UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2019 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: 001-39041

Satsuma Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**81-3039831**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
400 Oyster Point Boulevard, Suite 221	
South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 410-3200
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	STSA	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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 Section 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 Exchange Act 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 a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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

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

The aggregate market value of the voting stock and non-voting common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant's common stock on December 31, 2019 as reported by the Nasdaq Global Market on such date, was approximately $177.4 million. The registrant has elected to use December 31, 2019, which was the last business day of the registrant's most recently completed fiscal year, as the calculation date because on June 30, 2019 (the last business day of the registrant's most recently completed second fiscal quarter), the registrant was a privately-held company. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of February 29, 2020, the registrant had 17,382,047 shares of common stock, $0.0001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement relating to the 2020 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2019.

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SATSUMA PHARMACEUTICALS, INC.
Annual Report on Form 10-K for the Fiscal Year Ended December 31, 2019

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends affecting the financial condition of our business. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith beliefs as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements.

Forward-looking statements include all statements that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, or similar expressions and comparable terminology intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including those set forth under the section titled "Risk Factors" and elsewhere in this report. Forward-looking statements include, but are not limited to, statements about:

- our expectations regarding the potential market size and size of the potential patient populations for STS101, if approved for commercial use;
- our clinical and regulatory development plans;
- our expectations with regard to the data to be derived from our ongoing and planned Phase 3 clinical trials;
- the timing of commencement of future nonclinical studies and clinical trials and research and development programs;
- our intentions and our ability to establish collaborations and/or partnerships;
- the timing or likelihood of regulatory filings and approvals for STS101;
- our commercialization, marketing and manufacturing plans and expectations;
- the pricing and reimbursement of STS101, if approved;
- the implementation of our business model and strategic plans for our business and STS101;
- the scope of protection we are able to establish and maintain for intellectual property rights covering STS101, including the projected terms of patent protection;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our use of proceeds from our initial public offering;
- our future financial performance; and
- developments and projections relating to our competitors and our industry, including competing therapies and procedures.
- our expectations for and timing of remediation of the material weakness identified in the prospectus filed with the U.S. Securities and Exchange Commission on September 12, 2019.

All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward- looking statements, and you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Satsuma" the "Company," "we," "us," and "our" refer to Satsuma Pharmaceuticals Inc.

PART I

ITEM 1. BUSINESS

Overview

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company developing a novel therapeutic product for the acute treatment of migraine. Our product candidate, STS101, is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate, or DHE, which can be quickly and easily self-administered with a proprietary pre-filled, single-use, nasal delivery device. DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine and have significant advantages over other therapeutics for many patients. However, broad use has been limited by invasive and burdensome administration and/or sub-optimal clinical performance of available injectable and liquid nasal spray products. STS101 is specifically designed to deliver the clinical advantages of DHE while overcoming these shortcomings. We have completed a Phase 1 clinical trial in 42 healthy volunteers, in which STS101 demonstrated rapid and sustained DHE plasma concentrations, low pharmacokinetic variability, and a favorable safety and tolerability profile. In July 2019, we initiated our Phase 3 EMERGE efficacy trial of STS101 and expect to report topline data in the second half of 2020.

Migraine is a chronic and debilitating neurological disorder characterized by attacks of often severe headache and accompanying neurological symptoms lasting four to 72 hours. More than 90% of individuals suffering from migraine attacks are unable to work or function normally during a migraine attack, with many experiencing comorbid conditions such as depression, anxiety and insomnia. Failure to effectively treat migraine attacks can lead to disease progression, increased frequency of attacks and greater migraine-related disability.

Based on reported prevalence data, approximately 39 million individuals in the United States and over 100 million individuals in Europe suffer from migraine. Migraine is most prevalent among adults ages 18 to 44 and disproportionately affects women over men on a three-to-one basis. With a global prevalence of greater than one billion, migraine ranks as the world's third most prevalent illness, the sixth highest specific cause of disability worldwide, and the leading cause of disability in people under 50 years of age. In addition, migraine is the second leading cause of disability worldwide in terms of number of years lost to disability. It has been estimated that migraine results in up to $36 billion in healthcare and lost productivity costs and up to 157 million lost workdays annually in the United States. Despite its high prevalence and burden, migraine remains a highly underdiagnosed and undertreated illness due to lack of awareness, stigma and the inherent limitations of currently available therapies.

Acute treatments are categorized as non-specific therapies, including nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen, and migraine-specific therapies, such as triptans and ergot alkaloids (including DHE-based products). In addition, two new migraine-specific acute treatments were approved in late 2019 by the U.S. Food and Drug Administration (FDA): lasmiditan, an oral $5HT_{1F}$ agonist; and ubrogepant, an oral calcitonin gene-related peptide (CGRP) antagonist. In 2018, more than 15 million prescriptions for migraine-specific acute therapies were written in the United States. This figure excludes prescriptions for non-specific therapies and therefore likely significantly understates the total number of prescriptions written for the acute treatment of migraine. Oral triptans are currently the predominant class of drug for acute treatment of migraine, accounting for over 90% of migraine-specific acute therapy prescriptions. However, triptans have been reported to have a number of shortcomings, including that they have inconsistent efficacy across patients and migraine types, require early treatment, cause various side effects, may cause medication overuse headache, or MOH, and have slow and variable onset of action and short duration of effect that necessitates retreatment. DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine and have significant clinical advantages over other therapeutics, including triptans, for many patients. However, approved DHE products have drawbacks that have resulted in limited clinical use. For instance, injectable DHE, while effective, has invasive administration requirements, and in the case of intravenous (IV) delivery, generally must be administered by a healthcare provider, typically in the hospital or clinic setting, requires specialized equipment and may often result in side effects, in

particular, nausea and vomiting. Similarly, intramuscular (IM) and or subcutaneous (SC) injections are invasive, require administration via injection by the patient, caregiver or healthcare provider and patients typically prefer non-injectable therapies. In addition, DHE liquid nasal sprays have complex, time-consuming and burdensome administration, as well as high variability and slow absorption that may result in inconsistent and sub-optimal clinical performance. Further, due to DHE's low oral bioavailability, there are no approved oral DHE products in the United States.

STS101 was designed to be a reliable and convenient DHE product capable of delivering the clinical advantages of DHE while overcoming the shortcomings of existing DHE products. STS101 has a number of key attributes that we believe may provide significant advantages over existing acute treatments for migraine and result in robust and consistent clinical performance and thereby facilitate broad adoption and use. These attributes are primarily the result of our proprietary dry-powder formulation, which incorporates a mucoadhesive drug carrier and engineered drug particle technologies, and our proprietary nasal delivery device. Key STS101 attributes include:

- *Targeted plasma concentrations rapidly achieved and sustained.* In our Phase 1 clinical trial, administration of STS101 resulted in achievement within 10 minutes of a mean DHE plasma concentration of 1.0 ng/ml, which we estimate is the minimum threshold concentration necessary for therapeutic response to DHE. In addition, DHE exposure (plasma concentration over time expressed as area-under-curve) following STS101 administration at all times exceeded that for Migranal DHE mesylate liquid nasal spray 2.0 mg, which is the only DHE product marketed in the United States that has been approved by the FDA based upon demonstration of efficacy and safety in clinical studies. Further, DHE exposure following STS101 administration was similar to or greater than DHE exposures reported with DHE mesylate IM injection, which is marketed in the United States but has not been approved by the FDA based on demonstration of efficacy, and DHE administered via pulmonary inhalation (MAP0004), which met all four of its primary efficacy endpoints in a large Phase 3 clinical trial, but was later discontinued and has not been approved by the FDA. For instance, although peak DHE plasma concentration following administration of STS101 5.2 mg did not reach peak concentration levels associated with IV or IM delivery of DHE, DHE exposure was approximately 83% of that achieved with a DHE mesylate IM injection in our Phase 1 clinical trial.
- *Low variability*. In our Phase 1 clinical trial, STS101 demonstrated significantly lower variability in peak DHE plasma concentration and DHE exposure as compared to Migranal® DHE mesylate liquid nasal spray, which may lead to more reliable clinical performance.
- *Quick and convenient self-administration.* STS101 utilizes a convenient, patient-friendly, single-use, nasal delivery device designed to enable self-administration of a full dose of DHE into a single nostril in a matter of seconds.
- *Well tolerated.* In our Phase 1 clinical trial, all treatments were well tolerated, all adverse events were mild and transient, and no subject withdrew from the trial due to an adverse event. Moreover, STS101 did not exhibit the rapid and high peak concentration associated with IV delivery of DHE, which may often result in side effects, in particular, nausea and vomiting.

We believe the foregoing attributes of STS101 could lead to it having a favorable therapeutic response profile as compared to IV, IM or SC delivery of DHE and Migranal DHE mesylate liquid nasal spray. The faster a DHE product can produce the threshold DHE plasma concentration necessary for a therapeutic response, the more quickly following administration it may be able to achieve a therapeutic response. At the same time, we believe that rapid and high peak DHE plasma concentrations that greatly exceed the threshold therapeutic level may result in adverse side effects. For example, IV delivery of DHE has demonstrated peak DHE plasma concentrations of 50 ng/ml or more within several minutes of administration, and is reported to more frequently result in side effects (including nausea and vomiting, increases in blood pressure, flushing, dizziness, extremity pain, and abnormal skin sensations) than delivery of DHE by other routes of administration, such as IM or SC injection, nasal or pulmonary, which exhibit much lower peak DHE plasma concentrations that generally have not been reported to exceed approximately 3 to 4 ng/ml. Based on published DHE PK and clinical efficacy trial data relating to DHE plasma concentrations and clinical efficacy and safety data of different DHE doses, we estimate that 1.0 ng/ml is the threshold concentration necessary for therapeutic response to DHE. As demonstrated in Part 2 of our Phase 1 clinical trial, administration of STS101 5.2 mg and DHE mesylate IM injection resulted in DHE plasma concentrations rising rapidly, with mean concentrations exceeding 1.0 ng/ml at 10 minutes and 5 minutes after dosing, respectively. While, STS101's peak DHE plasma concentration (approximately 2.2 ng/ml) did not exceed the peak DHE plasma concentration of DHE mesylate IM injection (approximately 3.3 ng/ml), DHE exposure following administration of STS101 5.2 mg was

approximately 83% of that achieved with a DHE mesylate IM injection. In contrast, the mean maximum DHE plasma concentration after Migranal DHE mesylate liquid nasal spray administration did not reach 1.0 ng/ml.

While subjects treated with STS101 5.2 mg reported a higher frequency of nasal adverse events than those treated with DHE mesylate IM injection or Migranal DHE mesylate liquid nasal spray, all adverse events were mild and transient, and subjective nasal symptom severity scores self-reported by subjects were very low, with all nasal symptom severity scores averaging less than five on a zero to one hundred scale in which zero represents absence of the symptom and one hundred represents presence of the symptom with the worst imaginable severity. Subjective nasal symptom severity scores self-reported in Part 1 of our Phase 1 clinical trial by subjects treated with STS101 1.3 mg and 2.6 mg were negligible. As a result, we do not believe the tolerability of STS101 should present a barrier to patient adoption or use, if approved.

In July 2019, we initiated our Phase 3 EMERGE efficacy trial of STS101, a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in approximately 1,140 migraine patients, and we expect to report topline data in the second half of 2020. In our EMERGE trial, STS101 will be self-administered by patients to treat a single migraine attack and the two co-primary endpoints to be assessed at two hours after STS101 administration are freedom from pain and freedom from most bothersome symptom. In addition, we expect to prospectively evaluate a number of secondary endpoints and the performance of STS101 in a number of patient subgroups that could enhance the differentiated clinical profile of STS101. After the completion of our Phase 3 EMERGE efficacy trial, we plan to initiate a 12-month safety trial of STS101, with a new drug application, or NDA, filing with the FDA, anticipated by the end of 2021.

Our management team has extensive pharmaceutical industry experience in drug development, regulatory approval, manufacturing, reimbursement, commercialization and finance from their prior roles at other pharmaceutical and biotechnology companies, including ALZA, AstraZeneca, Athena Neurosciences, Elan Pharmaceuticals, GlaxoSmithKline, Ilypsa, Immunex, Jazz Pharmaceuticals, Johnson & Johnson, Pearl Therapeutics, Protagonist Therapeutics, Relypsa, Roivant Sciences, and Wyeth Laboratories. Collectively, our management team has materially contributed to the clinical development, registration and/or commercialization of over 50 approved drug products, including 15 drug-device combination products, 13 of which are delivered via inhalation.

Our Strategy

Our strategy is to develop and commercialize STS101 and address the significant unmet medical needs of a large number of people with migraine. Key elements of our strategy include:

- *Advance STS101 through clinical development and regulatory approval for the acute treatment of migraine.* In July 2019, we initiated our Phase 3 EMERGE efficacy trial, with a target enrollment of 1,140 patients. We expect to report topline data from this trial in the second half of 2020. We expect to commence a 12-month safety trial in the third quarter of 2020, with an NDA filing anticipated by the end of 2021.
- *Commercialize STS101 in the United States.* If approved, we plan to commercialize STS101 in the United States by building a specialized sales organization focusing on headache specialists, as well as general neurologists and primary care physicians who are high prescribers of migraine therapeutics.
- *Pursue market opportunities for STS101 outside the United States with one or more partners.* We believe there is a significant market opportunity for STS101 in markets outside the United States. To address these markets, we plan to seek one or more ex-U.S. partners who can commercialize STS101.
- *Maximize commercial potential of STS101.* We may conduct additional clinical trials and consider additional headache indications for STS101 to maximize its commercial potential.

Migraine Overview

Migraine is a chronic and debilitating neurological disorder characterized by attacks of often severe headache and accompanying neurological symptoms lasting four to 72 hours. More than 90% of individuals suffering from migraine are unable to work or function normally during a migraine attack, with many experiencing comorbid conditions such as depression, anxiety and insomnia. Failure to effectively treat migraine attacks can lead to disease progression, increased frequency of attacks and greater migraine-related disability. Migraine is often accompanied by one or more of the following disabling symptoms:

- extreme sensitivity to light, sound, touch or smell;
- nausea and/or vomiting;
- dizziness;
- visual disturbances;
- tingling or numbness in the extremities or face; and
- neck pain.

Based on reported prevalence data, approximately 39 million individuals in the United States and over 100 million individuals in Europe suffer from migraine. Migraine is most prevalent among adults ages 18 to 44 and disproportionately affects women over men on a three-to-one basis. With a global prevalence of greater than one billion, migraine ranks as the world's third most prevalent illness, the sixth highest specific cause of disability worldwide, and the leading cause of disability in people under 50 years of age. In addition, migraine is the second leading cause of disability in terms of number of patient-years lost to disability. It has been estimated that migraine results in up to $36 billion in healthcare and lost productivity costs and up to 157 million lost workdays annually in the United States. In 2018, more than 15 million prescriptions for migraine-specific acute therapies were written in the United States. This figure excludes prescriptions for non-specific therapies, such as NSAIDs and acetaminophen, and therefore likely significantly understates the total number of prescriptions written for the acute treatment of migraine.

The underlying causes of migraine are not well understood; however, both genetics and environmental factors appear to be relevant. Further, the underlying biology of migraine is complex and multifactorial, and it is believed that migraine susceptibility arises from genetic predisposition to generalized neuronal hyperexcitability. During a migraine attack, hyperexcitable neurons cause the release of various vasoactive, pro-inflammatory and neuroactive substances, including calcitonin gene-related peptide (CGRP), substance P, histamine, inducible nitric oxide synthase (iNOS), cyclooxygenase-2 (COX-2) and serotonin, leading to vasodilation, neurogenic inflammation and neurological symptoms, including headache and pain.

Migraine treatment can generally be categorized as either acute or preventive. Treatment guidelines indicate that all patients should be offered acute treatment, which is focused on stopping the migraine attack quickly and restoring the patient's ability to function with minimal side effects. In addition to receiving acute treatments, a subset of patients (typically those with more severe and/or frequent migraine attacks) may also receive preventive treatment, which is focused on reducing the frequency, duration or severity of migraine attacks or the associated disability caused by such attacks. Historically, preventive therapies, such as anti-convulsants, beta blockers and onabotulinumtoxinA injections, have lacked strong efficacy for many patients, have been associated with significant side effects or required burdensome administration. The recent introduction of anti-CGRP antibodies as a new class of preventive therapy is raising awareness of the treatment opportunities in migraine and may lead to an increase in the number patients being diagnosed and treated for migraine. However, these new therapies do not alleviate the need for acute therapies, as such products on average result in patients experiencing a reduction of only two migraine days per month. Despite its high prevalence and burden, migraine remains a highly underdiagnosed and undertreated illness due to lack of awareness, stigma and the inherent limitations of currently available therapies.

Current Acute Treatment Paradigm

Patients typically seek acute treatment for migraine to relieve pain and associated symptoms. The current treatment guidelines from the American Headache Society define the five goals of acute therapy as:

- Rapid and consistent freedom from pain and associated symptoms without recurrence;
- Restored ability to function;
- Minimal need for repeat dosing or rescue medications;
- Optimal self-care and reduced subsequent use of resources (e.g., emergency room visits, diagnostic imaging, healthcare provider and ambulatory infusion center visits); and
- Minimal or no side effects.

