 shares of the Company’s common stock at a purchase price of $5.552 per Share and 4,615,555 pre-funded warrants to purchase shares of common stock at a purchase price of $5.551 per pre-funded warrant ("2024 Private Placement") in connection with a Securities Purchase Agreement (the “2024 Purchase Agreement”). The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The holders of pre-funded warrants may not exercise a pre-funded warrant if the holder, together with its affiliates, would beneficially own more than 19.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. The holders of pre-funded warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days’ prior notice to the Company. In connection with the 2024 Private Placement, the Company filed a registration statement to register shares on Form S-3, which was declared effective on December 20, 2024. The gross proceeds of the 2024 Private Placement were $53.0 million and the Company incurred $3.4 million in issuance costs. Certain executive officers and senior management of the Company participated in this 2024 Private Placement, purchasing $475 thousand in shares of common stock at a purchase price of $5.552 per share.

We had cash and cash equivalents of approximately $77.0 million as of December 31, 2025. We believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least 12 months from the filing date of this Form 10-K.

Future Capital Requirements

We have not generated any revenue from product sales or from out-licensing. We do not know when, or if, we will generate any revenue. We expect to incur ongoing losses as we develop FB102, which we believe has potentially broad application for autoimmune and autoimmune-related indications such as celiac disease, vitiligo, alopecia areata and type 1 diabetes. FB102 is currently in clinical development in two Phase 1b and one Phase 2 clinical trials. Our future capital requirements are difficult to forecast and will depend on many factors, including but not limited to:

- the initiation and progress of additional clinical trials and preclinical studies for our product candidate in other indications of FB102;

- the terms and timing of any strategic alliance, licensing and other arrangements that we may establish;
- the number of programs we pursue;
- the outcome, timing and cost of regulatory approvals;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in patent filing, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of our product candidates manufactured.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any equity or debt financing may contain terms that are not favorable to us or our stockholders. In addition, our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the conflicts in Eastern Europe, and otherwise. If we are unable to raise additional funds when needed, we may be required to delay, reduce or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to other parties rights to develop or commercialize our drug candidates that we would prefer to retain.

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

Summary Consolidated Statements of Cash Flows

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31, 2025	2024
Net cash (used in) provided by:		
Operating activities	$ (50,882)	$ (30,745)
Investing activities	36,234	(35,993)
Financing activities	69,361	51,857
Net increase (decrease) in cash	$ 54,713	$ (14,881)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2025 was $50.9 million and consisted primarily of a net loss of $69.4 million adjusted for non-cash stock-based compensation of $6.3 million and a decrease in net operating assets of $12.4 million.

Net cash used in operating activities for the year ended December 31, 2024 was $30.7 million and consisted primarily of a net loss of $35.5 million adjusted for non-cash stock-based compensation of $3.1 million and a decrease in net operating assets of $1.7 million.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2025 was primarily due to proceeds received from the redemption of U.S. treasury bills.

Net cash used in investing activities for the year ended December 31, 2024 was primarily due to the purchase of U.S treasury bills.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was primarily due to proceeds received from the Offering of $75.0 million and from the exercise of the underwriters' option of $1.8 million, which were partially offset by the

payment of financing costs incurred in connection with the Offering, the underwriters' option exercise, and the 2024 Private Placement costs incurred in 2024 but paid in 2025.

Net cash provided by financing activities for the year ended December 31, 2024 was primarily due to the net proceeds of $51.9 million received from our 2024 Private Placement of 4,931,389 shares of the Company's common stock at a purchase price of $5.552 per share, and 4,615,555 pre-funded warrants to purchase shares of common stock at a purchase price of $5.551 per pre-funded warrant.

Indemnification

As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity pursuant to indemnification agreements. We believe the fair value of the indemnification rights and agreements is minimal. Accordingly, we have not recorded any liabilities for these indemnification rights and agreements as of December 31, 2025 and 2024.

Contractual Obligations

See Note 6 Commitments and Contingencies to the Consolidated Financial Statements included elsewhere in this Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Item 8. Financial Statements and Supplementary Data

The information required by this Item 8 is included in Part IV, Item 15 of this Annual Report on Form 10-K and is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Our management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the most recent fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

As a smaller reporting company and non-accelerated filer, we are not required to provide an attestation report on our internal control over financial reporting issued by the Company's independent registered public accounting firm.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and our Chief Financial Officer, believes that our disclosure controls, procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by management override of controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

Securities Trading Plans of Directors and Executive Officers

No officers or directors, as defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as defined in Regulation S-K Item 408, during the last fiscal quarter.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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

Item 11. Executive Compensation

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

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

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

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

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

Item 14. Principal Accounting Fees and Services

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

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) ***The following documents are filed as part of this Annual Report***

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

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

(b) ***Exhibits***

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

Exhibit Index

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on April 19, 2017.
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on June 15, 2020.
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on August 30, 2024.
3.4	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on February 9, 2023.
3.5	Certificate of Designation of Rights, Preferences and Privileges of Series A Participating Preferred Stock, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on 8-K filed on July 12, 2022.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
4.2	Description of Common Stock, incorporated by reference to Exhibit 4.2 of the Registrant's Report on Form 10-K filed on February 27, 2020.
4.3	Warrant to Purchase Stock, dated October 30, 2015, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
4.4	Warrant to Purchase Stock, dated October 30, 2015, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574) as amended, originally filed on March 9, 2017.
4.5	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.6 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.6	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.7 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.7	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.8 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.8	Warrant to Purchase Common Stock, dated May 18, 2018, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.9 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2018.
4.9	Form of Warrant to Purchase Common Stock of the Registrant issued on June 15, 2020, incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q filed on August 10, 2020.
4.10	Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed on August 1, 2023.
4.11	Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed on November 20, 2024.
4.12	Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K, filed on June 25, 2025.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.2+	Tocagen, Inc. 2017 Equity Incentive Plan, as amended, and Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise thereunder, incorporated by reference to Exhibit 10.3 of the Registrant's Annual Report on Form 10-K filed on February 27, 2019.

10.3+	Tocagen, Inc. 2017 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-216574), as amended, originally filed on March 9, 2017.
10.4	Tocagen, Inc. Annual Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 9, 2017.
10.5	Form of Restricted Stock Unit Grant Notice and Agreement, incorporated by reference to Exhibit 10.18 of the Registrant's Annual Report on Form 10-K filed on February 27, 2020.
10.6	At Market Issuance Sales Agreement between the Company and Ladenburg Thalmann & Co. Inc., dated September 4, 2020, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on September 4, 2020.
10.7+	2020 Inducement Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 11, 2020.
10.8+	Form of stock option agreements under the 2020 Inducement Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 11, 2020.
10.9+	Forte Subsidiary, Inc. 2018 Equity Incentive Plan, as amended, and Forms of Stock Option Agreement, Exercise Notice and Investment Representation Statement thereunder, incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.10+	Offer Letter, dated December 14, 2018, by and between Forte Subsidiary, Inc. and Paul A. Wagner, Ph.D., incorporated by reference to Exhibit 10.20 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.11+	Offer Letter, dated March 16, 2020, by and between Forte Subsidiary, Inc. and Antony Riley, incorporated by reference to Exhibit 10.21 of the Registrant's Registration Statement on Form S-4, as amended (File No. 333-237371), originally filed on March 25, 2020.
10.12+	At Market Issuance Sales Agreement between the Company and Ladenburg Thalmann & Co. Inc. incorporated by reference to Exhibit 10.1 of the Registrants Current Report on Form 8-K filed on April 1, 2022.
10.13+	Amended and Restated 2021 Equity Incentive Plan, and forms of agreements thereunder, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on 10-Q filed on May 15, 2025.
10.14+	Amended and Restated Non-Employee Director Compensation Policy, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed on May 15, 2025.
10.15+	Form of Change in Control and Severance Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2022.
10.16	Securities Purchase Agreement, dated July 28, 2023, by and among the Company and the Purchasers thereto, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed on August 1, 2023.
10.17	Registration Rights Agreement, dated July 28, 2023, by and among the Company and the Purchasers thereto, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K, filed on August 1, 2023.
10.18	Securities Purchase Agreement, dated November 19, 2024, by and among the Company and the Purchasers thereto, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K, filed on November 20, 2024.
10.19	Registration Rights Agreement, dated November 19, 2024, by and among the Company and the Purchasers thereto, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K, filed on November 20, 2024.
10.20	Standstill and Voting Agreement dated June 11, 2024, by and between the Company and the Camac Group, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 14, 2024.

10.21	Letter Agreement, dated November 21, 2024, by and among the Company, OrbiMed Private Investments IX, LP, OrbiMed Genesis Master Fund, L.P., and The Biotech Growth Trust PLC, incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2025.
10.22	Letter Agreement, dated November 21, 2024, by and between the Company and Tybourne Strategic Opportunities Fund II, LP, incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2025.
19.1	Amended and Restated Insider Trading Policy, incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2025.
21.1	List of Subsidiaries, incorporated by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2025.
23.1*	Consent of Independent Registered Public Accounting Firm (KPMG LLP).
24.1*	Powers of Attorney (contained in the signature page to this Annual Report on Form 10-K).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Compensation Recovery Policy, incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2025.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan.

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

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

SIGNATURES

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

Forte Biosciences, Inc.

Date: March 31, 2026 By: /s/ Paul Wagner

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

Date: March 31, 2026 By: /s/ Antony Riley

Antony Riley
Chief Financial Officer
(Principal Financial Officer)

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

Name	Title	Date
/s/ Paul A. Wagner, Ph.D. **Paul A. Wagner, Ph.D.**	Chairman and Chief Executive Officer	March 31, 2026
/s/ Antony Riley **Antony Riley**	Chief Financial Officer	March 31, 2026
/s/ Scott Brun, M.D. **Scott Brun, M.D.**	Director	March 31, 2026
/s/ Stephen Doberstein, Ph. D. **Stephen Doberstein, Ph. D.**	Director	March 31, 2026
/s/ Barbara K. Finck, M.D. **Barbara K. Finck, M.D.**	Director	March 31, 2026
/s/ David Gryska **David Gryska**	Director	March 31, 2026
/s/ Shiv Kapoor **Shiv Kapoor**	Director	March 31, 2026
/s/ Steven Kornfeld **Steven Kornfeld**	Director	March 31, 2026
/s/ Rich Vincent **Rich Vincent**	Director	March 31, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Forte Biosciences, Inc. and subsidiaries (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accounting for warrants issued in 2025

As described in Note 7 to the consolidated financial statements, in June 2025, the Company issued 5,630,450 shares of the Company's common stock and 619,606 pre-funded warrants to purchase shares of common stock in a public offering. The Company determined that the June 2025 pre-funded warrants meet the criteria for equity-classified instruments and were, therefore, recorded in additional paid-in capital at issuance and are not subject to remeasurement. At December 31, 2025, additional paid-in capital included $71.6 million related to the June 2025 issuance of common stock and pre-funded warrants.

We identified the assessment of the accounting for the June 2025 pre-funded warrants to purchase common stock, specifically the classification as liabilities or equity, as a critical audit matter. A high degree of challenging and complex auditor judgment was involved in assessing the warrant features, which required interpretation of the complex terms of the agreements in order to apply the appropriate accounting guidance.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the terms and conditions of the pre-funded warrant agreements and assessed the appropriateness of management's interpretation and application of the relevant accounting literature, including consideration of whether certain actions were within the Company's control, to assess the equity classification of the warrants on the balance sheet.

We have served as the Company's auditor since 2023.

/s/ KPMG LLP

San Diego, California

March 31, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 76,957	$ 22,244
Short-term investments	-	36,121
Prepaid expenses and other current assets	3,632	2,981
Total current assets	80,589	61,346
Property and equipment, net	129	77
Other assets	2,061	138
Total assets	$ 82,779	$ 61,561
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,989	$ 4,879
Accrued liabilities	10,762	4,202
Total current liabilities	20,751	9,081
Income tax payable	1,037	-
Total liabilities	21,788	9,081
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Common stock, $0.001 par value: 200,000,000 shares authorized as of December 31, 2025 and December 31, 2024; 12,948,308 and 6,393,323 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	13	6
Additional paid-in capital	284,348	206,461
Accumulated other comprehensive income	3	11
Accumulated deficit	(223,373)	(153,998)
Total stockholders' equity	60,991	52,480
Total liabilities and stockholders' equity	$ 82,779	$ 61,561