Acute treatments are typically administered orally, via injection or nasally. Orally-administered acute treatments have significant limitations, including relatively slow onset of effect due to the time required for absorption of the drug from the gastrointestinal tract following ingestion. During a migraine attack, absorption of orally-administered treatments can be delayed due to gastric stasis, which commonly occurs in people with migraine both during and between attacks. In addition, orally-administered acute treatments are inappropriate for the many migraine patients who experience significant nausea or vomiting with their attacks or who have trouble swallowing orally-administered medications. Injectable therapies, while often offering the fastest means of achieving therapeutic blood levels of the administered drug product, often require the involvement of a healthcare provider, can be difficult to self-administer and typically result in greater side effects than non-injectable therapies. As a result, patients generally prefer non-injectable therapies over injectable therapies. While nasal administration of acute treatments has the potential to address certain of these limitations by facilitating rapid absorption of drug from the linings of the nasal passages into the bloodstream while simultaneously limiting side effects, currently available and development-stage nasally-administered acute treatments have drawbacks and limitations. These drawbacks and limitations may include one or more of the following:

- Efficacy that is comparable or only incrementally better than orally-administered acute treatments;
- Partial or variable absorption in the nose, with the remaining fraction of drug delivered into the nasal passage, running down the back of the throat, being swallowed and subsequently absorbed in the gastrointestinal tract;
- Variable pharmacokinetics (PK), resulting in inconsistent and sub-optimal clinical performance and perceived lack of reliability;
- For liquid nasal spray formulations, the administered drug product often drips out of the nose and runs-off down the back of throat, which can result in unpleasant taste;
- Non-intuitive and cumbersome administration procedures, including the need for assembly, priming and multiple administrations (sprays or insufflations) over time in order to deliver a full dose. For example, this is the case with Migranal DHE mesylate liquid nasal spray, for which the self-administration procedure requires four sprays, one in each nostril initially, followed by an additional spray in each nostril 15 minutes later, to administer a full dose; and
- Large size, which reduces practicality of transport for patients and ability to discreetly self-administer.

Acute treatments are categorized as non-specific therapies, including NSAIDs and acetaminophen, and migraine-specific therapies, such as triptans and ergot alkaloids (including DHE-based products), as well as oral CGRP antagonist and oral $5HT_{1F}$ antagonist products recently approved by the FDA. Non-specific therapies are generally recommended for the acute treatment of migraine with mild to moderate pain, and migraine-specific therapies are generally recommended for the acute treatment of migraine with moderate to severe pain. However, none of the currently available treatment options adequately achieve the acute treatment goals for a significant percentage of migraine patients.

Triptans

Oral triptans are currently the predominant class of drug for acute treatment of migraine, accounting for over 90% of migraine-specific acute therapy prescriptions, or more than 14 million prescriptions in the United States in 2018. Triptans are serotonergic agonists, typically with selective activity on a limited number of serotonergic receptors, including the 5-HT_{1B} and 5-HT_{1D} receptors. While widely prescribed, triptans have been reported to have low treatment persistence, with up to 66% of patients never refilling their initial triptan prescriptions. A substantial majority of patients who discontinue triptans cite a lack of efficacy and side effects as the reasons for discontinuation. Triptans have been reported to have a number of shortcomings, including the following:

- *Inconsistent and sub-optimal efficacy*. Approximately 40% of migraine patients do not respond to oral triptan therapy (assessed based on pain relief at two hours from the administration of treatment) and up to 80% do not achieve sustained freedom from pain. In addition, triptans have been reported to have poor effectiveness in multiple common migraine types, including migraine with allodynia (painful touch), migraine with aura (visual or olfactory disturbance), prolonged migraine, menstrual-related migraine, migraine with multiple recurrences, severe migraine, and migraine upon awakening.
- *Side effects and medication overuse headache*. Triptans may produce unpleasant “triptan sensation” side effects, including tightening of the throat, chest, neck and limbs with paresthesias, or tingling, and hot or cold sensations. In addition, triptans have the potential to cause MOH, which can require inpatient detoxification and significantly complicate migraine management. As a result, triptans carry a label warning against use on 10 or more days per month.
- *Requirement for early treatments*. While triptans have been shown to be more effective when taken early in the course a migraine attack, the opportunity for early treatment has been estimated to exist in only 50% of all migraine attacks. Moreover, migraine patients often wait to treat following the onset of a migraine attack due to uncertainty with respect to the peak severity of a particular migraine attack, concern over side effects or dosing limitations, or inability to treat early (for instance, in cases of migraine upon awakening). In one published study, 79% of patients experienced freedom from pain when attacks were treated within one hour of pain onset, but only 21% experienced freedom from pain when attacks were treated four hours after the onset of pain. As a result, many patients may not fully benefit from triptan therapy.
- *Slow and variable onset of action and short duration of effect*. With oral and nasal triptan therapies, the onset of pain relief tends to be relatively slow and variable due to inconsistent systemic absorption via oral and nasal routes of administration.
- *Recurrence within 24 hours*. Migraine recurrence within 24 hours occurs in up to 45% of attacks treated with triptans, resulting in the need for rescue medication and/or re-treatment. Published studies have reported that recurrence of migraine, or the recurrence within 24 hours of an effectively treated migraine, is a common reason given for dissatisfaction among people with migraine and is reported to be a significant unmet need with current acute treatments.

DHE

DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine. DHE has broader pharmacological activity than triptans across multiple receptor types, including serotonergic, adrenergic and dopaminergic receptors, represses CGRP release, and is thought to inhibit neuroinflammation and central sensitization via adrenergic receptors. In addition, DHE has a long pharmacodynamic half-life thought to be attributed to slow receptor dissociation. Because of its differentiated clinical attributes, many headache specialists consider DHE to be a preferred treatment for many difficult-to-treat migraine types, including severe migraine, migraine with allodynia, migraine upon awakening, fast onset migraine, prolonged and recurrent migraine attacks, including menstrual-related migraine, and migraine attacks requiring late treatment (i.e., more than one hour after onset of attack). In addition, DHE is considered a standard-of-care treatment for MOH and for status migrainosus, which is a condition characterized by debilitating migraine attacks that last more than 72 hours. Given the complexity of migraine biology and the redundancy and interdependence of migraine disease pathways, DHE’s activity across multiple receptors is thought to offer the potential for better responses for many migraine patients.

DHE has a number of differentiating clinical attributes providing advantages for the acute treatment of migraine, including:

- *Effective in patients who are non-responsive or refractory to triptan therapy.* Published data indicate that approximately half of all patients who have previously failed to adequately respond to triptan therapy, do respond to DHE therapy.
- *Effective in migraine attacks with allodynia.* Allodynia is present in up to two-thirds of migraine attacks, and its presence is associated with poor response to triptans and most other acute treatments. DHE, however, has demonstrated strong efficacy in migraine attacks in which allodynia is present.
- *Effective irrespective of when administered during the time course of a migraine attack.* Unlike triptans and certain other acute treatments for migraine, which are most effective when administered within one hour of onset of pain, DHE remains effective when administered late after onset of attack.
- *Low risk of headache recurrence.* DHE has been demonstrated in head-to-head controlled studies to have significantly lower headache recurrence rates than available triptan therapies.
- *Lower risk of causing MOH.* DHE is thought to have a lower potential for causing MOH with frequent use and, unlike triptan class therapies, currently approved DHE products do not contain a label warning for MOH potential.

Based on published DHE PK and clinical trial data relating to DHE plasma concentrations and clinical efficacy of different DHE doses, we estimate that 1.0 ng/ml is the threshold concentration necessary for therapeutic response to DHE. Due to its chemical properties and structure, DHE has low bioavailability (approximately 1%) when administered orally and, as a result, oral forms have generally not been effective for the acute treatment of migraine. There are currently no approved oral DHE treatments in the United States. Approved DHE products include injectable and liquid nasal spray dosage forms, which have drawbacks that have resulted in limited clinical use.

Due to DHE's vasoconstrictive effects, DHE products are not recommended for use in patients with cardiovascular risk factors. In addition, approved DHE products carry a "black box" warning in their labels for a risk that the coadministration of DHE and certain other drugs, including specific antivirals and antibiotics, may result in elevated levels of DHE in the blood, potentially causing vasospasm that may result in inadequate blood flow to the extremities or the brain. Unless we can successfully demonstrate by conducting a drug-drug interaction study that the coadministration of DHE and certain other drugs does not result in inhibition of DHE metabolism and elevated DHE levels, the FDA is likely to require the label for STS101, if approved, to include such warning, and this could result in STS101 not achieving its full commercial potential.

Injectable DHE

IV delivery is the fastest means of achieving plasma concentration levels of DHE that we estimate to be necessary to effectively treat a migraine attack, with anti-migraine responses reported as quickly as 15-20 minutes following administration. IV-delivered DHE is typically administered by a healthcare provider in a hospital, clinic or infusion center setting, which is expensive and requires the patient to travel to one of these locations while suffering from a migraine attack. Because IV delivery of DHE results in rapid achievement of high DHE blood levels, side effects are more common with IV administration than with other routes of administration, with nausea and vomiting being particularly common and typically requiring coadministration of anti-nausea medication. DHE can also be administered by IM or SC injection. However, IM and SC administration require a patient, caregiver or healthcare provider to use proper technique during a migraine attack to draw the correct dose of DHE solution for injection from a vial or glass ampule into a syringe and then inject the solution into the muscle or subcutaneous layer of the skin. Although generally considered effective, the challenges of injectable DHE and the fact that migraine patients typically prefer non-injectable therapies for acute treatment of attacks make injectable DHE a less favored treatment option for many people with migraine.

DHE Liquid Nasal Spray

DHE may also be delivered via liquid nasal spray. However, Migranal, the only FDA-approved DHE mesylate liquid nasal spray product, and development-stage DHE liquid nasal spray products may have a number of limitations and complexities related to their liquid nasal spray formulation and delivery devices, including the following:

- *High variability and slow absorption.* The required administration of DHE via multiple liquid nasal sprays often results in highly variable delivered doses of DHE and highly variable DHE plasma concentrations. Moreover, absorption of DHE following administration of Migranal is relatively low and slow in comparison with injectable DHE products, and often fails to achieve plasma concentration levels of DHE of at least 1.0 ng/ml, which we estimate is the minimum threshold concentration necessary for therapeutic response to DHE. For example, in our Phase 1 clinical trial, 65% of subjects receiving Migranal DHE mesylate liquid nasal spray administration did not achieve 1.0 ng/ml at any time following administration. The low, slow, and highly variable DHE plasma levels achieved with Migranal DHE mesylate liquid nasal spray administration can result in inconsistent and unreliable clinical performance and sub-optimal therapeutic response for many patients. This may be evidenced by the fact that in only one of the four pivotal efficacy studies described in the U.S. prescribing information for Migranal, did Migranal demonstrate a statistically significant effect on migraine pain at 2 hours post-dose. Moreover, this statistically significant effect was on the endpoint of migraine pain relief (i.e., reduction in pain) at two hours post-dose, which is generally considered a lower hurdle to achieve than the current FDA-accepted co-primary endpoints of freedom from pain and most bothersome symptom at two hours post-dose.
- *Complex and burdensome administration*. The administration of DHE liquid nasal spray typically requires a complex and burdensome multi-step process, including the opening of the glass vial containing the nasal liquid spray solution and the assembly and priming of a nasal spray device. Due to the low aqueous solubility of DHE, an adequate dosage of DHE via liquid nasal spray requires multiple sprays. For example, Migranal requires four sprays, one in each nostril initially, followed by an additional spray in each nostril 15 minutes later, to administer a full dose. Following administration, liquid can drip out of the nose and run-off down the back of throat, which can result in bad taste.
- *Inconvenient packaging and degradation potential.* Formulations of DHE liquid nasal spray are sensitive to heat, light and oxygen, which necessitates packaging in a sealed, amber-colored, glass vial that cannot be stored in warm environments. In addition, any unused DHE liquid nasal spray remaining after eight hours since the opening of a DHE glass vial must be discarded.

Headache specialists articulate a need for a patient-friendly, self-administered, non-injected DHE product that consistently and reliably provides the rapid, durable and robust efficacy that is currently available only with injectable DHE therapies. Given the differentiated clinical features of DHE, we believe DHE, if made available in a non-injectable dosage form that is well tolerated, facilitates quick and convenient administration and delivers rapid and sustained achievement of therapeutic concentrations with low variability, could provide significant benefits over existing acute treatments for migraine and help a large number of people with migraine better achieve migraine treatment goals.

Our Solution: STS101 for the Acute Treatment of Migraine

STS101 is a drug-device combination of a proprietary dry-powder formulation of DHE administered by a proprietary pre-filled, single-use, nasal delivery device. STS101 is specifically designed to deliver the clinical advantages of DHE while overcoming the shortcomings that have limited the utility of DHE for the acute treatment of migraine. The proprietary and foundational dry-powder formulation and nasal delivery device technologies incorporated in STS101 were developed over more than 15 years by a dedicated team at Shin Nippon Biomedical Laboratories, Ltd., or SNBL.

Subsequent to licensing such technology from SNBL, we advanced the development of STS101 by developing and optimizing the STS101 formulation, establishing analytical methods and scalable manufacturing performed in accordance with good manufacturing practices, conducting extensive analytical characterization of STS101 and its components, and completing toxicology studies in accordance with good laboratory practices. The manufacturing processes we established employ standard technologies that are commonly utilized in the pharmaceutical industry for the manufacture of approved drug and drug-device combination products and that we believe will be reproducible on commercial-scale equipment. Furthermore, we have completed a Phase 1 clinical trial in 42 healthy volunteers and a preliminary human factors study that we believe validates the STS101 instructions for use that are being utilized in the EMERGE Phase 3 efficacy trial, and we have obtained written feedback from the FDA on various aspects of our STS101 Phase 3 development program, including the protocol for our EMERGE Phase 3 efficacy trial, which we initiated in July 2019. Following our Phase 3 efficacy trial, we expect to commence a 12-month safety trial in the third quarter of 2020, with an NDA filing anticipated by the end of 2021.

STS101 was designed to be a rapidly-acting, reliable, and convenient DHE therapeutic product. It has a number of key attributes that we believe may provide significant advantages over existing acute treatments for migraine and result in robust and consistent clinical performance and thereby facilitate broad adoption and use. These attributes are primarily the result of our proprietary dry-powder formulation, which incorporates a mucoadhesive drug carrier and engineered drug particle technologies, and our proprietary nasal delivery device. Key STS101 attributes include:

- *Targeted plasma concentrations rapidly achieved and sustained.* In our Phase 1 clinical trial, administration of STS101 resulted in achievement within 10 minutes of a mean DHE plasma concentration of 1.0 ng/ml, which we estimate is the minimum threshold concentration necessary for therapeutic response to DHE. In addition, DHE exposure (plasma concentration over time expressed as area-under-curve) following STS101 administration at all times exceeded that for Migranal DHE mesylate liquid nasal spray 2.0 mg, which is the only DHE product marketed in the United States that has been approved by the FDA based upon demonstration of efficacy and safety in clinical studies. Further, DHE exposure following STS101 administration was similar to or greater than DHE exposures reported with DHE mesylate IM injection, which is marketed in the United States, which was based upon demonstration of efficacy and safety in clinical studies, and DHE administered via pulmonary inhalation (MAP0004), which met all four of its primary efficacy endpoints in a large Phase 3 clinical trial, but was later discontinued and has not been approved by the FDA. For instance, although peak DHE plasma concentration following administration of STS101 5.2 mg did not reach peak concentration levels associated with IV or IM delivery of DHE, DHE exposure was approximately 83% of that achieved with a DHE mesylate IM injection in our Phase 1 clinical trial.
- *Low variability*. In our Phase 1 clinical trial, STS101 demonstrated significantly lower variability in peak DHE plasma concentration and DHE exposure as compared to Migranal, which may lead to more reliable clinical performance.

- *Quick and convenient self-administration.* STS101 utilizes a convenient, patient-friendly, single-use, nasal delivery device designed to enable self-administration of a full dose of DHE into a single nostril in a matter of seconds. The pre-filled device is pocket-sized and more compact than available DHE liquid nasal spray products, enabling portability and discreet use, and requires no assembly or priming. In addition, the STS101 dry-powder formulation has demonstrated favorable stability properties (including, insensitivity to light, heat or oxygen) we expect will enable storage across a wide range of temperatures and conditions.
- *Well tolerated.* In our Phase 1 clinical trial, all treatments were well tolerated, all adverse events were mild and transient, and no subject withdrew from the trial for an adverse event. Moreover, STS101 did not exhibit the rapid and high peak concentration associated with IV delivery of DHE, which may often result in side effects, in particular nausea and vomiting.

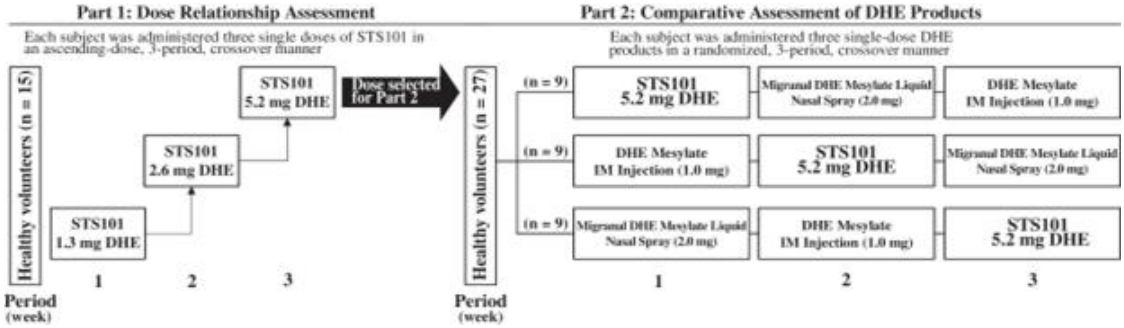
We believe the foregoing attributes of STS101 could lead to it having a favorable therapeutic response profile as compared to IV, IM or SC delivery of DHE and Migranal DHE mesylate liquid nasal spray. The faster a DHE product can produce the threshold DHE plasma concentration necessary for a therapeutic response, the more quickly following administration it may be able to achieve a therapeutic response. At the same time, we believe that rapid and high peak DHE plasma concentrations that greatly exceed the threshold therapeutic level may result in adverse side effects. For example, IV delivery of DHE has demonstrated peak DHE plasma concentrations of 50 ng/ml or more within several minutes of administration, and is reported to more frequently result in side effects (including nausea and vomiting, increases in blood pressure, flushing, dizziness, extremity pain, and abnormal skin sensations) than delivery of DHE by other routes of administration, such as IM or SC injection, nasal or pulmonary, which exhibit much lower peak DHE plasma concentrations that generally have not been reported to exceed approximately 3 to 4 ng/ml. Based on published DHE PK and clinical efficacy trial data relating to DHE plasma concentrations and clinical efficacy and safety data of different DHE doses, we estimate that 1.0 ng/ml is the threshold concentration necessary for therapeutic response to DHE.