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

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

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 57,647	$ 20,714
Research and development - related party	600	479
General and administrative	12,410	15,409
Total operating expenses	70,657	36,602
Loss from operations	(70,657)	(36,602)
Interest income	2,715	1,314
Other expense, net	(396)	(190)
Total other income, net	2,319	1,124
Net loss before taxes	(68,338)	(35,478)
Income tax expense	1,037	—
Net loss	$ (69,375)	$ (35,478)
Per share information:		
Net loss per share - basic and diluted	$ (4.71)	$ (12.17)
Weighted average shares and pre-funded warrants outstanding, basic and diluted	14,717,734	2,915,894
Comprehensive loss:		
Net loss	$ (69,375)	$ (35,478)
Unrealized (loss) gain on available-for-sale securities, net	(8)	7
Comprehensive loss	$ (69,383)	$ (35,471)

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

Forte Biosciences, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance — December 31, 2023	1,453,402	$ 1	$ 153,829	$ 4	$ (118,520)	$ 35,314
Issuance of common stock under ESPP	958	—	14	—	—	14
Issuance of common stock and pre-funded warrants in PIPE financing, net of offering costs of $3,436	4,931,389	5	49,559	—	—	49,564
Issuance of common stock upon vesting of restricted stock units, net	7,721	—	(35)	—	—	(35)
Stock based compensation	—	—	3,095	—	—	3,095
Unrealized gain on available-for-sale securities, net	—	—	—	7	—	7
Settlement of fractional shares paid in cash	(147)	—	(1)	—	—	(1)
Net loss	—	—	—	—	(35,478)	(35,478)
Balance — December 31, 2024	6,393,323	6	206,461	11	(153,998)	52,480
Issuance of common stock under ESPP	1,658	—	18	—	—	18
Issuance of common stock and pre-funded warrants in public offering, net of offering costs of $5,058	5,630,450	6	69,935	—	—	69,941
Issuance of common stock upon exercise of underwriter option, net of offering costs of $107	148,258	—	1,672	—	—	1,672
Issuance of common stock upon vesting of restricted stock units, net of taxes paid	31,972	—	(29)	—	—	(29)
Cashless exercise of warrants	251,082	—	—	—	—	—
Exercise of common stock options and warrants	491,565	1	33	—	—	34
Stock based compensation	—	—	6,258	—	—	6,258
Unrealized loss on available-for-sale securities, net	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(69,375)	(69,375)
Balance — December 31, 2025	12,948,308	$ 13	$ 284,348	$ 3	$ (223,373)	$ 60,991

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

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

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (69,375)	$ (35,478)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	64	39
Accretion of debt discount on available-for-sale securities	(237)	(158)
Stock-based compensation expense	6,258	3,095
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,574)	(1,373)
Accounts payable	5,543	3,021
Accrued liabilities	8,402	109
Income tax payable	1,037	—
Net cash used in operating activities	(50,882)	(30,745)
Cash flows from investing activities:		
Purchase of available-for-sale securities	—	(35,956)
Proceeds from redemptions of short-term investments	36,350	—
Purchase of property and equipment	(116)	(37)
Net cash provided by (used in) investing activities	36,234	(35,993)
Cash flows from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants	75,000	53,000
Payment of issuance costs associated with financings	(7,441)	(1,121)
Proceeds from issuance of common stock upon exercise of underwriters' option	1,779	—
Proceeds from issuance of common stock under ESPP	18	14
Proceeds from exercise of warrants and options	34	—
Taxes paid related to net share settlement of equity awards	(29)	(35)
Settlement of fractional shares paid in cash	—	(1)
Net cash provided by financing activities	69,361	51,857
Net increase (decrease) in cash and cash equivalents	54,713	(14,881)
Cash and cash equivalents — beginning of year	22,244	37,125
Cash and cash equivalents — end of year	$ 76,957	$ 22,244
Supplemental disclosure of non-cash investing and financing activities:		
Unpaid issuance costs recorded in accounts payable and accrued liabilities	$ 41	$ 2,316

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

Forte Biosciences Inc.
Notes to Consolidated Financial Statements

1. Organization and Description of Business

Forte Biosciences, Inc. (www.fortebiorx.com) and its subsidiaries, referred to herein as the “Company” or "Forte", is a clinical- stage biopharmaceutical company focused on developing FB102, which is a proprietary anti-CD122 monoclonal antibody therapeutic candidate with potentially broad autoimmune and autoimmune-related indications. In June 2025, the Company announced positive data from a celiac disease Phase 1b study and has subsequently commenced a Phase 2 study for celiac disease. The Company is also advancing clinical development of FB102 in patient-based trials for non-segmental vitiligo and alopecia areata.

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

Reverse Stock Split

On August 27, 2024, the Company effected a 1-for-25 reverse stock split of its issued and outstanding common stock. The par value and authorized shares were not adjusted as a result of the reverse split. The reverse stock split also affected the Company’s outstanding common stock options and pre-funded warrants and resulted in the shares underlying such instruments being reduced and the exercise price being increased proportionately. All issued and outstanding shares of common stock and per share amounts contained in the consolidated financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented.

Liquidity and Risks

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The consolidated financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary if the Company is unable to continue as a going concern.

Since inception, the Company has incurred losses and negative cash flows from operations. As of December 31, 2025, the Company had an accumulated deficit of $223.4 million and used $50.9 million of cash and cash equivalents in operating activities during the year ended December 31, 2025. Management expects to continue to incur additional losses in the foreseeable future as the Company focuses its development efforts on advancing FB102 through clinical trials.

The Company had cash and cash equivalents of approximately $77.0 million as of December 31, 2025. The Company’s cash and cash equivalents are held at financial institutions that exceed federally insured limits. The Company believes that its existing cash and cash equivalents will be sufficient to allow the Company to fund its operations for at least 12 months from the filing date of this Form 10-K.

The Company will need to secure significant additional funding in the future in order to carry out all of the Company’s planned research and development activities and regulatory activities, conduct any substantial additional development requirements requested by the FDA, and commercialize product candidates. Management may fund future operations through the sale of equity and debt financings and may also seek additional capital through arrangements with strategic partners or other sources. There can be no assurance that additional funding will be available on terms acceptable to the Company, if at all. If the Company is unable to raise additional funding to meet its working capital needs in the future, it may be forced to delay or reduce the scope of its research and development programs and/or limit or cease its operations.