The STS101 administration procedure is shown in the figure below:

Phase 1 Pharmacokinetic and Safety Trial Results

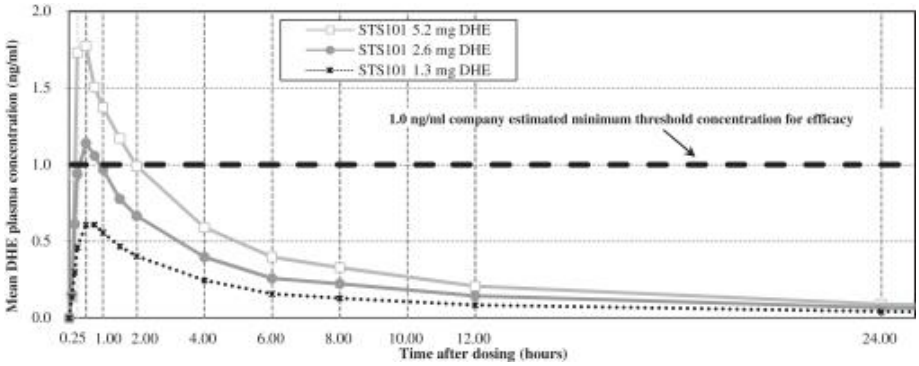
We completed a Phase 1 clinical trial of STS101, which demonstrated favorable PK, safety and tolerability, and which established the doses of STS101 to be evaluated in our Phase 3 EMERGE efficacy trial. Our Phase 1 clinical trial evaluated STS101 in 42 healthy volunteers in a single-center, single-dose, open-label, 2-part, 3-period crossover, PK and safety trial. As reflected in the figure below, in Part 1 of the trial, 15 subjects each received three ascending doses of STS101 per a 3-period crossover design. The active pharmaceutical ingredient in each dose of STS101 is DHE and, like all currently approved migraine products that contain DHE, the STS101 formulation also contains mesylate salt. Per a request from the FDA, our dose strengths of STS101 are calculated as the active moiety without including the mesylate salt. As a result, for purposes of the following discussion, all references to STS101 doses herein are to the DHE content of such doses, whereas the doses for the Migranal and DHE mesylate IM injection include the mesylate in accordance with the commercially-available versions of such products. The STS101 DHE doses used in Part 1 of the trial were 1.3 mg (equivalent to 1.5 mg DHE mesylate), 2.6 mg (equivalent to 3.0 mg DHE mesylate) and 5.2 mg (equivalent to 6.0 mg DHE mesylate). Based on the results from Part 1, the STS101 5.2 mg (DHE) dose was selected for Part 2 of the clinical trial in which 27 subjects received STS101, Migranal DHE mesylate liquid nasal spray and an DHE mesylate IM injection in a random order.

STS101 Phase 1 Trial Design



As reflected in the figure below, Part 1 of the clinical trial demonstrated that DHE was rapidly absorbed after intranasal administration of single doses of STS101 1.3 mg, 2.6 mg, and 5.2 mg, with mean DHE plasma concentrations increasing in a dose-dependent manner. DHE plasma concentrations for STS101 2.6 and 5.2 mg rapidly exceeded 1.0 ng/ml. Based on published DHE PK and clinical trial data relating to DHE plasma concentrations and clinical efficacy of different DHE doses, we estimate that 1.0 ng/ml is the minimum threshold concentration necessary for therapeutic response to DHE. This conclusion is supported by data from certain clinical trials of Migranal DHE mesylate liquid nasal spray conducted by third parties, which have demonstrated that DHE plasma concentrations resulting from Migranal DHE mesylate liquid nasal spray are dose dependent and linear. In certain such studies, the administration of 2.0 mg of Migranal DHE mesylate resulted in a mean maximum concentration of approximately 1.0 ng/ml, while the administration of smaller doses of Migranal (e.g., 1.5 mg DHE mesylate) did not reach such maximum concentrations and failed to show statistically significant efficacy in controlled studies.

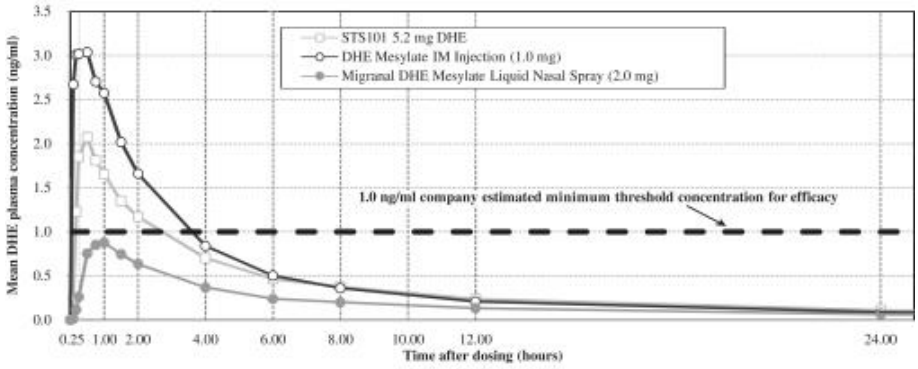
Phase 1, Part 1: Mean DHE Plasma Concentrations in Healthy Subjects after Administration of a Single Dose of STS101 (1.3 mg, 2.6 mg and 5.2 mg DHE)

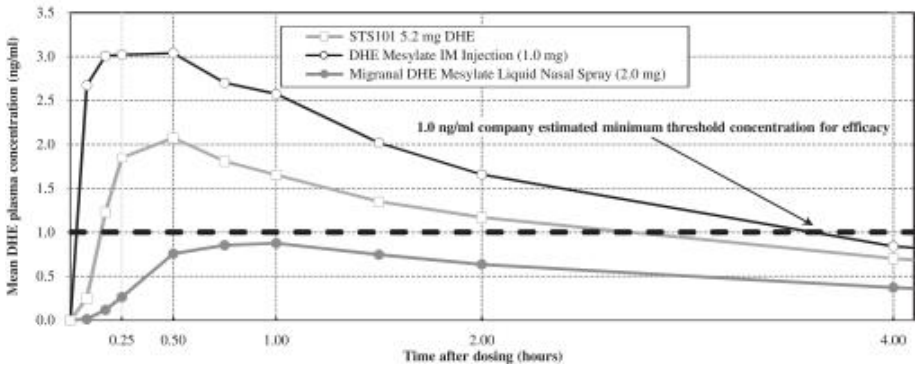


Based on the PK, safety and tolerability data from Part 1 of our Phase 1 clinical trial, we selected STS101 5.2 mg for evaluation in Part 2 of the clinical trial.

As reflected in the figure below, in Part 2 of our Phase 1 clinical trial, DHE plasma concentrations rose rapidly after administration of STS101 5.2 mg and DHE mesylate IM injection, with mean concentrations exceeding 1.0 ng/ml at 10 minutes and 5 minutes after dosing, respectively. In contrast, the mean maximum DHE plasma concentration after Migranal DHE mesylate liquid nasal spray administration did not reach 1.0 ng/ml. In general, the amount of DHE delivered by STS101 5.2 mg into systemic circulation over time was approximately 2-fold greater as compared with Migranal DHE mesylate liquid nasal spray and was approximately 83% of the amount delivered by an DHE mesylate IM injection. Importantly, in our Phase 1 clinical trial, the DHE plasma concentration profiles observed following administration of Migranal DHE mesylate liquid nasal spray and DHE mesylate IM injection were consistent with historical data, including those data included in the Migranal summary basis of approval.

Phase 1, Part 2: Mean DHE Plasma Concentration in Healthy Subjects after Administration of a Single Dose of STS101 5.2 mg DHE, DHE Mesylate IM Injection 1.0 mg, and Migranal DHE Mesylate Liquid Nasal Spray 2.0 mg





Safety and Tolerability Profile

In our STS101 Phase 1 clinical trial, all treatments were well tolerated, all adverse events were mild and transient, and no subject withdrew from the trial for an adverse event. Subjects treated with STS101 reported a higher frequency of nasal adverse events than those treated with DHE mesylate IM injection or Migranal DHE mesylate liquid nasal spray. The treatment emergent adverse events reported after STS101 administration, all of which were mild and transient, were nasal discomfort (STS101 5.2 mg (34%), IM injection (0%) and Migranal (7%)) nasal congestion (STS101 5.2mg (13%), IM Injection (0%) and Migranal (0%)), nasal itch (STS101 5.2mg (7.3%), IM Injection (0%), Migranal (0%)), rhinalgia (pain in the nose) (STS101 5.2mg (12%), IM Injection (0%) and Migranal (4%)), bitter or sour taste (STS101 5.2 mg (22%), IM Injection (0%) and Migranal (7%)), runny nose (STS101 5.2mg (15%), IM Injection (0%) and Migranal (0%)), shedding of tears (STS101 5.2 mg (7.3%), IM Injection (0%), Migranal (0%)), sneezing (STS101 5.2 mg (4.9%), IM Injection (0%), Migranal (0%)) and abdominal pain (STS101 5.2 mg (4.9%), IM injection (0%), Migranal (0%)). Patients receiving lower doses of STS101 reported fewer adverse events. No adverse events involving nausea or vomiting were reported after administration of STS101, IM injection or Migranal.

We further assessed nasal symptoms utilizing a subjective nasal symptom severity score self-reported by subjects on the visual analog scale, or VAS score, on a zero to one-hundred scale in which zero represents absence of the symptom and one-hundred represents presence of the symptom with the worst imaginable severity. The average scores for nasal symptoms (including, abnormal taste, nasal blockage or obstruction, nasal burning, nasal discomfort, nasal itching, nasal pain, runny nose and sneezing) were all under 5 mm following administration of STS101 5.2 mg. In addition, subjective nasal symptom severity scores self-reported in Part 1 of our Phase 1 clinical by subjects treated with STS101 1.3 mg and 2.6 mg were negligible.

Based on the safety and tolerability profile observed in our Phase 1 clinical trial, including the results of nasal examinations and subjective nasal symptom scores reported by subjects, we do not believe the tolerability of the STS101 5.2 mg dose should present a barrier to patient adoption or use, if approved.

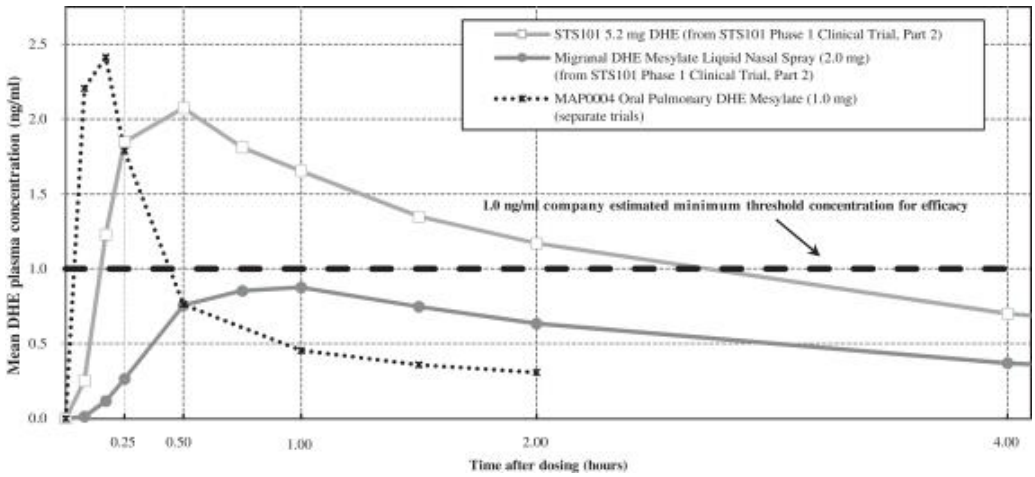
Comparison of STS101 PK Data to Other Non-Injectable DHE Products

We conducted a further analysis comparing data from our Phase 1 clinical trial data of STS101 5.2 mg and Migranal DHE mesylate liquid nasal spray 2.0 mg to published data from earlier Phase 1 clinical trials of MAP0004, another company's orally-inhaled, pulmonary-route DHE product candidate. Following such Phase 1 clinical trials, MAP0004 met all four of its primary efficacy endpoints and demonstrated a favorable safety profile, but was later discontinued by Allergan. The discontinuation of MAP0004 (previously referred to as the brand names Levadex and Semprana) followed multiple requests from the FDA that the developer address certain issues relating to chemistry, manufacturing, and controls, after certain manufacturing deficiencies were identified during the FDA's inspection of a facility operated by a third party manufacturer. As a result, MAP0004 was never approved by the FDA and no determination was made by the FDA with respect to its efficacy and safety.

As the data presented below is based on a cross-trial comparison and not a head-to-head clinical trial, such data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of STS101 compared to other product candidates that may be approved or that are or were in development for the acute treatment of migraine. In particular, our Phase 1 clinical trial and the Phase 3 clinical study of MAP0004 (FREEDOM-301) conducted by a third party used similar study designs with different patient eligibility criteria. While our Phase 1 clinical trial was conducted in healthy volunteers, the MAP0004 study (FREEDOM-301) required participants to have a one-year history of migraine according to the International Classification of Headache Disorders and a baseline frequency of two to eight migraine attacks per month. In addition, our Phase 1 clinical trial was designed to provide PK, safety and tolerability data for STS101, whereas the MAP0004 study (FREEDOM-301), used four co-primary endpoints at the 2-hour post dosing time point: pain relief, photophobia-free, phonophobia-free, and nausea-free. The MAP0004 study (FREEDOM-301) reported similar age ranges, gender and race among the participants as our Phase 1 clinical trial of STS101.

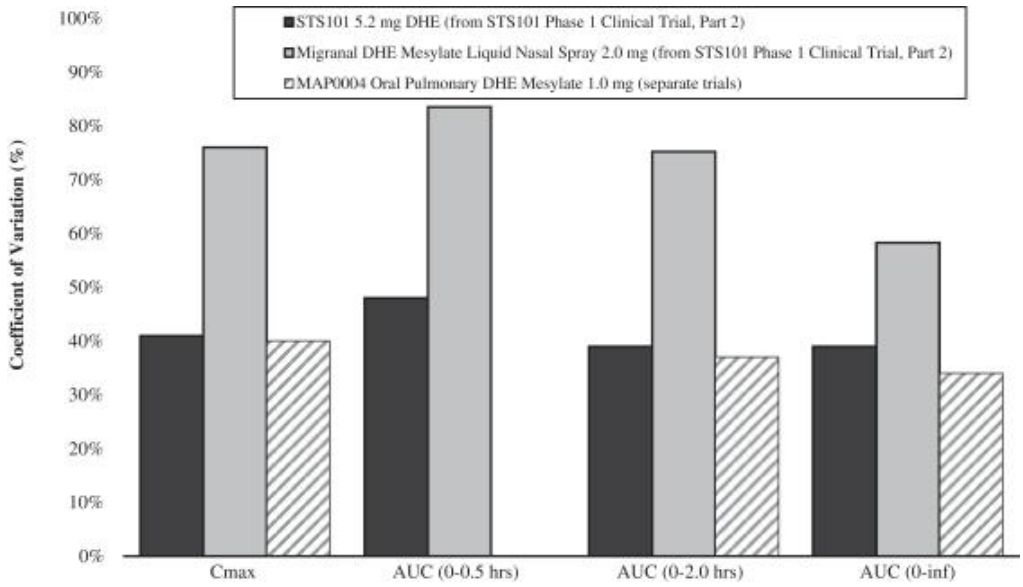
As reflected in the figures below, in our Phase 1 clinical trial, STS101 5.2 mg achieved greater DHE exposure by approximately 30 minutes and all time points thereafter as compared to DHE exposure achieved by MAP0004 in Phase 1 clinical trials conducted by its developer.

Mean DHE Plasma Concentration in Healthy Subjects after Administration of a Single Dose of STS101 5.2 mg DHE, Migranal DHE Mesylate Liquid Nasal Spray 2.0 mg and MAP0004 1.0 mg



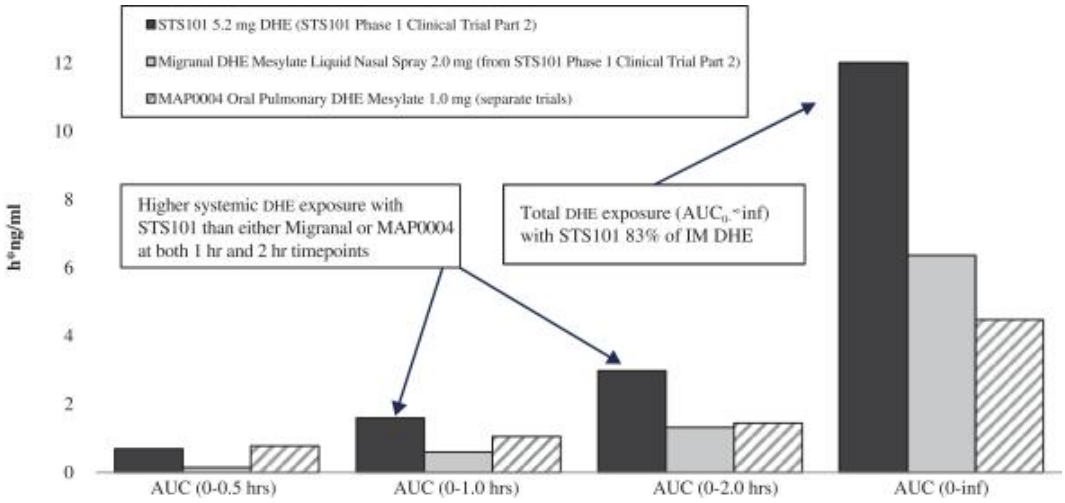
In addition, in our Phase 1 clinical trial, STS101 5.2 mg showed significantly lower variability in peak DHE plasma concentrations and the amounts of DHE delivered into systemic circulation over 0.5, 2 and 48 hours after administration as compared to Migranal DHE mesylate liquid nasal spray. The variability of STS101 in peak plasma concentrations and in DHE exposure expressed as area-under-curve, or AUC, over 2 and 48 hours was comparable to that of MAP0004 in a Phase 1 clinical trial conducted by its developer. The figure below reflects the PK variability of STS101 5.2 mg and Migranal DHE mesylate liquid nasal spray from our Phase 1 clinical trial and the previously reported third-party Phase 1 clinical trial data for MAP0004 measured by a mean percent coefficient of variation, which represents the variability of the specified data points.

PK Variability of STS101 5.2 mg DHE vs. Other Non-Injectable DHE Products



As reflected in the figure below, total DHE exposure with STS101 5.2 mg in our Phase 1 clinical trial was almost three times greater than reported for MAP0004 in a Phase 1 clinical trial conducted by its developer. Within one hour after administration, STS101 5.2 mg delivered greater amounts of DHE into systemic circulation as compared to the amounts of DHE delivered into systemic circulation by Migranal DHE mesylate liquid nasal spray and MAP0004 over two hours.

DHE Exposure (AUC) for STS101 5.2 mg DHE and Other Non-Injectable DHE Products



In summary, the results from the STS101 Phase 1 clinical trial showed that, within 10 minutes after administration, STS101 5.2 mg achieved target DHE plasma concentrations exceeding 1.0 ng/ml and remained above this level for over 2.5 hours. Furthermore, trial results showed that in comparison with Migranal DHE mesylate liquid nasal spray, STS101 5.2 mg achieved more than a 2-fold higher mean maximum DHE plasma concentration, achieved the maximum concentration much more rapidly, and delivered nearly 2-fold as much DHE into systemic circulation.

Based on our Phase 1 clinical trial data and published data from separate clinical trials conducted by others for different DHE products, including a large Phase 3 study conducted with MAP0004, we believe that the PK profile of STS101 may lead to strong clinical performance expressed in rapid onset of pain relief, excellent 2-hour pain free rates, and sustained efficacy and low recurrence rates at 24 and 48 hours. Accordingly, we believe STS101 has the potential to treat a broad spectrum of migraine types, including those that are often difficult to treat, such as menstrual-related migraine, migraine upon awakening, migraine with allodynia, migraine associated with severe pain and migraine with nausea and vomiting. We expect to prospectively evaluate the performance of STS101 in these subgroups during our Phase 3 EMERGE efficacy trial.

Comparing efficacy data of a third-party DHE product candidate, MAP0004, with efficacy data of other emerging treatments for migraine

We performed a cross-trial comparative analysis of the largest placebo-adjusted effect size for key endpoints in Phase 3 trials conducted by third parties of investigational and approved therapeutics for the acute treatment of migraine across a range of classes including inhaled DHE (MAP0004), oral CGRP antagonists (rimegepant, and ubrogepant) and an oral $5HT_{1F}$ agonist (lasmiditan). The comparative analysis indicated that the DHE product MAP0004 had a greater effect size across a range of efficacy measures relative to the other product candidates.

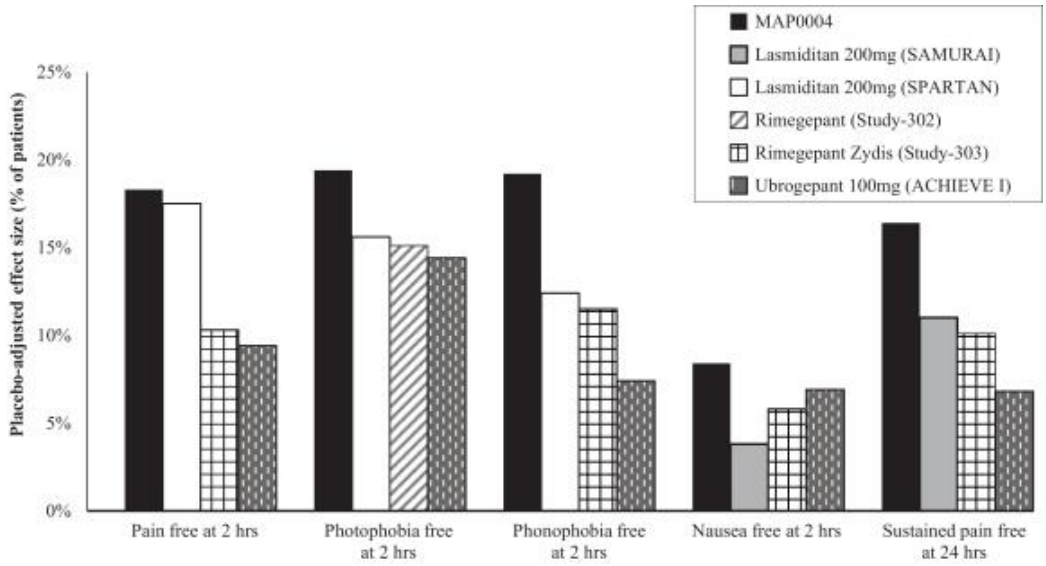
We also conducted a comparison of the migraine attack severity, timing-of-treatment in relation to migraine onset, and study design information available to us from the clinical trials of the various product candidates. This comparison indicated that a larger proportion of treated patients in the MAP0004 Phase 3 trial experienced severe migraine attacks versus those treated patients in the Phase 3 trials for lasmiditan, rimegepant, and ubrogepant. In addition, we believe the MAP0004 Phase 3 trial allowed for a longer time window for treatment relative to the other trials.

The data presented below for each product candidate represents data from the trial with the largest placebo-adjusted effect size for each endpoint (the percentage of responding patients treated with study medication less the percentage of responding patients treated with placebo), where multiple trials have been conducted for a product candidate. Not all available trial data is presented. As the data presented below is based on a cross-trial comparison and not head-to-head clinical trials, such data may not be directly comparable due to differences in study protocols, statistical analysis methods, conditions and patient populations. Accordingly, cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of product candidates that may be approved or that are or were in development for the acute treatment of migraine.

The Phase 3 clinical studies with rimegepant, ubrogepant, lasmiditan and MAP0004 were all conducted between 2008 to 2018 and used substantially similar study designs and patient eligibility criteria. All studies required participants to have a one-year history of migraine according to the International Classification of Headache Disorders and a baseline frequency of two to eight migraine attacks per month. All studies were double-blinded, placebo-controlled and assessed the efficacy and safety of self-administered study medication or placebo in the outpatient setting following the treatment of a single migraine attack with moderate or severe pain during the treatment period. The lasmiditan studies allowed the use of a second dose for rescue, but the primary analyses were based on the first dose administered. The MAP0004 study (FREEDOM-301) used four co-primary endpoints at the 2-hour post dosing time point: pain relief, photophobia-free, phonophobia-free, and nausea-free. Pain free at two hours was used as a secondary endpoint. The studies with rimegepant, ubrogepant, and lasmiditan used freedom from pain and most bothersome symptom (selected by the patient from among photophobia, phonophobia and nausea) at 2-hours post dosing as co-primary endpoints. Pain relief, photophobia-free, phonophobia-free, and nausea-free were used as secondary endpoints. All studies reported similar age ranges, gender and race among the participants. Placebo-adjusted effect sizes, are shown for the different endpoints to account for possible differences in the placebo response rates in the studies.

In addition, while MAP0004 was a DHE-based product candidate, none of the clinical trials presented below studied STS101. The performance of STS101 across these or other efficacy measures in our planned clinical trials may differ materially from any results that could be inferred from this cross-trial comparison, including due to differences between MAP0004 and STS101, as well as differences in study protocols, statistical analysis methods, conditions and patient populations.

Placebo-adjusted efficacy data (% of patients) from the clinical trials of various product candidates for migraine



Development Plan

Our development plan for STS101 is informed by published FDA guidance as well our discussions with the FDA. Following completion of our Phase 1 study, the FDA provided us with written feedback on our proposed STS101 development program, which is comprised of a single Phase 3 efficacy trial and a single Phase 3 safety trial to support approval of STS101 for the acute treatment of migraine headaches with or without aura. Our development program is intended to support registration of STS101 through the 505(b)(2) approval pathway. We plan to conduct both trials in the United States.

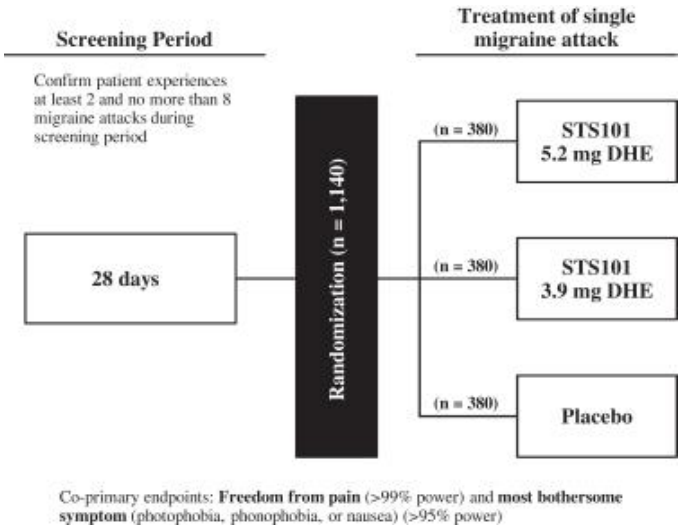
Phase 3 Efficacy Trial

Our Phase 3 EMERGE efficacy trial is a multi-center, single-dose, randomized, double-blind, placebo-controlled, parallel group study in approximately 1,140 patients experiencing episodic migraine attacks. To establish eligibility, study participants must have at least two but no more than eight migraine attacks during a 28-day screening period. After establishing full eligibility, the study participants are randomized (1:1:1) to receive one of three treatments: STS101 DHE 3.9 mg, STS101 DHE 5.2 mg or matching placebo. After randomization, the trial participants are instructed to treat their next migraine attack of at least moderate pain severity with the allocated blinded study medication. All study participants are trained multiple times in the STS101 administration procedure prior to use, and we provide each participant with an electronic device preloaded with diary software designed to capture relevant trial data.

Our EMERGE trial follows certain of the recommendations outlined in the FDA Guidance Migraine: Developing Drugs for Acute Treatment, February 2018. In particular, the two co-primary endpoints of our EMERGE trial to be assessed at two hours after STS101 administration are freedom from pain and freedom from most bothersome symptom. We believe the trial is powered to achieve these endpoints (i.e. at greater than 99% power for the freedom from pain endpoint and greater than 95% power for the freedom from most bothersome symptom endpoint). In addition, several secondary endpoints, including those suggested in the FDA guidance, are incorporated into the trial protocol. Such endpoints include rescue medication usage, headache relapse measurements, and functional impairment scales. Further, we expect to prospectively evaluate the performance of STS101 in patient subgroups, including menstrual-related migraine, migraine upon awakening, migraine with allodynia, migraine associated with severe pain and migraine with nausea and vomiting, during our Phase 3 EMERGE efficacy trial to assess whether further study may be of interest. If both doses are successful in our EMERGE trial, then both doses may be submitted in the NDA.

The figure below provides details of the trial design of our Phase 3 EMERGE efficacy trial:

STS101 Phase 3 EMERGE Efficacy Trial Design



If successful, we believe our EMERGE trial's differentiated secondary endpoints and clinical performance in prospectively-defined patient subgroups, could provide us with a strong foundation for promotion and commercialization. Labels for current DHE products, such as D.H.E. 45® and Migranal, do not address the differentiating attributes of DHE and its potential to address unmet needs of many patients with difficult-to-treat migraine types, which we believe has led to low clinical awareness of its benefits by physicians other than headache specialists.

We initiated our EMERGE trial in July 2019 and expect topline data in the second half of 2020.

Phase 3 Safety Trial

We also plan to initiate a Phase 3 safety trial of STS101. This safety trial is expected to be a multi-center, open-label, 12-month trial in episodic migraine patients, with target enrollment depending on results of the EMERGE Phase 3 trial. After establishing eligibility, the study participants will be expected to use STS101 on an as-needed basis to treat migraine attacks for up to 12 months. Consistent with written feedback from FDA, we anticipate that at least 150 and 50 subjects will complete six and twelve months, respectively. Following the completion of this trial, if successful, we expect to submit our NDA to the FDA by the end of 2021.

Additional Trials

We may undertake additional clinical trials with STS101 to enhance its clinical profile. For example, unless we can successfully demonstrate by conducting a drug-drug interaction study that the coadministration of STS101 and certain other drugs does not result in inhibition of DHE metabolism and elevated DHE levels, the FDA is likely to require a "black box" warning in the label for STS101, if approved, in line with the warnings that are included in the labels for other approved DHE products.

Because migraine affects adolescents (12 to 17 years of age) and children (six to eleven years of age), pediatric studies are required under the Federal Food, Drug, Cosmetic Act, or the FDCA. To address such requirements, we designed an initial pediatric study plan, or iPSP, consistent with the FDA guidance *Migraine: Developing Drugs for Acute Treatment, February 2018*, which we submitted as an amendment to the STS101 investigational new drug application in May 2019. In August 2019, the FDA provided comments to our iPSP in which the FDA agreed with our plan to request a waiver of clinical studies in children under age six. We have

revised the iPSP to address the FDA's comments on our proposed study plan for children (six to eleven years of age) and adolescents (12 to 17 years of age) and our requests for a deferral of any pediatric studies until after the initial approval of STS101 in the adult population in October 2019, and the revised iPSP is currently under review by the FDA. While we plan to work with the FDA to finalize the iPSP, and to our knowledge the FDA has not previously required initiation of pediatric studies for any drug for the acute treatment of migraine prior to its approval in the adult population, there can be no assurance that the FDA will ultimately grant our proposed waiver and/or deferrals. As a result, we could be required to conduct pediatric studies in such patient populations prior to or following any approval of STS101. Under the pediatric exclusivity provision of the FDCA, if FDA issues a written request for the pediatric studies and they are conducted pursuant to the written request, STS101 could qualify for an additional six months of marketing exclusivity. Moreover, if the conducted iPSP leads to an approval of STS101 for pediatric migraine patients this population could use STS101.

To date, we and SNBL have completed preliminary human factor studies that we believe support self-administration of STS101 in the outpatient setting for the treatment of migraine and validate the STS101 instructions for use that we are utilizing in our Phase 3 EMERGE efficacy trial, which we initiated in July 2019. We anticipate conducting further human factor studies.

Regulatory Pathway

Since DHE is well characterized and previously approved, we intend to seek FDA marketing approval of STS101 under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, which provides an alternate path to FDA approval for modifications to formulations of products previously approved by the FDA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from non-clinical studies and clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. By utilizing this pathway, and based on our discussions with the FDA, we believe we would be able to forego a Phase 2 clinical trial of STS101 by establishing that STS101 has comparative bioavailability to a reference listed drug with the PK results of our Phase 1 clinical trial.

In the United States, we intend to pursue a 505(b)(2) NDA for STS101 referencing the NDAs for D.H.E. 45 (DHE mesylate injectable solution) and Migranal (DHE mesylate liquid nasal spray). Migranal has no therapeutic equivalents (other than an authorized generic) and is not covered under any unexpired patents that could delay approval of our NDA. We believe this development strategy could provide both an expeditious and cost-efficient approval pathway for STS101 in the United States, including by enabling us to forego a Phase 2 clinical trial. Our Phase 3 efficacy trial is intended to clinically and commercially differentiate STS101 from the reference products.

Manufacturing

Our manufacturing and regulatory teams, although limited in size, have substantial experience in manufacturing process development, registration and the commercial manufacture of drug-device combination products, including inhalation-route drug-device combination products. We do not have any manufacturing facilities and all of our manufacturing processes, which must comply with current good manufacturing practices, or cGMP, are outsourced to third parties with oversight by our internal managers. We rely on third-party manufacturers to produce sufficient quantities of drug product for use in clinical trials. We intend to continue this practice for any future clinical trials and large-scale commercialization of STS101.

We selected processes for manufacturing of STS101 that we believe are readily scalable and transferable, and all of our STS101 manufacturing processes employ standard technologies that are commonly utilized in the pharmaceutical industry for the manufacture of approved drug and drug-device combination products. However, certain processes for the manufacture of STS101 involve trade secrets and/or require custom or semi-custom equipment that is not available for off-the-shelf purchase, requires substantial investment, and/or has long lead times associated with its design, manufacture, delivery, installation and qualification.

For clinical supplies used in the development of STS101, we contract with CMOs to manufacture the final powder drug formulation and to semi-automatically fill the powder formulation into and manually assemble the STS101 nasal delivery device.

The drug substance of STS101 is supplied by a drug substance manufacturer, which has extensive experience manufacturing the STS101 drug substance under cGMP, has an active Drug Master File, or DMF, registered with FDA, and has the capacity to meet our anticipated clinical and commercial supply needs. We believe there are additional drug substance manufacturers with active DMFs registered with the FDA that could potentially serve as back-up suppliers for us.

The proprietary STS101 nasal powder delivery device plastic components are manufactured by two third-party CMOs using widely available common standard injection-molding and blow-molding equipment processes, and we are currently in the process of procuring the mold tooling, which we will own, that we plan to use for the manufacture of STS101 registration batches and commercial supplies.