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

Businesses throughout the Company's industry have been and will continue to be impacted by a number of challenging and unexpected global and national events and circumstances that continue to evolve, including without limitation the military conflicts in

Eastern Europe and the Middle East, increased economic uncertainty, inflation, rising interest rates, recent and any potential future financial institution failures, and other geopolitical tensions. The extent of the impact of these events and circumstances on the Company's business, operations, development timelines and plans remains uncertain, and will depend on certain developments, including the duration and scope of the events and their impact on the Company's development activities, third parties with whom it does business, as well as its impact on regulatory authorities and its key scientific and management personnel. The Company has been and continues to actively monitor the potential impacts that these various events and circumstances may have on its business and the Company takes steps, where warranted, to minimize any potential negative impacts on its business resulting from these events and circumstances.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company prepares its consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"), as found in the Accounting Standards Codification ("ASC"), the Accounting Standards Update ("ASU"), of the Financial Accounting Standards Board ("FASB"), and the rules and regulations of the US Securities and Exchange Commission ("SEC").

Principles of Consolidation

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

Use of Estimates

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

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available operating accounts, U.S. treasury bills, money market funds and deposits with commercial banks. Cash equivalents are defined as short-term, highly liquid investments with maturities of 90 days or less from the date of purchase.

Available-for-Sale Securities

The Company's available-for-sale securities consist of U.S. treasury bills. Securities with maturities from the date of purchase of 90 days or less are included in cash equivalents and 91 days or more are included in short-term investments. The Company classifies its marketable securities as available-for-sale and records such assets at estimated fair value in the consolidated balance sheets, with unrealized gains and losses, if any, reported as a component of other comprehensive loss within the consolidated statements of operations and comprehensive loss and as a separate component of stockholders' equity. Realized gains and losses are calculated on the specific identification method and recorded as interest income (loss).

Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Accretion of discounts are recorded in interest income in the consolidated statements of operations and comprehensive loss.

Fair Value of Financial Instruments

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

- *Level 1* - Valuations based on quoted prices in active markets for identical assets or liabilities.

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

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

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

The carrying amounts of financial instruments consisting of cash and cash equivalents, accounts payable and accrued liabilities included in the Company's financial statements are reasonable estimates of fair value, primarily due to their short maturities. Short-term investments are recorded at fair value, with any unrealized gains or losses reported as accumulated other comprehensive income or loss.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation, subject to review for impairment. Property and equipment, net are depreciated over the estimated useful lives of the assets, generally three to five years, using the straight-line method.

Impairment of Property and Equipment

The Company reviews its property and equipment for impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the book values of the assets to future net undiscounted cash flows that the assets or the asset groups are expected to generate. If such assets are considered impaired, the impairment to be recognized is measured by the amount 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 property and equipment have been recorded for the years ended December 31, 2025 or 2024.

Pre-Funded Warrants

Pre-funded warrants are accounted for as either derivative liabilities or as equity instruments depending on the specific terms of the agreement. The pre-funded warrants are equity-classified instruments that were recorded in additional paid-in capital at issuance and are not subject to remeasurement. The Company periodically evaluates changes in facts and circumstances that could impact the classification of warrants.

Research and Development Costs

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

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

Research and Development Tax Incentive

The Company is eligible to receive a cash refund from the Australian Taxation Office for eligible research and development ("R&D") expenditures under the Australian R&D Tax Incentive Program (the "Australian Tax Incentive"). The Australian Tax Incentive is recognized as a reduction to R&D expense when the relevant expenditure has been incurred, the amount can be reliably measured and it is probable that the Australian Tax Incentive will be received. The Company has not recorded any reductions to R&D expense under the Australian Tax Incentive. The Company has received $0.9 million under this program which was recorded in accrued liabilities at December 31, 2025.

Patent Costs

Costs related to filing and pursuing patent applications, including direct application fees and the legal and consulting expenses related to making such applications, are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses within the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions from non-owner sources. Other comprehensive loss includes unrealized gains on available-for-sale securities, which was the only difference between net loss and comprehensive loss for the applicable periods.

Net Loss Per Share

The Company's net loss is equivalent to net loss attributable to common stockholders for all periods presented. Basic net loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of common shares, without consideration for common stock equivalents. The weighted average number of shares of common stock used in the basic and diluted net loss per share calculation include the pre-funded warrants outstanding during the period as they are exercisable at any time and their exercise requires only nominal consideration for the delivery of shares. During the year ended December 31, 2025, 740,112 pre-funded warrants were exercised and as of December 31, 2025 pre-funded warrants to purchase an aggregate of 4,882,615 shares of common stock were outstanding.

Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock and common stock equivalents outstanding during the period in accordance with the treasury stock method. The following number of unexercised stock options, restricted stock units, warrants, and shares expected to be purchased under the Company's 2017 Employee Stock Purchase Plan ("ESPP"), which are common stock equivalents, have been excluded from the diluted net loss calculation as their effect would have been anti-dilutive for the periods presented.

	Year Ended December 31,	
	2025	2024
Options	2,620,103	212,501
Restricted stock units	47,237	28,537
Warrants	—	176
ESPP	2,739	66
Total	2,670,079	241,280

Stock-Based Compensation

The Company issues stock-based awards to employees, directors and non-employees, generally in the form of stock options, restricted stock units or rights granted to employees under the Employee Stock Purchase Plan ("ESPP"). The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*.

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

Stock-based compensation expense for an award with a performance condition is recognized when the achievement of the performance condition has been determined to be probable. If the outcome of such performance condition has not been determined to be probable, or has not been met, no compensation expense is recognized and any previously recognized compensation expense is reversed. For rights granted under the ESPP, the fair value of each purchase is estimated at the beginning of the offering period using the Black-Scholes option pricing model.

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

Foreign Currency Transactions

Transaction gains and losses that arise from exchange rate fluctuations on transactions denominated in currencies other than the US dollar are recorded to other expenses, net in the consolidated statements of operations and comprehensive loss and were not material for the periods presented. The Company's subsidiaries use the U.S. dollar as their functional currency.

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.

Recently Adopted Accounting Standards

In December 2023, the FASB issued Accounting Standards Update (ASU) 2023-09, Improvements to Income Tax Disclosures, which does not change accounting for income taxes but requires new disclosures focusing on the effective rate reconciliation and taxes paid. The Company adopted the standard and applied the disclosure requirements on a prospective basis for the year ended December 31, 2025. Adoption of this ASU did not have a material impact on the consolidated financial statements and related disclosures.

Recently Issued Accounting Standards Not Yet Adopted

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

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures, which requires disclosure of additional information about specific expense categories in the notes to the consolidated financial statements on an interim and annual basis. The standard is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the disclosure requirements related to this new standard.

3. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2025 and 2024 consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Prepaid manufacturing and research expenses	$ 1,908	$ 1,982
Prepaid insurance	262	286
Prepaid professional fees	223	377
GST receivable	817	128
Other	422	208
Total prepaid expenses and other current assets	$ 3,632	$ 2,981

Property and Equipment, Net

Property and equipment, net as of December 31, 2025 and 2024 consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Equipment	$ 223	$ 107
Furniture and Fixtures	18	18
Property and equipment, at cost	241	125
Less accumulated depreciation	(112)	(48)
Total property and equipment, net	$ 129	$ 77

Other Assets

Other assets as of December 31, 2025 and 2024 consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Prepaid insurance	$ —	$ 87
Clinical trial deposits	2,036	25
Other	25	26
Total other assets	$ 2,061	$ 138

Accrued Liabilities

Accrued liabilities as of December 31, 2025 and 2024 consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued legal and professional fees	$ 163	$ 97
Accrued compensation	2,250	1,551
Accrued manufacturing and research expenses	7,374	541
Accrued issuance costs	40	1,881
Deferred R&D credit	927	—
Accrued other expenses	8	132
Total accrued liabilities	$ 10,762	$ 4,202

4. Fair Value

The following tables provide a summary of the assets that are measured at fair value on a recurring basis as of December 31, 2025 and December 31, 2024 (in thousands):

Cash and cash equivalents	Fair Value Measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash	$ 3,280	$ —	$ —	$ 3,280
Money Market Funds	53,713	-	-	53,713
U.S. Treasury Bills	-	19,964	-	19,964
Total	$ 56,993	$ 19,964	$ —	$ 76,957

Cash, cash equivalents and short-term investments	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash	$ 1,464	$ —	$ —	$ 1,464
Money Market Funds	20,780	-	-	20,780
U.S. Treasury Bills	-	36,121	-	36,121
Total	$ 22,244	$ 36,121	$ —	$ 58,365

Money market funds are valued at the closing price reported by the fund sponsor from an actively traded exchange. Money market funds and U.S. Treasury bills were included as cash and cash equivalents in the consolidated balance sheet as of December 31, 2025. The Company's U.S Treasury Bills were included in short-term investments as of December 31, 2024, due to an original maturity greater than 90 days. The Company obtains the fair value of its Level 2 cash equivalents and short-term investments from third-party pricing services. The pricing services utilize industry standard valuation models whereby all significant inputs, including benchmark yields, reported trades, broker/dealer quotes, issuer spreads, bids, offers, or other market-related data, are observable.

5. Available-for-Sale Securities

The following table summarizes the Company's available-for-sale securities as of December 31, 2025 and December 31, 2024 (in thousands).

Cash equivalents	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury Bills	$ 19,961	$ 3	$ —	$ 19,964
Total available-for-sale securities	$ 19,961	$ 3	$ —	$ 19,964

Short-term investments	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. Treasury Bills	$ 36,110	$ 11	$ —	$ 36,121
Total available-for-sale securities	$ 36,110	$ 11	$ —	$ 36,121

6. Commitments and Contingencies

Concentrations of Credit Risk

The Company limits its credit risk associated with its cash and cash equivalents by placing them with financial institutions it believes are highly creditworthy. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250 thousand. The Company’s cash accounts significantly exceed the FDIC limits.

Indemnifications

As permitted under Delaware law, the Company indemnifies its officers, directors, and employees for certain events and occurrences while the officer, employee or director is, or was, serving at the Company’s request in such capacity. As of December 31,

2025, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded any related liabilities.

Lease Agreements

The Company has entered into agreements for certain office and laboratory space that are cancellable by the Company at any time with a six-month notice. Total rent expense was $408 thousand and $300 thousand for the years ended December 31, 2025 and 2024, respectively.

Clinical and Preclinical Services

The Company has entered into various agreements with third-party vendors for preclinical and clinical services. The estimated remaining commitments as of December 31, 2025 under these agreements were approximately $18.8 million. The Company entered into agreements with a clinical research organization ("CRO") for clinical trials of FB102, its current product candidate. The Company has agreed to pay third-party costs associated with those agreements. The CRO agreements are subject to termination at any time, with or without cause, by the Company, in which case only costs earned or non-cancellable to the date of termination would remain subject to reimbursement.

Legal Proceedings

Camac Fund, LP v. Paul A. Wagner, et al., C.A. No. 2023-0817-MTZ (Del. Ch.)

In August 2023, Camac Fund LP (the "Plaintiff") filed a complaint (the “Complaint”) against the members of the Company's Board of Directors and entities affiliated with certain of the Company’s investors. The Complaint alleged amongst other things that the Directors breached their fiduciary duties by causing the Company to enter into a July 2023 private placement. The Company subsequently took certain actions to moot Camac’s claims in the action which Camac acknowledged. The Company made a payment to Plaintiff’s counsel in September 2024 for its fees and expenses in the amount of $1.5 million. The Court subsequently closed the case.

Forte Biosciences, Inc. v. Camac Fund, LP, et al., Case No. 3:23-cv-02399-N (N.D. Tex.)

In October 2023, the Company filed a complaint (the “Texas Complaint”), captioned Forte Biosciences, Inc. v. Camac Fund, LP, et al., Case No. 3:23-cv-02399-N, in the U.S. District Court for the Northern District of Texas. The Texas Complaint alleged that the Texas Defendants issued false and misleading disclosures in connection with their efforts to elect two directors to Forte’s board of directors at the 2023 annual meeting. In October 2024, to resolve all claims and potential claims asserted by the parties, the Texas Defendants entered into a settlement agreement and release with Forte, and all Texas Defendants other than Camac entered into standstill and voting agreements. The Company paid $650 thousand related to these agreements during the year ended December 31, 2024 which does not include any potential insurance recoveries. The Company expenses legal fees as they are incurred.

Forte Biosciences, Inc. v. Wesco Insurance Co., et al., Case No. N24C-10-015 VLM CCLD (Del. Super. Ct.)