For commercial supply of STS101, we intend to contract with one of the same CMOs that we utilize to manufacture the final nasal powder formulation for our clinical supplies, and we expect to use the same standard equipment and processes as used in the manufacture of such clinical supplies. For large-scale automated filling, automated assembly and packaging of the STS101 nasal powder delivery device for commercialization, we intend to contract with a CMO that we are utilizing to semi-automatically fill and manually assemble the STS101 delivery devices to be used in the STS101 Phase 3 clinical trial program. Automated filling, assembly and packaging of STS101 commercial supplies will utilize semi-custom equipment for which we have contracted, and, with respect to packaging, intend to contract.

Commercial Operations

We recently hired an experienced Chief Commercial Officer. However, we currently have no other marketing staff and do not have sales organization. If approved by the FDA for the acute treatment of migraine, we intend to market and commercialize STS101 in the United States by building a specialized sales organization focusing on headache specialists, as well as general neurologists and primary care physicians who are high prescribers of migraine therapeutics. Outside the United States, we intend to establish commercialization strategies for STS101 as we approach possible commercial approval in each market, which may include collaborations with other companies.

Competition

The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. If approved for the acute treatment of migraine, we anticipate that STS101 would compete against other marketed migraine therapies for the acute treatment of migraine and may compete with products currently under development by other companies.

In 2018, over 15 million prescriptions for migraine-specific acute therapies were written in the United States. This figure excludes prescriptions of non-specific therapies, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen, and thus likely understates the total number of prescriptions written for the acute treatment of migraine. The majority of the prescriptions written were for generic triptans. There are seven FDA-approved triptan molecules available in branded and branded generic/generic oral dosage forms, and two of these molecules are also available in injectable and/or liquid nasal spray dosage forms that may have faster onset of action than oral dosage forms. With respect to DHE products, we will compete with Bausch Health’s Migranal and its authorized generic, both of which are DHE liquid nasal spray products, as well as branded and generic DHE injectable products. In addition, we believe Impel NeuroPharma is developing a DHE liquid nasal spray product utilizing the same liquid formulation as Migranal, but with a different propellant-powered, single-use delivery device for which Impel NeuroPharma has indicated it plans to file an NDA in the second half of 2020. In addition, Promius Pharma has previously reported that it is developing a DHE nasal liquid spray product. We believe these products will suffer from many of the same limitations as Migranal and have not been reported to significantly improve DHE absorption or pharmacokinetics as compared with Migranal to an extent that we believe likely to be clinically relevant. Impel NeuroPharma in particular has indicated that it plans to pursue approval of its product on the basis of a clinical development program that includes only a comparative pharmacokinetic study and an open-label, uncontrolled, repeat-dose safety trial (and not a randomized, controlled, double-blinded Phase 3 efficacy study which the FDA typically requires to support any product-specific marketing claims relating to efficacy). There can be no assurance that we will be able to successfully bring STS101 to the market faster than these liquid nasal spray candidates or compete against such products, if approved.

We may also face competition from acute treatments for migraine recently approved by the FDA such as Eli Lilly's lasmiditan, an oral $5HT_{1F}$ agonist, and oral CGRP antagonists ubrogepant (Allergan) and rimegepant (Biohaven). Because lasmiditan, ubrogepant, and rimegepant are thought to act by mechanisms other than vasoconstriction, recommended use is not restricted to patients who do not have cardiovascular risk factors or disease, as is the case for triptan and ergot alkaloid products (including DHE) due to their vasoconstrictive actions. Although the labels for lasmiditan, ubrogepant and rimegepant do not limit use to patients without cardiovascular risk factors or disease, we believe these products have disadvantages. For example, lasmiditan has been reported to commonly cause central nervous system adverse events such as dizziness, somnolence and paresthesia, and the lasmiditan label includes warnings for driving impairment and operation of machinery for at least eight hours after taking a lasmiditan dose, central nervous system depression, serotonin syndrome, and medication overuse headache. Additionally, because lasmiditan has shown potential for abuse and dependence, the U.S. Drug Enforcement Agency, or DEA, has designated lasmiditan as a controlled substance; this designation imposes licensing and documentation requirements upon prescribers and as well restricts distribution. With ubrogepant and rimegepant, reported efficacy is modest in comparison with efficacy historically reported with triptan and DHE products. Moreover, prescribing of ubrogepant, and to a lesser extent rimegepant, may be complicated by the potential for interactions with a variety of prescription and over-the-counter medicines, vitamins and herbal supplements, with this potential necessitating dose adjustment of or contraindication to ubrogepant. As well, although the ubrogepant and rimegepant labels do not contain liver toxicity warnings, the oral CGRP receptor antagonist class has previously been associated with rare but serious liver toxicity.

Further, preventive treatment of migraine, could, if broadly adopted and used successfully, reduce the need and demand for acute treatment options. Injectable formulations of anti-CGRP monoclonal antibodies (e.g. erenumab, fremanezumab, and galcanezumab) have recently been approved for prevention of migraine attacks and Allergan and Biohaven have also reported that they are conducting clinical trials of oral CGRP antagonists for prevention of migraine attacks and Allergan and Biohaven have also reported that they are conducting clinical trials of oral CGRP antagonists for prevention of migraine attacks. In addition, Lundbeck (formerly Alder Biopharmaceuticals) recently announced it was commencing a study of its intravenously injected monoclonal CGRP antibody therapeutic, eptinezumab, which was approved in February 2020 by the FDA for prevention of migraine attacks, to evaluate it as an acute treatment for migraine.

There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products which may target the same markets as STS101. We expect any future products we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects experienced and convenience of administration and drug delivery. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than us, obtain approvals for such products from the FDA more rapidly than us or develop alternative products or therapies that are safer, more effective and/or more cost effective than any future products developed by us. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize STS101 in our target commercial areas outside the United States. Many of these companies have greater financial resources, marketing capabilities and experience in obtaining regulatory approvals for product candidates.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for STS101, manufacturing and process discoveries, and other know how, to operate without infringing the proprietary rights of others, and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trade secrets, know how, continuing technological innovation and potential in licensing opportunities to develop and maintain our proprietary position.

With regard to STS101, we have patents and applications to formulations, dosages, devices, and methods of use.

As of January 31, 2020, we have an exclusive license to 6 issued U.S. patents and 9 issued foreign patents, which include granted European patent rights that have been validated in various EU member states, and own or have an exclusive license to various pending U.S. non-provisional patent applications, U.S. provisional patent applications, and pending foreign patent applications, and an international Patent Cooperation Treat (PCT) patent application. Issued U.S. patents relating to STS101 are estimated to expire between 2029 and the end of 2033. If issued, future patents resulting from pending U.S. patent applications relating to STS101 would be estimated to expire between 2034 and 2039. All issued U.S. and foreign patents relating to STS101 were exclusively licensed from SNBL. The pending U.S. and foreign patent applications (including U.S. provisionals) relating to STS101 are solely owned by us or exclusively licensed from SNBL.

The patent portfolio for STS101 is directed to cover formulations, dosages, devices, and methods of treatment. This patent portfolio includes issued U.S. patents, pending U.S. patent applications and corresponding foreign national and regional counterpart patents and patent applications. The U.S. issued formulation patents and device patents are exclusively licensed from SNBL. Royalties on products covered by this exclusive license are payable on a product-by-product and country-by-country basis until the latter of the expiration of the last-to-expire patent covering such product and the ten year anniversary of the first commercial sale of such product in such country. For more information on the SNBL License, see the section titled “Business—Licenses and Collaborations.” We own U.S. patent applications relating to the formulations, dosages, and methods of use of STS101 for treatment.

The terms of patents and patent applications, if issued, relating to STS101 in other jurisdictions (some of the major foreign jurisdictions include Europe, Japan, China, India, Canada, Australia, Brazil, Korea, Mexico, Russia), if the appropriate maintenance, renewal, annuity and other government fees are paid, are expected to expire between 2025 and 2039. We also protect our proprietary technology and processes, in part, by confidentiality and invention assignment agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, scientific advisors or other contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of third parties. It is uncertain whether the issuance of any third party patent would require us to alter our development or commercial strategies, alter our drugs or processes, obtain licenses or cease certain activities. Our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future drugs may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the United States Patent and Trademark Office, or USPTO, to determine priority of invention.

Licenses and Collaborations

In June 2016, we and SNBL, entered into a licensing and assignment agreement, or the SNBL License, which was amended and restated in December 2016 and further amended in January 2017, April 2017, and October 2017. We currently rely and intend to continue to rely on the SNBL License for purposes of our development and potential commercialization of STS101. From the time we entered into the SNBL License until the consummation of our Series A convertible preferred stock financing in December 2016, we were a subsidiary of SNBL and SNBL continues to hold over 5% of our outstanding capital stock. Under the SNBL License, SNBL assigned to us certain patent rights and know-how that are directed to SNBL’s proprietary nasal drug delivery technology, including its proprietary nasal delivery device, or the Device, and formulation technologies, for use with DHE, or the DHE Product. SNBL granted to us an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights and know-how, other than the assigned patent rights and know-how, to develop, make, use, and commercialize DHE Products in the field of treatment, prevention or prophylaxis of all indications and human medical conditions, as well as the products consisting of the Device used to deliver a combination of DHE and one or more active pharmaceutical ingredients other than DHE, or DHE Combination Products, in the field of treatment, prevention or prophylaxis of migraine and non-migraine headaches. We granted to SNBL a non-exclusive, royalty-free, sublicensable license, under our rights in improvements to the Device, to develop, make, use, and commercialize products and devices other than DHE Products and DHE Combination Products. During the term of the SNBL License, we, SNBL, and our and SNBL’s affiliates are not permitted to develop or commercialize, or to

enable third parties to develop or commercialize, a product containing DHE as an active ingredient for delivery through nasal tissues or the respiratory system, other than pursuant to the SNBL License. We will be responsible, at our cost, for the development, manufacture and commercialization of DHE Products and DHE Combination Products under the SNBL License. We are required to use commercially reasonable efforts to develop and commercialize at least one such product, initially in the United States.

Under the SNBL License, in 2016 we reimbursed SNBL for approximately $80,000 of costs relating to our incorporation and prosecution and maintenance of the product-specific patents. We also agreed to make royalty payments based on a low single-digit percentage of worldwide net sales of DHE Products and DHE Combination Products, payable on a product-by-product and country-by-country basis until the latest of the expiration of the last-to-expire patent covering such product and the ten year anniversary of the first commercial sale of such product in such country. The royalty payments are subject to reductions based on royalties paid to any third party under a license to such third party's patent rights.

We have the sole right to control the prosecution and maintenance of, and to enforce, the patent rights that SNBL assigned to us. SNBL has the first right to control the prosecution and maintenance of the patent rights that SNBL licensed to us. We have step in rights if SNBL does not continue such prosecution and maintenance. We also have the first right to enforce such licensed patent rights with respect to certain infringing products. If we do not bring an action to enforce such patents against infringing activities that involve such infringing products, SNBL has the right to bring such an action.

The SNBL License will continue on a country-by-country and product-by-product basis until the expiration of the obligation to pay royalties with respect such product and country. We may terminate the SNBL License in its entirety without cause on ninety days' prior written notice. SNBL may terminate the SNBL License for our material breach that remains uncured for ninety days. SNBL may also terminate the SNBL License if we challenge the licensed patents, or if we assist any third party in challenging such patents. In addition, SNBL has the right to terminate the license agreement upon our insolvency.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, marketing and promotion, distribution, post-approval monitoring and reporting, sampling, and import and export of products, such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Our product candidate, STS101, is subject to regulation in the United States as a drug-device combination product. If marketed individually, the drug component and the propriety device component would be subject to different regulatory pathways and would require approval of independent marketing applications by the FDA. A combination product, however, is assigned to a Center within FDA that will have primary jurisdiction over the product's regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of STS101, the FDA has confirmed that the primary mode of action is attributable to the drug component of the product. Accordingly, STS101 will be regulated as a drug product by the FDA's Center for Drug Evaluation and Research, or CDER, which will have primary jurisdiction over premarket development and approval. We plan to seek approval of STS101 through a single new drug application, or NDA, submitted to CDER through the 505(b)(2) approval pathway. We do not expect that the FDA will require separate marketing authorization for the proprietary device constituent of STS101. However, the drug delivery device component of STS101 will be subject to consulting review by FDA's Center for Devices and Radiological Health, and we will be required to comply with applicable provisions of the medical device Quality System Regulation as part of ensuring STS101 complies with cGMP. The FDA will also require that we conduct human factors studies to support approval of STS101. To date, we and SNBL have completed preliminary human factor studies that we believe support self-administration of STS101 in the outpatient setting for the treatment of migraine and validate the STS101 instructions for use that we are utilizing in our Phase 3 EMERGE efficacy trial, which we initiated in July 2019. We anticipate conducting further human factor studies.

U.S. Drug Regulation

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use or new formulation of a previously approved drug, can be marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA clinical holds, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board, or IRB, representing each clinical site before a clinical study may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, regulations to establish the safety and efficacy of the product candidate for each proposed indication;
- preparation of and submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility(ies) where the product is manufactured to assess compliance with current good manufacturing practice, or cGMP, regulations, and of selected clinical investigation sites to assess compliance with GCP; and
- FDA review and approval of an NDA to permit commercial marketing of the product for its particular labeled uses in the United States.

Preclinical and Clinical Studies

The preclinical and clinical testing and approval process can take many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or condition being treated.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of preclinical tests must comply with federal regulations and requirements, including GLP. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls and any available human data or literature to support use of the product in humans. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical studies. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical studies can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development along with any subsequent changes to the investigational plan.

Clinical studies involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for participation in each clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical study site's IRB before a study may be initiated at the site, and the IRB must monitor the study until completed. Sponsors of clinical trials generally must register and report ongoing clinical studies and clinical study results to public registries, including the website maintained by the U.S. National Institutes of Health, ClinicalTrials.gov.

For purposes of NDA approval, human clinical trials are typically divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug is initially introduced into healthy human subjects or into patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks and preliminarily evaluate efficacy.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical study sites to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational product and to provide an adequate basis for product approval.
- Phase 4. In some cases, the FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical studies after approval. In other cases, a sponsor may voluntarily conduct additional clinical studies after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical studies.

The FDA, the IRB or the clinical study sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. We may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate, and must 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, must include 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 does not undergo unacceptable deterioration over its shelf life.

Submission of an NDA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development and testing are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The submission of an NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

An NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of a product, or from a number of 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 effectiveness of the investigational product to the satisfaction of the FDA.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, standard review and priority review. Priority review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. According to PDUFA performance goals, the FDA endeavors to review applications subject to standard review within ten to twelve months, whereas the FDA's goal is to review priority review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to assure that relevant study data was obtained in compliance with GCP requirements.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities, it may issue an approval letter or a complete response letter. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A tentative approval may be issued for an NDA submitted under Section 505(b)(2) of the FDCA if the sponsor must await the expiration of applicable patents or other exclusivity covering the previously approved product referenced in the application before obtaining final approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, program to help ensure that the benefits of the drug outweigh its risks. If the FDA determines a REMS program is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. For 505(b)(2) NDAs, FDA will typically require a REMS if the reference product is required to have a REMS. A REMS program may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, or other elements to assure safe use, such as limitations on who may prescribe or dispense the drug, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, all REMS programs must include a timetable to periodically assess the strategy following implementation.

Further, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety and efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Moreover, changes to the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities may require submission and FDA approval of a new NDA or NDA supplement before the changes can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that supporting the original approval, and the FDA uses similar procedures in reviewing supplements as it does in reviewing original applications.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. 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.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved NDA. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval of a product if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with 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 studies 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 a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA may also require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Amendments established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an abbreviated new drug application, or ANDA, with the FDA.

An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA suitability petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug or is intended for a different use, and it is not otherwise subject to an approved suitability petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the reference drug has expired.

Non-Patent Exclusivity

In addition to patent exclusivity, NDA holders may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a pharmaceutical manufacturer may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by FDA in any other NDA.

A non-NCE drug, including one approved under Section 505(b)(2), may qualify for a three-year period of exclusivity for a particular condition of approval or change to a previously approved product, such as a new formulation or method of administration for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted or sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has concluded. However, unlike NCE exclusivity, the FDA can accept an application and being the review process during the exclusivity period. A drug approved under Section 505(b)(2) may also be eligible for pediatric exclusivity if the FDA issues a Written Request for one or more pediatric studies, the manufacturer conducts the studies and submits written reports to the FDA, and such studies meet the conditions of the Written Request. If granted, pediatric exclusivity extends any existing marketing exclusivity or patent protection for the product by an additional six months.

International Regulation

In addition to regulations in the United States, we could become subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products if we seek to market STS101 in other jurisdictions. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare 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 and state fraud and abuse laws, including anti-kickback, false claims, civil monetary penalties laws, consumer protection and transparency laws as well as similar foreign laws in the jurisdictions outside the U.S. For example, the federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act and the civil monetary penalties statute. The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation. The federal

Physician Payments Sunshine Act requires certain manufacturers of 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 report annually to CMS information related to payments or other transfers of value made to physicians, certain other healthcare professionals beginning in 2022, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical 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 or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives. Violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, civil and criminal penalties, damages, fines, additional reporting obligation, the curtailment or restructuring of operations, exclusion from participation in governmental healthcare programs and individual imprisonment.

Data Privacy and Security Laws

Pharmaceutical companies may be subject to U.S. federal and state health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the U.S., HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the Department of Health and Human Services, or HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent, broader in scope or offer greater individual rights with respect to protected health information, or PHI, than HIPAA and many of which may differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context.