In October 2024, the Company filed a complaint (the “Wesco Complaint”), captioned Forte Biosciences, Inc. v. Wesco Insurance Co., et al., Case No. N24C-10-015 VLM CCLD, in the Superior Court of the State of Delaware, against its Directors & Officers liability insurance, Wesco Insurance Company, Beazley Insurance Company, and Palms Insurance Company, Limited (collectively, “Insurance Defendants”), seeking declaratory relief, breach of contract, and bad faith for the Insurance Defendants’ refusal to acknowledge and perform their insurance obligations in connection with the action captioned Camac Fund, LP v. Paul A. Wagner, et al., C.A. No. 2023-0817-MTZ (Del. Ch.), described above, and related Books and Records demands (“Underlying Action”). On January 8, 2026, the Delaware Superior Court entered judgment on the pleadings in favor of Forte Biosciences, finding that Wesco Insurance Co., and Palms Insurance Co. were liable up to their combined $5 million policy limits for Forte’s defense and settlement costs incurred in connection with the Underlying Action. Forte has moved for entry of final judgment consistent with the Court’s January 8th ruling, and is seeking payment of prejudgment interest. That motion is pending with the Delaware Superior Court. In March 2026, Palms Insurance Co. paid the Company $2.3 million as an interim payment, under a reservation of rights.

7. Equity

Preferred Stock

The Company has 10 million authorized shares of Series A Preferred Stock, par value $0.001, with no shares outstanding as of December 31, 2025 and 2024.

Common Stock

In March 2025, the Company filed a new shelf registration statement on Form S-3 that was declared effective by the SEC in April 2025 for the issuance of up to $300.0 million in securities.

On June 25, 2025, the Company closed a public offering (the “Offering”) pursuant to which it sold 5,630,450 shares of common stock at a price to the public of $12.00 per share and pre-funded warrants to purchase 619,606 shares of common stock at a price to the public of $11.999 per pre-funded warrant, which represents the per share public offering price for the shares less the exercise price for each pre-funded warrant. The Company also granted the underwriters an option (the "Option"), exercisable for a period of 30 days, to purchase up to an additional 937,508 shares of common stock. The pre-funded warrants have an exercise price of $0.001 per share, are immediately exercisable and remain exercisable until exercised in full. The holder of the pre-funded warrants will not be entitled to exercise any portion of any pre-funded warrants that, upon giving effect to such exercise, would cause the aggregate number of shares of common stock beneficially owned by the holder, together with its affiliates, to exceed 9.9%. However, the holder of the pre-funded warrant may increase or decrease such percentage to any other percentage not in excess of 19.99% upon at least 61 days’ prior notice from the holder to the Company. The gross proceeds from the Offering were $75.0 million and the Company incurred approximately $5.1 million in underwriting discounts, commissions and offering expenses. In July 2025, the underwriters of the Offering exercised the Option and purchased 148,258 shares of common stock for gross proceeds of $1.8 million and the Company incurred issuance costs of $0.1 million.

In November 2024, the Company issued 4,931,389 shares of the Company’s common stock at a purchase price of $5.552 per Share and 4,615,555 pre-funded warrants to purchase shares of common stock at a purchase price of $5.551 per pre-funded warrant ("2024 Private Placement") in connection with a Securities Purchase Agreement (the “ 2024 Purchase Agreement”). The pre-funded warrants have an exercise price of $0.001 per share of common stock, are immediately exercisable and remain exercisable until exercised in full. The holders of pre-funded warrants may not exercise a pre-funded warrant if the holder, together with its affiliates, would beneficially own more than 19.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise. The holders of pre-funded warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days’ prior notice to the Company. In connection with the 2024 Private Placement, the Company filed a registration statement to register shares on Form S-3, which was declared effective on December 20, 2024. The gross proceeds of the 2024 Private Placement were $53.0 million and the Company incurred $3.4 million in issuance costs. Certain executive officers and senior management of the Company participated in this 2024 Private Placement, purchasing $475 thousand in shares of common stock at a purchase price of $5.552 per share.

In connection with, and as a condition to, the closing of the 2024 Private Placement, the Company has agreed to enter into letter agreements with two investors. Pursuant to the terms of the letter agreements, the Company has agreed that, during the period beginning ninety (90) days after the closing date of the 2024 Private Placement and ending on the three (3) year anniversary of the closing date of the 2024 Private Placement (or earlier upon investors failing to meet certain ownership thresholds), if the Company’s common stock trades within certain specified parameters for thirty (30) consecutive trading days, each of the investors shall be entitled to designate one individual to serve on the Board, in each case pursuant and subject to the terms of the applicable letter agreement and compliance with applicable Nasdaq and SEC regulations and the Board’s fiduciary duties under applicable law. In addition, for the duration of the applicable designation period, the Company shall also include such designee in the slate of nominees recommended by the Board for election at each annual or special meeting of the Company’s stockholders at which directors of such designee’s class are to be elected. The letter agreement also provides one investor a participation right in future offerings of the Company’s equity securities.

As of December 31, 2025, 740,112 pre-funded warrants were exercised and pre-funded warrants to purchase an aggregate of 4,882,615 shares of common stock remain outstanding. The 4,882,615 and 5,003,121 shares of common stock issuable upon the exercise of the pre-funded warrants is not included in the number of issued and outstanding shares of common stock as of December 31, 2025 and December 31, 2024.

Shares of common stock reserved for future issuance as of December 31, 2025 were as follows:

	Shares
Pre-funded warrants outstanding	4,882,615
Stock options outstanding	2,620,103
Reserved for issuance under equity incentive plans	1,736,669
RSUs outstanding	47,237
Reserved for issuance under employee stock purchase plan	41,825
Total	9,328,449

8. Stock-Based Compensation

Equity Plans

In May 2021 the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"). As amended and restated in February 2025, the 2021 Plan has an aggregate of 3,340,000 authorized shares.

The 2021 Plan provides for the grant of incentive stock options ("ISOs"), non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, other forms of equity compensation and performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of the Company and its affiliates. Service-based awards generally vested over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service with the remaining awards vesting monthly in equal installments over the following thirty-six months. For certain service-based awards to the board of directors, vesting occurs in thirty-six equal monthly installments over a three-year period for initial grants and in twelve equal monthly installments over a twelve-month period for subsequent grants. As of December 31, 2025, there were 935,469 shares available for issuance under the 2021 Plan.

On July 26, 2020, the Company adopted the 2020 Inducement Equity Incentive Plan (the "2020 Inducement Plan"). The 2020 Inducement Plan, as amended and restated in September 2025, has an aggregate of 1,080,000 authorized shares. As of December 31, 2025, there were 801,200 shares available for issuance under the 2020 Inducement Plan.