European Union member states, the United Kingdom, Switzerland and other jurisdictions have also adopted data protection laws and regulations, which impose significant compliance obligations. In the EEA and the United Kingdom, the collection and use of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or GDPR. The GDPR became effective on May 25, 2018, repealing its predecessor directive and increasing responsibility and liability of pharmaceutical companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which add to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. No uniform policy exists for coverage and reimbursement for products exists among U.S. third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Existing acute treatments for migraine are generally covered or reimbursed by third-party payers and, based on preliminary primary market research we have conducted with certain third-party payers, we believe that STS101, if approved, would qualify for coverage and reimbursement substantially similar to other branded acute treatments for migraine; however, such research is preliminary and we cannot guarantee the availability of coverage or adequacy of reimbursement at this time.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union 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. 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. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. Furthermore, there can be no assurance that a product will be considered medically reasonable and necessary for a specific indication, that a product will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available or that the third-party payors' reimbursement policies will not adversely affect the ability to sell a product profitably.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent 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; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs, implemented 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; expanded eligibility criteria for Medicaid programs; creates a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2029 absent additional congressional action. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Further, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. 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, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Employees

As of December 31, 2019, we had 17 employees, all of whom were full-time. None of our employees is represented by a labor union or a collective bargaining agreement. We consider our relationship with our employees to be good.

Segment Information

We have one primary business activity and operate one reportable segment.

Facilities

Our corporate headquarters are located in South San Francisco, California, where we lease approximately 4,148 square feet of office space pursuant to a lease dated January 9, 2018, which continues through April 30, 2021. In addition, we lease approximately 5,043 square feet of office space in Research Triangle Park, North Carolina pursuant to a lease dated August 1, 2019, which continues through July 31, 2022. We believe these facilities are sufficient for our near-term needs, and expect to expand to new and/or additional space as we grow. We believe the biotechnology environment in the South San Francisco area offers suitable additional space on commercially reasonable terms to enable our expansion.

Legal Proceedings

We are not currently involved in any litigation or legal proceedings that, in management's opinion, are likely to have any material adverse effect on our company.

Corporate Information

We were founded on June 21, 2016 as a Delaware corporation under the name Satsuma Pharmaceuticals, Inc. Our principal executive offices are located at 400 Oyster Point Boulevard, Suite 221, South San Francisco, CA 94080, and our telephone number is (650) 410-3200. Our website address is www.satsumarx.com. The information on, or that can be accessed through, our website is not incorporated by reference in this annual report on Form 10-K or in any other filings we make with the Securities and Exchange Commission, or SEC. We have included our website address as an inactive textual reference only.

Available Information

We make available on or through our website certain reports and amendments to those reports that we file with or furnish to the SEC in accordance with the Securities Exchange Act of 1934, as amended. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at www.sec.gov. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

ITEM 1A. RISK FACTORS

RISK FACTORS

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Annual Report on Form 10-K, including our audited financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Business

We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our prospects.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale, have not generated any revenue from product sales and have incurred losses in each year since our inception in June 2016. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. In July 2019, we initiated our Phase 3 EMERGE efficacy trial for our product candidate, STS101. We have no other experience as a company conducting Phase 3 clinical trials, submitting applications for regulatory approvals, such as a new drug application, or NDA, or commercializing any products.

We have had significant operating losses since our inception. Our net losses for years ended December 31, 2019, 2018 and 2017 were approximately $28.2 million, $7.3 million and $5.2 million, respectively. As of December 31, 2019, we had an accumulated deficit of $43.0 million. Substantially all of our losses have resulted from expenses incurred in connection with the development of STS101 and general and administrative costs associated with our operations. STS101 will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. In addition, we expect to incur additional costs associated with operating as a public company. We also do not yet have a sales organization or commercial infrastructure and, accordingly, we will incur significant expenses to develop a sales organization or commercial infrastructure in advance of generating any commercial product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop STS101 through clinical trials and regulatory submissions. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We will require substantial additional financing to achieve our goals, and a failure to obtain this capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

Since our inception, we have invested substantially all of our efforts and financial resources in the development of STS101 for the acute treatment of migraine. We believe that we will continue to expend substantial resources for the foreseeable future in connection with the clinical development of STS101, including in connection with our Phase 3 clinical trials. These expenditures will include costs associated with clinical trials, obtaining regulatory approvals, and manufacturing and supply, as well as marketing and selling STS101, if approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of STS101.

As of December 31, 2019, we had resources consisting of cash, cash equivalents and marketable securities of $117.9 million. We believe our existing cash, cash equivalents and marketable securities, will be sufficient to fund our planned operations for at least 12 months from the issuance of our financial statements as of and for the year ended December 31, 2019 and through the end of 2021. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the scope, timing, rate of progress, results and costs of our clinical trials for STS101, including in connection with any clinical program we may pursue in foreign jurisdictions;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the cost of building a sales force in anticipation of commercialization of STS101;
- the cost and timing associated with commercializing STS101, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- any product liability or other lawsuits related to STS101;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of STS101;
- the extent to which we acquire or in-license other product candidates or technologies;
- the payment of royalty payments owed under our existing license agreement;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the costs associated with being a public company; and
- the timing, receipt and amount of sales of STS101, if approved.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate clinical studies or other development activities for STS101; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize STS101, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or STS101 that we would otherwise pursue on our own. We do not expect to realize revenue from sales of STS101 in the foreseeable future, if at all, unless and until STS101 is clinically tested, approved for commercialization and successfully marketed. To date, we have funded our operations through private placements of convertible preferred stock, a convertible promissory note, and long-term debt. We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Our business is entirely dependent on the successful development, regulatory approval and commercialization of STS101, our only product candidate under development.

We have invested substantially all of our efforts and financial resources in the development of STS101 for the acute treatment of migraine, which has not been approved for sale or commercial use. Currently, STS101 is our only product candidate and we have not licensed, acquired, or invented any other product candidates for pre-clinical or clinical evaluation. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. The success of our business, including our ability to finance our company and generate any revenue in the future, will, at this point, depend entirely on the successful development, regulatory approval and commercialization of STS101, which may never occur. We may have inadequate financial or other resources to advance STS101 through the clinical trial process, depending on the requirements of the FDA. In addition, our clinical development program for STS101 may not lead to regulatory approval from the FDA and similar foreign regulatory agencies if we fail to demonstrate that STS101 is safe and effective in our ongoing and planned Phase 3 clinical trials, and we may therefore fail to commercialize STS101. Even if approved, we may fail to obtain differentiated product labeling for STS101 as compared to other available dihydroergotamine mesylate, or DHE, products for migraine and, as a result, our commercial prospects may be impaired. Further, STS101 may not receive regulatory approval even if it is successful in planned and future clinical trials. Any failure to obtain regulatory approval of STS101 would have a material and adverse impact on our business. Even if we successfully obtain regulatory approvals to market STS101, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of STS101, even if approved.

We plan to seek regulatory approval to commercialize STS101 in the United States and potentially in selected foreign countries. The clinical and commercial success of STS101 will depend on a number of factors, including the following:

- our ability to raise any additional required capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support approval of STS101;
- acceptance of our co-primary endpoint assessments relating to the proposed indication of STS101 by the FDA and similar foreign regulatory authorities;
- our ability to consistently manufacture STS101 on a timely basis;
- our ability, and the ability of any third parties with whom we contract, to remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk-benefit profile of STS101;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with STS101;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to STS101;
- the differentiation of STS101 from other available DHE products and other acute treatments of migraine, and the willingness of physicians, operators of hospitals and clinics and patients to adopt and utilize STS101;

- our ability to successfully develop a commercial strategy and thereafter commercialize STS101 in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third-party payors for STS101;
- patients' willingness to pay out-of-pocket for STS101 in the absence of coverage and/or adequate reimbursement from third-party payor;
- the convenience of the administration of STS101;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of STS101, if approved;
- patient demand for STS101, if approved;
- our ability to establish and enforce intellectual property rights in and to STS101; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize STS101. Even if regulatory approvals are obtained, we may never be able to successfully commercialize STS101. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of STS101 to continue our business or achieve profitability.

While the scope of regulatory approval generally is similar in other countries, in order to obtain separate regulatory approval in other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior to granting approval. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of STS101, and we may be required to expend significant resources to obtain regulatory approval and to comply with ongoing regulations in these jurisdictions. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

We have only recently begun testing STS101 in patients with migraine to assess its effectiveness, and, while we believe that it will be an effective acute treatment for migraine based on the historical pharmacokinetic profiles and effective usage of DHE products, we are utilizing a novel dry-powder formulation and delivery device which may not achieve better or similar levels of efficacy as other DHE products. Further, the results of earlier studies and trials of other DHE products, including cross-trial comparisons of results that are not derived from head-to-head clinical trials, may not be predictive of future trial results for STS101.

STS101 is a drug-device combination of a proprietary dry-powder formulation of DHE, which incorporates novel mucoadhesive drug carrier and engineered drug particle technologies, and our proprietary nasal delivery device. While we have completed a Phase 1 clinical trial for STS101 in 42 healthy volunteers in which STS101 demonstrated rapid and sustained DHE plasma concentrations, low pharmacokinetic variability, and a favorable safety and tolerability profile, STS101 has not yet been tested in any patients with migraine to assess its effectiveness, and there can be no assurance that we will be able to demonstrate to the satisfaction of the FDA the safety, efficacy and acceptable risk-benefit profile of STS101 during our ongoing and planned Phase 3 clinical trials. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in Phase 3 clinical trials, even after positive results in earlier clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any promising results in our preclinical studies and Phase 1 clinical trial, we cannot be certain that we will not face similar setbacks.

In July 2019, we initiated our Phase 3 efficacy trial of STS101 with a target enrollment of 1,140 patients and expect to report topline data from this Phase 3 trial in the second half of 2020. The results of our preclinical testing and Phase 1 clinical trial, as well as preclinical and clinical testing by third parties of other DHE products and product candidates, may not be predictive of the results of our ongoing and planned Phase 3 clinical trials. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, our ongoing and planned Phase 3 clinical trials will involve the administration of STS101 by the patient in the patient's home or other outpatient settings rather than a clinical setting, and decreased compliance with product instructions for use may negatively impact results. As a further example, based on published DHE pharmacokinetic and clinical trial data relating to DHE plasma concentrations and clinical efficacy of different DHE doses with other DHE products, we estimate that 1.0 ng/ml is the threshold concentration necessary for therapeutic response to DHE. While the administration of STS101 2.6 mg and 5.2 mg during our Phase 1 clinical trial consistently resulted in healthy subjects achieving DHE plasma concentrations in excess of 1.0 ng/ml, our estimation that such threshold may be sufficient for the effective treatment of migraine may be based on invalid assumptions or inferences and may not be correct. As a result, even if STS101 does achieve similar DHE plasma concentrations in our Phase 3 efficacy trial, there can be no assurance that STS101 will exhibit similar or improved efficacy as compared to previously-approved DHE products.

In addition, while DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine, STS101 is specifically designed to have a differentiated pharmacokinetic profile and administration procedure as compared to such products, including injectable DHE and DHE liquid nasal spray. As such, even though STS101 demonstrated favorable safety, tolerability and pharmacokinetic profile in our Phase 1 clinical trial, there can be no assurance that STS101 will exhibit comparable or more favorable clinical performance in our Phase 3 clinical trial as compared to other DHE products. Furthermore, while in our Phase 1 clinical trial STS101 demonstrated greater DHE plasma concentration and lower pharmacokinetic variability than Migranal DHE mesylate liquid nasal spray and higher DHE exposure (plasma concentration over time expressed as area-under-curve) and comparable pharmacokinetic variability than certain other DHE products, such results may not be indicative of the comparative efficacy of STS101. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants.

Further, certain of our hypotheses regarding the potential clinical and therapeutic benefit of STS101 compared to other DHE products and product candidates are based on cross-trial comparisons of results that were not derived from head-to-head clinical trials. Such clinical trial data may not be directly comparable due to differences in study protocols, conditions and patient populations. Accordingly, these cross-trial comparisons may not be reliable predictors of the relative efficacy or other benefits of STS101 compared to other product candidates that may be approved or that are or were in development for the acute treatment of migraine.

As a result of the foregoing, even if we are able to complete any planned and future clinical trials of STS101, the results may not be sufficient to obtain regulatory approval.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. In July 2019, we initiated our Phase 3 efficacy trial of STS101 and expect to commence a Phase 3 safety trial in the second half of 2020. The FDA has agreed in principle with the proposed study design of our Phase 3 efficacy trial, dose strengths, statistical analysis and that a single efficacy study could be sufficient to support an NDA. However, changes in regulatory requirements and guidance may occur and we may need to amend our clinical trial protocols to reflect these changes with appropriate regulatory authorities. In addition, we may experience delays in initiating or completing our planned studies and trials of STS101. Furthermore, we cannot be certain that studies or trials for STS101 will begin on time, not require redesign, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a trial;

- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board, or IRB, approval at each trial site;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient quantities of STS101 for use in clinical trials from third-party suppliers on a timely basis.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials that could delay or prevent our ability to receive marketing approval or commercialize STS101, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of STS101 may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon our development program for STS101;
- the number of patients required for clinical trials of STS101 may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we or our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls, or be unable to produce sufficient product supply to conduct and complete clinical trials of STS101 in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of STS101 for various reasons, including non-compliance with regulatory requirements, a finding that STS101 has undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of STS101 may be greater than we anticipate;
- the quality of STS101 or other materials necessary to conduct clinical trials of STS101 may be insufficient or inadequate;
- regulators may revise the requirements for approving STS101, or such requirements may not be as we anticipate; and
- future collaborators may conduct clinical trials in ways they view as advantageous to them but that are sub-optimal for us.

If we are required to conduct additional clinical trials or other testing of STS101 beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of STS101 or other testing, if the results of these trials or tests are not positive or are only moderately positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for STS101 or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;

- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements, which could be expensive and time consuming; or
- have the treatment removed from the market after obtaining marketing approval.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our 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 candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we could do for STS101, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing STS101.

If any of our clinical trials of STS101 are unsuccessful, delayed or terminated, its commercial prospects may be harmed, and our ability to generate revenues from sales of STS101 will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our STS101 development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, 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 STS101. If STS101 generally proves to be ineffective, unsafe or commercially unviable, it would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may be unable to obtain regulatory approval for STS101 under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization of STS101 and adversely impact our potential to generate revenue, our business and our results of operations.

We have not previously submitted an NDA or any other marketing application to the FDA or similar filings to comparable foreign regulatory authorities. An NDA or other similar regulatory filing requesting approval to market a product candidate must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, effective, pure and potent for each desired indication. The NDA or other similar regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pharmaceutical products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market STS101 in the United States or in any foreign countries until it receives the requisite approval from the applicable regulatory authorities of such jurisdictions.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of STS101 for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that STS101 is safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that the clinical and other benefits of STS101 outweigh any safety or other perceived risks; the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling or specifications of STS101;
- the FDA's or the applicable foreign regulatory agency's failure to approve our manufacturing processes and facilities or the facilities of third-party manufacturers upon which we rely; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of pharmaceutical products in development, only a small percentage successfully complete the FDA or other regulatory bodies' approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval from the FDA or applicable foreign agencies for STS101, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials which may be required after approval. For example, because migraine affects adolescents (12 to 17 years of age) and children (six to eleven years of age), pediatric studies are required under the Federal Food, Drug, Cosmetic Act, or the FDCA. To address such requirements, we designed an initial pediatric study plan, or iPSP, consistent with the FDA guidance *Migraine: Developing Drugs for Acute Treatment, February 2018*, which we submitted as an amendment to the STS101 investigational new drug application in May 2019. In August 2019, the FDA provided comments to our iPSP in which the FDA agreed with our plan to request a waiver of clinical studies in children under age six. We have revised and resubmitted the iPSP to address the FDA's comments on our proposed study plan for children (six to eleven years of age) and adolescents (12 to 17 years of age) and our requests for a deferral of any pediatric studies until after the initial approval of STS101 in the adult population. While we plan to work with the FDA to finalize the iPSP, there can be no assurance that the FDA will ultimately grant our proposed waiver and/or deferrals. As a result, we could be required to conduct pediatric studies in such patient populations prior to or following any approval of STS101. The FDA or the applicable foreign regulatory agency also may approve STS101 for a more limited indication or a narrower patient population than we originally requested, and the FDA, or applicable foreign regulatory agency, may not approve it with the labeling that we believe is necessary or desirable for the successful commercialization.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of STS101 and would materially adversely impact our business and prospects.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. In particular, in July 2019, we initiated our Phase 3 efficacy trial of STS101 with a target enrollment of 1,140 patients and we may experience difficulties enrolling patients due to the availability of approved preventive and acute treatments for migraine. The enrollment of patients depends on many additional factors, including:

- the patient eligibility criteria defined in the protocol;
- the general willingness of patients to enroll in the trial;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- the clinical site's ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for product candidates that seek to treat migraine, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of STS101.

STS101 may cause undesirable side effects or have other properties that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

The results of our clinical trials may show that STS101 may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities. In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

While STS101 was generally well-tolerated in our Phase 1 clinical trial, subjects treated with STS101 5.2 mg reported a higher frequency of nasal adverse events than those treated with DHE mesylate IM injection or Migranal DHE mesylate liquid nasal spray. However, all adverse events were mild and transient, and subjective nasal symptom severity scores self-reported by subjects were very low, with all nasal symptom severity scores averaging less than five on a zero to one hundred scale in which zero represents absence of the symptom and one hundred represents presence of the symptom with the worst imaginable severity. Subjective nasal symptom severity scores self-reported in Part 1 of our Phase 1 clinical trial by subjects treated with STS101 1.3 mg and 2.6 mg were negligible. As a result, we do not believe the tolerability of STS101 should present a barrier to patient adoption or use, if approved. Nevertheless, if unacceptable side effects arise in any of our Phase 3 clinical trials or other trials we may conduct in the future, we, the FDA, or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of STS101 for its targeted indications.