S***tock Options***

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

All option awards generally expire ten years from the date of grant. 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.

During 2024, the expected volatility assumption utilized a weighted approach by blending the Company's own historical price data with the historical volatility of a group of similar companies in the life sciences industry whose shares are publicly traded. The Company selected the peer group based on comparable characteristics, including development stage, product pipeline, and market capitalization. Effective January 1, 2025, the Company elected to remove peer group companies and determined its expected volatility assumption based solely on the volatility of the Company's historical share prices using the closing share price beginning on June 15, 2020 and through the current period.

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

The weighted average grant-date fair value of stock options granted in the years ended December 31, 2025 and 2024 was $7.39 and $14.25, respectively. The weighted-average assumptions used to value these stock options using the Black-Scholes option-pricing model were as follows.

	Year ended December 31, 2025	Year Ended December 31, 2024
Risk-free interest rate	4.05%	4.08%
Dividend yield	0.00%	0.00%
Expected term of options (years)	5.83	5.98
Volatility	117.26%	110.15%

The table below summarizes the stock option activity during the year ended December 31, 2025:

	Number of Shares Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2024	212,501	$ 103.51	7.82	$ 760
Granted	2,580,000	$ 8.57	—	—
Exercised	(2,837)	$ 11.21	—	—
Cancelled/Forfeited	(169,561)	$ 18.62	—	—
Balances at December 31, 2025	2,620,103	$ 15.62	9.10	$ 47,072
Vested and expected to vest at December 31, 2025	2,620,103	$ 15.62	9.10	$ 47,072
Exercisable at December 31, 2025	755,316	$ 31.60	8.68	$ 13,084

The total intrinsic value of options exercised was $12 thousand for the year ended December 31, 2025. There were no options exercised in 2024. The aggregate intrinsic value of stock options as of December 31, 2025 is based on the Company's closing stock price of $27.27 per share.

Restricted Stock Unit Awards

Restricted stock units vest over four years with one sixteenth of the restricted stock units vesting every quarter.

Restricted stock unit award transactions during the year ended December 31, 2025 were as follows:

	Shares	Weighted Avg Grant Date Fair Value
Outstanding at December 31, 2024	28,537	$ 38.50
Granted	55,000	$ 10.16
Forfeited/Cancelled	(2,400)	$ 25.75
Issued as Common Stock	(33,900)	$ 11.43
Outstanding at December 31, 2025	47,237	$ 25.58

The aggregate fair value of RSUs vested during the year ended December 31, 2025 was $505 thousand.

2017 Employee Stock Purchase Plan

In May 2021, the Company's board of directors reactivated the Company's 2017 Employee Stock Purchase Plan ("ESPP") which had previously been suspended. The ESPP allows eligible employees to withhold up to 15% of their earnings to purchase shares of the Company's common stock at a price per share equal to the lower of (i) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (ii) 85% of the fair market value of a share of the Company's common stock on the date of purchase. The Company had 41,825 shares available for future issuance under the ESPP as of December 31, 2025. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year through January 1, 2027, by the lesser of (a) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (b) 12,000 shares, or (c) a number determined by the Company's board of directors that is less than (a) and (b). The Company issued 1,658 and 958 shares under the ESPP during the year ended December 31, 2025 and 2024, respectively.

The ESPP is considered a compensatory plan. The Company recorded stock-based compensation expense related to its ESPP of $74 thousand and $8 thousand for the years ended December 31, 2025 and 2024, respectively.

The fair value of the rights granted to employees under the ESPP was estimated using a Black-Scholes option-pricing model with the following weighted-average valuation assumptions:

	Year ended December 31, 2025	Year Ended December 31, 2024
Fair value of common stock	$ 12.44	$ 16.34
Risk-free interest rate	4.29%	5.32%
Dividend yield	0.00%	0.00%
Expected term of options (years)	0.51	0.50
Volatility	145.00%	72.58%

Stock-Based Compensation Expense

Stock-based compensation expenses included in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 are as follows (in thousands):

	Year Ended December 31, 2025	2024
Research and development	$ 1,711	$ 1,075
General and administrative	4,547	2,020
Total	$ 6,258	$ 3,095

As of December 31, 2025, there was unrecognized stock-based compensation expense of $14.4 million related to stock options and restricted stock units with service conditions, which is expected to be recognized over a weighted-average period of 2.29 years. Total unrecognized stock-based compensation as of December 31, 2025 was approximately $0.5 million related to restricted stock units with performance based vesting. The performance based conditions are tied to development milestones which have not been met.

9. Income Taxes

The components of net loss before income taxes consisted of the following (in thousands):

	Year Ended December 31, 2025	2024
United States	$ (72,485)	$ (30,905)
International	4,147	(4,573)
Net loss before taxes	$ (68,338)	$ (35,478)

The federal and state income tax provision is summarized as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Current		
Federal	$ —	$ —
State	—	—
Foreign	1,037	—
Total current tax expense	1,037	—
Deferred		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred tax expense	—	—
Total tax expense	$ 1,037	$ -

The Company adopted ASU 2023-09 “Income Taxes (Topic 740): Improvements To Income Tax Disclosures” on a prospective basis beginning with the year ended December 31, 2025. The following table presents required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory tax amount and rate to our actual global effective amount and rate for the year ended December 31, 2025:

	Year Ended December 31, 2025	
U.S. federal statutory tax rate	$ (14,351)	21.0%
State and local income taxes, net of federal income tax effect (1)	—	0.0%
Foreign tax effects		
Other foreign	166	-0.2%
Effect of changes in tax laws or rates enacted in the current period	—	0.0%
Effects of cross-border tax laws		
Global intangible low-taxed income	871	-1.3%
Tax credits		
Other	(294)	0.4%
Changes in valuation allowance	14,587	-21.3%
Nontaxable or nondeductible items		
Other	58	-0.1%
Changes in unrecognized tax benefits	—	0.0%
Effective tax rate	$ 1,037	-1.50%
(1) State income taxes in all jurisdictions is zero.		