In addition, if undesirable side effects caused by other available DHE products or DHE products in development, the development and successful commercialization of STS101, if approved, could be negatively affected. Treatment-related side effects in our clinical trials or in the use of approved DHE products could also affect patient recruitment or the ability or willingness of enrolled patients to complete any of our clinical trials, and/or result in potential product liability claims. Due to DHE's vasoconstrictive effects, DHE products are not recommended for use in patients with cardiovascular risk factors. In addition, approved DHE products carry a "black box" warning in their labels for a risk that the coadministration of DHE and certain other drugs, including specific antivirals and antibiotics, may result in elevated levels of DHE in the blood, potentially causing vasospasm that may result in inadequate blood flow to the extremities or the brain. Unless we can successfully demonstrate by conducting a drug-drug interaction study that the coadministration of DHE and certain other drugs does not result in inhibition of DHE metabolism and elevated DHE levels, the FDA is likely to require the label for STS101, if approved, to include such warning, and this could result in STS101 not achieving its full commercial potential. Treatment-related side effects in our clinical trials or in the use of approved DHE products could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims.

If STS101 receives marketing approval and we or others later identify undesirable side effects caused by such product or by other DHE products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication similar to those that are currently included with the labels of DHE products;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business.

We may be unable to rely on Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA), which could result in a longer development program and more costly trials than we anticipate.

We may not be able to seek FDA marketing approval of STS101 under Section 505(b)(2) of the FDCA. Section 505(b)(2), if applicable to us, would allow any NDA we file with the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved DHE products, which could expedite the development program for STS101 by potentially decreasing the overall scope of work we must do ourselves. If we are unable to rely on Section 505(b)(2), the development program for STS101 would be longer than we expect, and we would also have to conduct more costly trials than we anticipate, which would harm our business.

STS101 is a drug-device combination product, which may result in additional regulatory risks.

Our finished drug product and nasal delivery device will be regulated as a drug-device combination product. There may be additional regulatory risks for drug-device combination products. We may experience delays in obtaining regulatory approval of STS101 given the increased complexity of the review process when approval of the product and a delivery device is sought under a single marketing application. In the United States, each component of a combination product is subject to the requirements established by the FDA for that type of component, whether a drug, biologic or device. The delivery system device will be subject to FDA device requirements regarding design, performance and validation as well as human factors testing, among other things. Delays in or failure of the studies conducted by us, or failure of our company, our collaborators, if any, or our third-party providers or suppliers to obtain or maintain regulatory approval could result in increased development costs, delays in or failure to obtain regulatory approval, and associated delays in STS101 reaching the market.

Even if STS101 obtains regulatory approval, it may fail to achieve broad market acceptance.

Even if STS101 receives FDA or other regulatory approvals, its commercial success will depend significantly on its broad adoption and use by physicians and patients for approved indications. The degree of market acceptance of STS101, if approved, will depend on a number of factors, including:

- the safety and efficacy of STS101 as compared to other available acute therapies for treatment of migraine;
- patient satisfaction with the results and administration of STS101 and overall treatment experience, including, the ease and convenience of administration of STS101;
- the clinical indications for which STS101 is approved and patient demand for approved products that treat those indications;
- our ability to manufacture and release adequate commercial supplies on a timely basis;
- the availability of coverage and adequate reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid) and other third-party payors for STS101;
- the cost of treatment with STS101 in relation to alternative treatments and patients' willingness to pay out-of-pocket for the product, if approved, in the absence of coverage and/or adequate reimbursement from third-party payors;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe, effective and easy to administer treatment;
- physician and patient willingness to adopt a new therapy over other available preventive and acute therapies for treatment of migraine;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for STS101, such as a "black box" warning or a contraindication similar to those that are currently included with the labels of DHE products;

- the willingness of physicians, operators of hospitals and clinics and patients to utilize or adopt our product as a solution;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about STS101 or favorable publicity about competitive products;
- patients' willingness to take a dry-powder intranasal medication; and
- potential product liability claims.

We cannot assure you that STS101, if approved, will achieve broad market acceptance among physicians and patients. Any failure by STS101, if approved, to achieve market acceptance or commercial success would adversely affect our results of operations.

We face, and will continue to face, significant competition in an environment of rapid technological and scientific change and our failure to effectively compete may prevent us from achieving significant market penetration for STS101, if approved. Most of our competitors have significantly greater resources than we do and we may not be able to successfully compete.

The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these companies have greater financial resources, marketing capabilities and experience in obtaining regulatory approvals for product candidates. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engaged in research and development of products which may target the same markets as STS101. We expect STS101 to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects experienced and convenience of administration. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than us, obtain approvals for such products from the FDA more rapidly than us or develop alternative products or therapies that are safer, more effective and/or more cost effective than STS101. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize STS101 in our target commercial areas.

The majority of the prescriptions written for the acute treatment of migraine are for generic triptans. There are seven FDA-approved triptan molecules available in branded and branded generic/generic oral dosage forms, and two of these molecules are also available in injectable and/or liquid nasal spray dosage forms that may have faster onset of action than oral dosage forms.

With respect to DHE products, we will compete with Bausch Health's Migranal and its authorized generic, both of which are DHE liquid nasal spray products, as well as branded and generic DHE injectable products. In addition, we believe Impel NeuroPharma is developing a DHE liquid nasal spray product utilizing the same liquid formulation as Migranal, but with a different propellant-powered, single-use delivery device for which Impel NeuroPharma has indicated it plans to file an NDA in 2020. In addition, Promius Pharma has previously reported that it is developing a DHE nasal liquid spray product. Impel NeuroPharma in particular, has indicated that it plans to pursue approval of its product on the basis of a clinical development program that includes only a comparative pharmacokinetic study and an open-label, uncontrolled, repeat-dose safety trial (and not a randomized, controlled, double-blind Phase 3 efficacy study which the FDA typically requires to support any product-specific marketing claims relating to efficacy). There can be no assurance that we will be able to successfully bring STS101 to the market faster than these liquid nasal spray candidates or compete against such products, if approved.

We may also face competition from non-DHE acute treatments for migraine that have recently been approved. For instance, inhibition of CGRP is a therapeutic strategy for migraine. CGRP is normally produced in neurons, but elevated levels of CGRP in the trigeminovascular system can have adverse effects on neurovascular and neurological function, leading to symptoms of migraine. Allergan's ubrogepant and Biohaven's rimegepant, both oral CGRP receptor antagonists, recently received FDA approval for the acute treatment of migraine. Furthermore, Eli Lilly has recently received FDA approval for lasmiditan (REYVOW™), an oral $5HT_{1F}$ agonist, for the acute treatment of migraine, and the product has recently been designated a Schedule V controlled substance by the U.S.

Drug Enforcement Agency, reflecting that it has potential for abuse. In contrast with triptan and ergot alkaloid (including DHE) products, both CGRP and $5HT_{1F}$ products are thought to act by mechanisms other than vasoconstriction and are thus not contraindicated in patients with certain cardiovascular diseases and conditions for whom triptan and ergot alkaloid treatments are not recommended.

Further, preventive treatment of migraine, if broadly adopted and used successfully, could reduce the need and demand for acute treatment options. Injectable formulations of anti-CGRP monoclonal antibodies (e.g. erenumab, fremanezumab, galcanezumab and eptinezumab) have been approved for prevention of migraine attacks and Allergan and Biohaven have also reported that they are conducting clinical trials of oral CGRP antagonists for prevention of migraine attacks. In addition, Alder Biopharmaceuticals recently announced it was commencing a study of its intravenously injected monoclonal CGRP antibody therapeutic, eptinezumab, which was approved in February 2020 by the FDA for prevention of migraine attacks, to evaluate it as an acute treatment for migraine.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources and experience than we do. If we successfully obtain approval for STS101, we will face competition based on many different factors, including the safety and effectiveness of STS101, the ease with which STS101 can be administered and the extent to which patients accept the nasal route of administration, the timing and scope of regulatory approvals for STS101, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than STS101. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing STS101. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan. For additional information regarding our competition, see “Business—Competition.”

The successful commercialization of STS101 will depend in part on the extent to which governmental authorities, private health insurers, and other third-party payors provide coverage, adequate reimbursement levels and implement pricing policies favorable for it. Failure to obtain or maintain coverage and adequate reimbursement for STS101, if approved, could limit our ability to market our product and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by managed care plans, governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for STS101 by third-party payors will have an effect on our ability to successfully commercialize it. A decision by a third-party payor not to cover or separately reimburse for STS101, could reduce physician utilization if approved. Assuming there is coverage for STS101 by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for STS101 and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs have resulted in increasing challenges to prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and adequate reimbursement for particular drugs when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider STS101 as substitutable and only offer to reimburse patients for the less expensive product, if any. For example, there are currently generic versions of both DHE liquid nasal spray products and DHE injectable products, with which we may compete. Even if we show improved efficacy or improved convenience of administration with STS101, pricing of existing third-party therapeutics may limit the amount we will be able to charge for it. These third-party payors may deny or revoke the reimbursement status of STS101, if approved, or establish prices for it at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize STS101.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that may require us to provide scientific and clinical support for the use of STS101 to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries will likely put pressure on the pricing and usage of medical products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for STS101. Accordingly, in markets outside the United States, the reimbursement for STS101 may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell STS101 effectively in the United States and foreign jurisdictions, if approved, or generate product revenue.

We currently do not have a marketing or sales organization. In order to commercialize STS101, if approved, in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If STS101 receives regulatory approval, we expect to establish a sales organization in the United States with technical expertise and supporting marketing and distribution capabilities to commercialize it, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain, and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of STS101. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize STS101. If we are not successful in commercializing STS101, either on our own or through arrangements with one or more third parties, we may not be able to generate product revenue and we would incur significant additional losses.

We rely, and intend to continue to rely, on qualified third parties to supply all components of STS101. As a result, we are dependent on several third parties, most of which are sole source suppliers, for the manufacture of STS101 and our supply chain, and if we experience problems with any of these suppliers, or they fail to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, it would materially and adversely affect our business.

We do not own or operate manufacturing facilities for clinical or commercial manufacture of either the proprietary dry-powder formulation of DHE component of STS101 or the proprietary pre-filled, single-use, nasal delivery device, including the drug substance and packaging. We have limited personnel with experience in drug-device product manufacturing and we lack the capabilities to manufacture either the drug or device components of STS101 on a clinical or commercial scale. We currently outsource all manufacturing and packaging of STS101 to third parties, and we do not plan to own or operate our own manufacturing and packaging facilities. There can be no assurance that our clinical development product supplies will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of any of our third-party suppliers could require significant effort and expertise because there may be a limited number of qualified replacements. In addition, we may encounter issues with transferring technology to a new third-party manufacturer, and we may encounter regulatory delays if we need to move the manufacturing of our products from one third-party manufacturer to

another. For example, we are in the process of transferring the STS101 formulation manufacturing process from the supplier responsible for manufacturing the STS101 formulation for our Phase 3 EMERGE efficacy trial to a new supplier, who will be responsible for manufacturing the STS101 formulation for our Phase 3 safety trial and any commercial supplies, if STS101 is approved. There can be no assurance that we will not experience a disruption to the supply of the formulation for STS101 in connection with such transfer or that the transfer will be successful.

In addition, we do not currently have long-term commercial supply agreements with third-party manufacturers for either the formulation or device components of STS101 or the STS101 finished product. We may be unable to enter into agreements for commercial supply with all third-party manufacturers, or may be unable to do so on acceptable terms. Even if we enter into these agreements or, for those agreements that we have already entered into, the various manufacturers utilized for STS101 will likely be single source suppliers to us for a significant period of time. We may not be able to establish additional sources of supply for STS101 prior to commercialization. Certain of such suppliers are subject to regulatory requirements covering manufacturing, testing, quality control and record keeping relating to STS101, and are subject to pre-approval and ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions to our manufacturing capacity while we seek to secure another supplier that meets all regulatory requirements.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured STS101 ourselves, including:

- reliance on the third parties for regulatory compliance, quality assurance and hazardous materials handling;
- the possible breach of the manufacturing and quality agreements by the third parties because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities; and
- with respect to any manufacturers with which we do not have a long-term agreement, the possibility that the manufacturer decides to stop supplying to us or changes the price or other terms of supply.

Any of these factors could cause the delay of required approvals or commercialization of STS101, could prevent us from commercializing it successfully, could cause the suspension of initiation or completion of clinical trials and regulatory submissions, and could lead to higher product costs.

In addition, the facilities used by our CMOs to manufacture STS101 are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not directly control manufacturing at our CMOs, and are completely dependent on them for compliance with current regulatory requirements. If our CMOs cannot successfully manufacture components of finished product that conforms to our specifications and the regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on them for the manufacture of STS101. For example, MAP0004, another company’s orally-inhaled, pulmonary-route DHE product candidate, met all four of its primary efficacy endpoints and demonstrated a favorable safety profile in a large Phase 3 clinical trial, but was later discontinued by Allergan. The discontinuation of MAP0004 (then known by the brand name Semprana) followed multiple requests from the FDA that the developer address certain issues relating to chemistry, manufacturing, and controls, after certain manufacturing deficiencies were identified during the FDA’s inspection of a facility operated by a third-party manufacturer. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds our facilities or those of our CMOs inadequate for the manufacture of STS101 or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or commercialize STS101 and the timing of any such approval and commercialization.

Additionally, our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide STS101 to patients in clinical trials, or to provide product for the treatment of patients once approved, would be jeopardized.

We rely, and intend to continue to rely, on third-party suppliers for materials used in the manufacture of STS101, and the loss of third-party suppliers or their inability to supply us with adequate key materials could harm our business.

We rely, and intend to continue to rely, on third-party suppliers, most of which are sole source suppliers, for certain key materials required for the production of the DHE dry-powder formulation of STS101. Our dependence on these third-party suppliers and the challenges we may face in obtaining adequate supplies of these materials involve several risks, including limited control over pricing, availability, quality and delivery schedules. As a small company, our negotiation leverage is limited and we are likely to get lower priority than other companies or purchasers that are larger than we are. We cannot be certain that our suppliers will continue to provide us with the quantities of these key materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced key materials could materially harm the manufacture of STS101 until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supplier in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and potential commercialization of STS101, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

We rely, and intend to continue to rely, on third parties in the conduct of all of our clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for STS101.

We currently do not have the ability to independently conduct any clinical trials. The FDA and comparable foreign regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP-compliant clinical trials of STS101 properly and on time. While we have agreements with these third parties, we monitor and control only certain aspects of their activities and have limited influence over their actual performance and the amount or timing of resources that they devote to our programs. Third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. Although we rely on these third parties to conduct our clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on these third parties does not relieve us of our regulatory responsibilities.

If the third parties conducting our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for STS101, our results our business and results of operations and the commercial prospects for STS101 would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

The terms of our loan agreement place restrictions on our operating and financial flexibility.

In October 2018, we entered into a loan and security agreement with Silicon Valley Bank, or the Loan Agreement, that is secured by a lien covering all of our tangible and intangible property. As of December 31, 2019, there was $4.8 million of principal balance outstanding under the Loan Agreement, which was funded in October 2018. An additional $5.0 million term loan may be drawn by us in $1.0 million increments. Under the terms of the Loan Agreement, we are required to make payments on a monthly basis commencing December 1, 2019, and the final maturity date of the loan is May 1, 2022. The Loan Agreement contains customary affirmative and negative covenants and events of default, including covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, engage in asset sales or sale and leaseback transactions, and declare dividends or redeem or repurchase capital stock. A failure to comply with these covenants could permit the lender under the Loan Agreement to declare the term loans, together with accrued interest and fees, to be immediately due and payable. In addition, if we default under the terms of the Loan Agreement, including failure to satisfy our operating covenants, the lender may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our loan agreement on terms less favorable to us or to immediately cease operations. Further, if we are liquidated, the lender's right to repayment would be senior to the rights of the holders of our common stock. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of December 31, 2019, we had 17 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize STS101. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- effectively manage our clinical trials and the development of STS101;
- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

We may be unable to successfully implement these tasks, which could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price.

If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our President and Chief Executive Officer, as well as other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of STS101, initiation or completion of our planned clinical trials or the commercialization of STS101.

Competition for qualified personnel in the pharmaceutical and biotechnology fields is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of STS101.

We face an inherent risk of product liability as a result of the planned clinical testing of STS101 and will face an even greater risk if we commercialize it. For example, we may be sued if STS101 allegedly causes injury. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, and a breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of STS101. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for STS101;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize STS101.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of STS101. We currently carry product liability insurance covering our clinical trials, however, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any dosage of STS101, we intend to expand our insurance coverage to include its sale; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.

We have limited director and officer insurance and product liability insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms, including deductibles and pricing, continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage, and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

We may conduct additional clinical trials and consider additional headache indications for STS101 to enhance its commercial potential; however, these trials may not produce results necessary to enable additional commercial potential or enhancement of its label.

In addition to our pursuit of initial regulatory approval and successful commercialization of STS101 in the United States, we may conduct additional clinical trials and consider additional headache indications for STS101 to expand its commercial potential, including by potentially conducting clinical programs outside the United States. However, any positive results from our ongoing or planned Phase 3 clinical trials of STS101 and results from clinical testing by third parties of other DHE products and product candidates, may not be predictive of the results of any such additional clinical trials. Therefore, there can be no assurance that we will ever be successful enhancing the commercial potential of STS101 or expanding its label.

Any future collaboration arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize STS101.

To the extent that we pursue collaborations relating to STS101 in the future, we may face significant competition in seeking appropriate collaborators and may not be able to ultimately enter into collaborations. Moreover, any such collaboration arrangements may be complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts with any such collaborator and we may never receive any milestone or royalty payments under any such agreements. Further, the terms of any collaborations or other arrangements that we may establish, may not be favorable to us.

The success of any collaboration arrangement will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include risks that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of STS101 or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with STS101;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of STS101;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- a collaborator’s sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.
- disputes may arise between us and a collaborator that causes the delay or termination of the development or commercialization of STS101 or that results in costly litigation or arbitration that diverts our management’s attention and resources;

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent and unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We or the third parties upon which we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in the San Francisco Bay Area, which in the past has experienced both severe earthquakes and wildfires. We do not carry earthquake insurance. In addition, we have a facility in North Carolina, which in the past has experienced severe hurricanes. Earthquakes, wildfires, hurricanes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or other facilities, that damaged our critical infrastructure or the critical infrastructure of our third-party suppliers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

We depend on our information technology systems, and any failure of these systems could harm our business. Any real or perceived security breaches, loss of data, and other disruptions or incidents could compromise the privacy, security, integrity or confidentiality of sensitive information related to our business or prevent us from accessing critical information and expose us to liability and reputational harm, which could adversely affect our business, results of operations and financial condition.