The following table presents the required disclosures prior to our adoption of ASU 2023-09 and reconciles the U.S. federal statutory income tax rate to the actual global effective income tax rate for the years ended December 31, 2024:

	Year Ended December 31, 2024	
Income tax expense (benefit) at federal statutory rate	$ (7,450)	21.0%
Increase/(decrease) in tax resulting from:		
State income taxes	—	0.0%
Change in valuation allowance	6,441	-18.2%
Nondeductible R&D Expenses	921	-2.6%
Stock-based compensation expense	90	-0.2%
Other	(2)	0.0%
Total	$ —	0.0%

The primary components of temporary differences which give rise to the Company's net deferred tax assets and liabilities as of December 31, 2025 and 2024 are as follows (in thousands):

	Year Ended December 31, 2025	2024
Deferred tax assets:		
Accrual to cash adjustment	$ 1,040	$ 499
Start-up costs	9,101	7,190
Patent costs	40	40
Stock-based compensation expense	1,937	1,432
Net operating loss	13,378	7,638
Capitalized R&D	12,619	6,813
Other deferred taxes	34	21
R&D credits	1,336	868
Total noncurrent deferred tax assets	39,485	24,501
Valuation allowance	(39,485)	(24,501)
Net deferred tax assets after valuation allowance	$ —	$ —

In July 2025, the One Big Beautiful Bill Act ("OBBBA") modified the Section 174 capitalization rules. Under the OBBBA provisions, the Company discontinued capitalization of domestic Section 174 costs beginning in tax year 2025, while continuing to capitalize foreign Section 174 costs. As a result, deferred tax assets related to capitalized research expenditures increased by $5.8 million during the year ended December 31, 2025.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based upon the Company's history of operating losses, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of December 31, 2025 and 2024. During 2025 and 2024, the valuation allowance increased by $15.0 million and $5.9 million, respectively.

As of December 31, 2025, the Company has federal and California research and development tax credit carryforwards of $1.2 million and $0.9 million, respectively. The federal research and development tax credits begin to expire in 2041 unless previously utilized. The California credits do not expire.

Net operating losses and tax credit carryforwards as of December 31, 2025 are as follows (in thousands):

	Amount	Expiration Years
Net operating losses, federal (Post December 31, 2017)	$ 59,836	Do Not Expire
Net operating losses, federal (Pre January 1, 2018)	$ 11	2037
Net operating losses, state	$ 11,602	2037
Net operating losses, foreign	$ —	Indefinite
Tax credits, federal	$ 1,172	2041
Tax credits, state	$ 933	Indefinite

The Company is subject to taxation in the U.S., Australia and California. As of December 31, 2025, Tocagen's tax years beginning 2007 to date are subject to examination by federal and California taxing authorities due to the carry forward of unutilized net operating losses and research and development tax credits. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities to the extent utilized in a future period.

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383, annual use of a company's net operating loss and tax credit carryforwards may be limited if there is a cumulative change in ownership of greater than 50% (by value) within a three-year period. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several equity offerings since its inception which may have resulted in a change in control as defined by Sections 382 and 383 of the IRC, or could result in a change in control in the future. The Company has not completed an IRC Section 382 and 383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Upon completion of such an analysis, there may be either increases

or decreases to the reported amount of the deferred tax assets for net operating losses and federal and California research and development credits. Any change in the amount of the deferred tax assets would have a corresponding change in the valuation allowance, and therefore is not expected to impact the Company's effective tax rate.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any appeals or litigation processes. Income tax positions must meet a more likely than not recognition at the effective date to be recognized.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for 2025 and 2024 is as following (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning Balance	$ 411	$ 251
Additions based on tax positions related to the current year	$ 221	$ 160
Ending Balance	$ 632	$ 411

The Company's policy is to record interest and penalties relating to uncertain tax positions as a component of income tax expense should the Company believe there is an uncertain tax position liability. As of December 31, 2025, and 2024, there was no accrued interest or penalties for uncertain positions.

10. Related Party Transactions

One member of the Company's board of directors received $600 thousand and $479 thousand for scientific consulting services during the years ended December 31, 2025 and 2024, respectively.

On November 21, 2024, certain executive officers and senior management of the Company participated in the 2024 Private Placement, purchasing $475 thousand in shares of common stock at a purchase price of $5.552 per share.

11. Employee Benefit Plan

The Company has a defined-contribution 401(k) plan for employees. Under the terms of the plan, employees may make voluntary contributions as a percentage of compensation. The Company matches employee contributions as permitted by the plan. The Company's total cost related to the 401(k) plan was $166 thousand and $138 thousand for the years ended December 31, 2025 and 2024, respectively.

12. Segment Information

The Company operates in one operating segment, which includes all activities related to the discovery and development of FB102, for the purposes of assessing performance, making operating decisions, and allocating Company resources. The Company's chief operating decision maker (CODM) is its chief executive officer, who considers net loss to evaluate overall expenses associated with conducting research and development activities, which includes evaluating the progress of ongoing clinical trials and the planning and execution of current and future research and development activities. Further, the CODM reviews and utilizes research and development expenses, general and administrative expenses and other income, net as reported in the statements of operations and comprehensive loss to manage the Company's operations. The measure of performance, significant expenses, and other items are each reflected in the statements of operations and comprehensive loss. In addition to the statements of operations and comprehensive loss, the CODM is regularly provided with forecasted expense information which is used to determine the Company's liquidity needs. The CODM also monitors the cash, cash equivalents and short-term investments as reported on the Company's consolidated balance sheets to determine funding for research and development activities. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

13. Subsequent Events

In February 2026, 925,773 of the pre-funded warrants issued in the 2024 Private Placement were exercised.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-265823, 333-235852, 333-244407, 333-217300, 333-223558, 333-229963, 333-255125, 333-271036, 333-278647, 333-284769, and 333-290610) on Form S-8 and (Nos. 333-274257, 333-283814, and 333-286226) on Form S-3 of our report dated March 31, 2026, with respect to the consolidated financial statements of Forte Biosciences, Inc. and subsidiaries.

/s/ KPMG LLP

San Diego, California
March 31, 2026

Exhibit 31.1

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

I, Dr. Paul Wagner, certify that:

1. I have reviewed this Form 10-K/Annual Report of Forte Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2026

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

Exhibit 31.2

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

I, Antony Riley, certify that:

1. I have reviewed this Form 10-K/Annual Report of Forte Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: March 31, 2026

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

Exhibit 32.1

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

In connection with the annual report of Forte Biosciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 31, 2026

By: /s/ Dr. Paul Wagner

Dr. Paul Wagner
President & Chief Executive Officer

Exhibit 32.2

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

In connection with the annual report of Forte Biosciences, Inc. (the "Company") on Form 10-K for the period ending December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: March 31, 2026

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