We collect and maintain data and information that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including systems infrastructure operated and maintained by our third party suppliers or providers. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems and facilities to prevent an information compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization (including employees or contractors), lost or stolen devices, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through social engineering attacks, cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a real or perceived security breach affects our systems (or those of our third party providers or suppliers) or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of or other processing of personally identifiable information or clinical trial data, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss, negative publicity, harm to our reputation, governmental investigation and/or enforcement actions, claims or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we begin to operate in foreign jurisdictions.

Our employees and independent contractors, including principal investigators, consultants, commercial collaborators, service providers and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state fraud and abuse laws, data privacy and security laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs or healthcare programs in other jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, other sanctions, 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.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of STS101 and other hazardous compounds. We and any third-party manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our 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 we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes.

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. For instance, the United Kingdom's election to withdraw from the European Union following its national referendum in June 2016 has led to a period of considerable uncertainty, particularly in relation to United Kingdom financial and banking markets as well as on the regulatory process in Europe. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for STS101, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

Risks Related to Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for STS101, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to STS101, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology in appropriate jurisdictions. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, we do not have a patent covering the composition of matter for DHE, the active ingredient in STS101. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use STS101 and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

We have applied, and we intend to continue applying, for patents covering aspects of STS101, proprietary technologies and their uses that we deem appropriate. However, we may not be able to apply for patents on certain aspects of STS101, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. As of January 31, 2020, we have an exclusive license to 6 issued U.S. patents and 9 issued foreign patents, which include granted European patent rights that have been validated in various EU member states, and own or have an exclusive license to various pending U.S. non-provisional patent applications, U.S. provisional patent applications, and pending foreign patent applications, and an international Patent Cooperation Treaty (PCT) patent application. All issued U.S. and foreign patents relating to STS101 were exclusively licensed from SNBL. The pending U.S. and foreign patent applications (including U.S. provisionals) relating to STS101 are solely owned by us or exclusively licensed from SNBL. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in issued patents relating to STS101 will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting STS101, proprietary technologies and their uses by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents owned or in-licensed by us may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already filed for or obtained patents that will limit, interfere with or eliminate our ability to make, use and sell STS101;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same compositions, methods or devices or by claiming subject matter that could dominate our patent position;
- any successful opposition or other post-grant challenges to any patents owned by or licensed to us could result in revocation or amendment to our patents so that they no longer cover STS101;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to STS101, proprietary technologies and their uses;
- an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Moreover, the patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, or the patent rights that we license from others, may be challenged in the courts or patent offices in the United States and abroad. Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical

products, or limit the duration of the patent protection of STS101. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us or licensor Shin Nippon Biomedical Laboratories, Ltd., or SNBL, which we have agreed to indemnify under certain circumstances, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering STS101 are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered STS101, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights. If we initiate lawsuits to protect or enforce our patents, or litigate against third party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect STS101;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell, or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize STS101 on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we or our licensors were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable products or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- the patents of others will not have an adverse effect on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

To the extent we obtain licenses from or collaborate with third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business.

The lives of our patents may not be sufficient to effectively protect STS101 and our business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering STS101, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of STS101, patents protecting it might expire before or shortly after it is commercialized. If we do not have sufficient patent life to protect STS101, proprietary technologies and their uses, our business and results of operations will be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information. We have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of STS101 that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

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. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third

parties in the development, manufacture, and distribution of STS101, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Our rights to develop and commercialize STS101 are subject in part to the terms and conditions of a license granted to us by SNBL. The patent protection, prosecution and enforcement for STS101 may be dependent on third parties.

We currently are reliant upon a license of certain patent rights and proprietary technology pursuant to a licensing and assignment agreement we entered with SNBL in June 2016, or the SNBL License. Such rights and technology are important or necessary to the development of STS101. This and other licenses we may enter into in the future may not provide adequate rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to develop and commercialize our technology and products in fields of use and territories for which we are not granted rights pursuant to such licenses.

Licenses to additional third-party technology that may be required for our development programs may not be available in the future or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

In some circumstances, we may not have the right to control the preparation, filing, prosecution and enforcement of patent applications, or to maintain the patents, covering technology that we license from third parties. In addition, in some instances, the SNBL License requires us to negotiate in good faith a strategy with respect to infringement, and in some instances, SNBL retains the sole right to initiate and control some infringing activities, before we can enforce patent rights. Therefore, we cannot be certain that SNBL or any future licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or by paying all applicable prosecution and maintenance fees related to intellectual property registrations for STS101. We also cannot be certain that our licensors have drafted or prosecuted the patents and patent applications licensed to us in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize STS101 may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

The SNBL License imposes a low single-digit royalty on net sales of STS101 along with certain other obligations on us, and any future licenses, if required, likely will impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, we may be required to pay damages and the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from developing and commercializing STS101 and proprietary technologies. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize STS101, we may be unable to achieve or maintain profitability.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents.

Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import STS101 or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical and biotechnology industries, including patent infringement lawsuits, interferences, oppositions, reexaminations, *inter partes* review proceedings and post-grant review proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields of STS101. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of STS101.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market STS101. Further, we may incorrectly determine that our technologies or STS101 are not covered by a third party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market STS101.

As the pharmaceutical industry expands and more patents are issued, the risk increases that STS101 may be subject to claims of infringement of the patent rights of third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell STS101. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties.

Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, STS101 or the use of STS101. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell STS101. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of STS101, and cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that STS101 may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;

- prevent us from commercializing STS101 until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

Although no third party has asserted a claim of patent infringement against us as of the date of this report, others may hold proprietary rights that could prevent STS101 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to STS101 or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market STS101. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Even if such licenses are available, we could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins, and the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. In addition, we cannot be certain that we could redesign STS101 or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing STS101, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing STS101.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. Also, we may be obligated under our agreements with our collaborators, licensors, suppliers and others to indemnify and hold them harmless for damages arising from intellectual property infringement by us.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful. Further, issued patents relating to STS101 could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at STS101, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include 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 also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation, or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring STS101 to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management 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 our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock.

We may fail to comply with our obligations under the SNBL License or any future agreements pursuant to which we may license or otherwise acquire intellectual property rights or technology, which could result in the loss of rights or technology that are material to our business.

Our business is dependent on the SNBL License for certain patent rights and know-how that are directed to SNBL's proprietary nasal drug delivery technology, including its proprietary nasal delivery device and formulation technologies, for use with DHE. Our rights under the SNBL License and any license for intellectual property or technology that we may enter into in the future are and will be subject to the continuation of and our compliance with the terms of these agreements. Disputes may arise regarding our rights to intellectual property licensed to us from a third party, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the creation or use of intellectual property by us, alone or with our licensors and collaborators;
- the scope and duration of our payment obligations;
- our rights upon termination of such agreement; and
- the scope and duration of exclusivity obligations of each party to the agreement.

Any disputes over intellectual property and other rights under the SNBL License could prevent or impair our ability to maintain the license on acceptable terms and our ability to successfully develop and commercialize STS101. In addition, if we fail to comply with our obligations under the SNBL License, it may be terminated or the scope of our rights under it may be reduced and we might be unable to develop, manufacture or market STS101.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical and biotechnology industries, in addition to our employees, we engage the services of consultants to assist us in the development of STS101. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical or biotechnology companies including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

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

Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Changes in patent law in the U.S. or in other countries could diminish the value of patents in general, thereby impairing our ability to protect STS101.

Our patent rights may be affected by developments or uncertainty in U.S. or ex-U.S. patent statutes, patent case laws in USPTO rules and regulations or in the rules and regulations of ex-U.S. patent offices. There are a number of recent changes to the U.S. patent laws that may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO, and may become involved in post-grant proceedings including opposition, derivation, reexamination, *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. This could have a negative impact on some of our intellectual property and could increase uncertainties surrounding obtaining and enforcement or defense of issued patents relating to STS101. In addition, Congress may pass patent reform legislation that is unfavorable to us. The 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

Similarly, statutory or judicial changes to the patent laws of other countries may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending all current and future patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with STS101, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the patents and/or applications. We employ reputable professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patents and patent applications that we own, and if we license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to make therapies that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Government Regulation

Even if we obtain regulatory approval for STS101, STS101 will remain subject to regulatory scrutiny.

If STS101 is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, 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.

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, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

We will have to comply with requirements concerning advertising and promotion for STS101. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote STS101 for indications or uses for which they do not have approval. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. We also must submit new or supplemental applications and obtain approval for certain changes to STS101, if approved, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of STS101 in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If we discover previously unknown problems with STS101, such as adverse events of unanticipated severity or frequency, or problems with the facility where STS101 is manufactured, or if the FDA disagrees with the promotion, marketing or labeling of STS101, the FDA may impose restrictions on it or us, including requiring withdrawal of it from the market. If we fail to comply with applicable regulatory requirements, the FDA and other regulatory authorities may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- require a product recall, seizure or detention.

Any government action or investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from STS101. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, 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 STS101. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions 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 we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we could lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

If STS101 obtains regulatory approval, competitors could enter the market with generic versions, which may result in a material decline in sales of affected products.

Under the Hatch-Waxman Amendments, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved drug product. A manufacturer may also submit a new drug application, or NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which may be for a new or improved version of the originally approved drug product. The Hatch-Waxman Amendments also provide for certain periods of regulatory exclusivity, which preclude FDA approval of an ANDA or 505(b)(2) NDA for a specific timeframe. In addition to this non-patent exclusivity, an NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

Accordingly, if STS101 is approved, including through the 505(b)(2) pathway, competitors could file ANDAs for generic versions of STS101. If there are patents listed for STS101 in the Orange Book, those ANDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for STS101. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, STS101 could immediately face generic competition and its sales would likely decline rapidly and materially.

The successful commercialization of STS101 will depend in part on the extent to which governmental authorities, private health insurers, managed care plans and other third-party payors provide coverage, adequate reimbursement levels and implement pricing policies favorable for STS101. Failure to obtain or maintain coverage and adequate reimbursement for STS101, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers, managed care plans and other third-party payors are essential for most patients to be able to afford medical services and pharmaceutical products such as STS101 that receive FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement by third-party payors for our products will have an effect on our ability to successfully commercialize STS101.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We cannot be sure that coverage will be available for any product that we may develop. A decision by a third-party payor not to cover STS101 could reduce physician utilization of our products once approved and adversely affect our business, financial condition, results of operations and prospects.

Assuming there is coverage for our products by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely. Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and adequate reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider STS101 as substitutable and only offer to reimburse patients for the less expensive product. For example, there are currently generic versions of both DHE liquid nasal spray products and DHE injectable products, which we may compete with. Even if we show improved efficacy or improved convenience of administration with STS101, pricing of other third-party therapeutics may limit the amount we will be able to charge for our products. These third-party payors may deny or revoke the reimbursement status of our products, if approved, or establish prices for our products at levels that are too low to enable us to realize an appropriate return on our investment. If reimbursement is not available, is decreased or eliminated in the future, or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on our products.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our products, if any. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute STS101, if approved. Such laws include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, 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 any U.S. federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal civil and criminal false claims and civil monetary penalties laws, including the civil federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually identifiable health information of covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers as well as their business associates, independent contractors of a covered entity that perform certain services involving the use or disclosure of individually identifiable health information on their behalf;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the government information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous U.S. state laws, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements
- and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and federal and state laws, regulations, standards and codes of conduct governing the privacy and security of personal information and 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;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- similar healthcare and data protection laws in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Economic Area, or the EEA and the United Kingdom (including health data).

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of the laws described above or any other governmental laws that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize STS101 and may affect the prices we may set.

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;
- an increase to the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and an extension the rebate program to individuals enrolled in Medicaid managed care organizations;
- 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;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 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;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the Tax Cuts and Jobs Act of 2017, or the Tax Act, which includes a provision that entered into effect on January 1, 2019, that repeals the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how these decisions, subsequent appeals, if any, and other efforts to challenge, repeal or replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional action is taken by Congress.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. The Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. While some measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for STS101 or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize STS101, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by

relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of STS101, restrict or regulate post-approval activities and affect our ability to commercialize STS101, if approved. In markets outside of the United States and European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, STS101 may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the United States and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or any service providers', contractors' or future collaborators' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the United States, California enacted the California Consumer Privacy Act, or the CCPA, on June 28, 2018, which went into effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our collaborators, service providers, including our CRO, and contractors must comply. For example, GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR has and will continue to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. As we expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, including the following:

- results from, and any delays in, our clinical trials for STS101;
- results of clinical trials of our competitors' products;
- competition from existing products or new products that may emerge;
- announcements by academic, guideline publishers or other third parties challenging the fundamental premises underlying our approach to treating migraine;
- announcements of regulatory approval or disapproval of STS101;
- failure or discontinuation of any of our research and development programs;
- manufacturing setbacks or delays of or issues with the supply of the materials for STS101;
- announcements relating to future licensing, collaboration or development agreements, including the early termination or failure of an existing strategic collaboration;
- delays in the commercialization of STS101;
- acquisitions and sales of new products, technologies or businesses;
- quarterly variations in our results of operations or those of our future competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products, significant contracts, commercial relationships, acquisitions or capital commitments;
- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- any major changes in our board of directors or management;
- new legislation in the United States or relevant foreign jurisdictions relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of STS101 or other DHE products;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic conditions in the United States and abroad.

In addition, the stock markets in general, and the markets for pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action litigation against the issuer. If we were to become involved in securities litigation, we could incur substantial costs and resources and the attention of our management could be diverted from the operation of our business.

An active, liquid and orderly market for our common stock may not develop.

Prior to our initial public offering in September, there had been no public market for shares of our common stock, and an active public market for our shares may not develop or be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses, applications, or technologies using our shares as consideration.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock or business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, demand for our common stock could decrease and our stock price could decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in Jumpstart Our Business Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved. In addition, as an "emerging growth company," the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2024, (2) the last day of the year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We incur increased costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404, which could result in sanctions or other penalties that would harm our business.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Global Market and the rules of the Securities and Exchange Commission, or the SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations associated with being a public company have increased our legal and financial compliance costs and make some activities more time-consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

We are subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal controls over financial reporting. We will remain an emerging growth company until the earlier of (1) December 31, 2024, (2) the last day of the year in which we have total annual gross revenue of at least $1.07 billion, (3) the last day of the year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by these rules. In connection with the contemporaneous audits of our financial statements for the years ended December 31, 2017 and 2018, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted a material weakness. While we believe we have fully remediated the material weakness in our internal controls, if additional material weaknesses in our internal controls over financial reporting are identified in the future, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we will depend on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Market or other adverse consequences that would materially harm to our business.

We may also be subject to more stringent state law requirements. For example, on September 30, 2018, the then California Governor Jerry Brown signed into law Senator Bill 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company's board of directors. By December 31, 2019, each public company with principal executive offices in California is required to have at least one female on its board of directors. By December 31, 2021, each public company is required to have at least two females on its board of directors if the company has at least five directors, and at least three females on

its board of directors if the company has at least six directors. The new law does not provide a transition period for newly listed companies. We do not currently meet the December 31, 2021 requirement. If we fail to comply with this new law, we could be fined by the California Secretary of State, with a $100,000 fine for the first violation and a $300,000 for each subsequent violation, and our reputation may be adversely affected.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock, including pursuant to our 2019 Incentive Award Plan and 2019 Employee Stock Purchase Plan. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

Our 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, 2019, our executive officers, directors, holders of 5.0% or more of our capital stock and their respective affiliates held approximately 78.5% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our 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 our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale lapse, the trading price of our common stock could decline. Based upon the number of shares outstanding as of December 31, 2019, we had outstanding a total of approximately 17.4 million shares of common stock, assuming no exercise of outstanding options or warrants. Of these shares, approximately 6.1 million of the shares of our common stock sold in the IPO are freely tradable, without restriction, in the public market.

The lock-up agreements pertaining to our IPO will expire on March 10, 2020, following which up to an additional approximately 11.3 million additional shares of common stock will be eligible for sale in the public market. The underwriters from our initial public offering may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The holders of approximately 10.9 million shares of our common stock, or approximately 65% of our total outstanding common stock as of December 31, 2019, are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to vesting schedules and to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset a portion of future taxable income, if any, until such unused losses expire, if ever.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. While we do not believe we have experienced ownership changes in the past, it is possible we have done so, and we may experience ownership changes in the future as a result of our initial public offering and/or subsequent shifts in our stock ownership (some of which shifts are outside our control). There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, or the Tax Act, the amount of post-2017 NOLs that are permitted to deduct from U.S. federal income taxes in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The Tax Act generally eliminates the ability to carry back any NOLs to prior taxable years, while allowing post-2017 unused NOLs to be carried forward indefinitely without expiration. Additionally, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Recent U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform legislation, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate income tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, providing for indefinite carryforwards for losses generated in tax years after December 31, 2017, imposing significant additional limitations on the deductibility of interest, allowing for the accelerated expensing of capital expenditures, and putting into effect the migration from a "worldwide" system of taxation to a largely territorial system. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial condition and results of operations.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;

- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by our chief executive officer or president or by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. For a description of our capital stock, see "Description of Capital Stock."

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Our amended and restated certificate of incorporation and amended and restated bylaws provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This 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 us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. Further, we are currently subject to covenants under our Loan Agreement that place restrictions on our ability to pay dividends. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our corporate headquarters are located in South San Francisco, California, where we lease approximately 4,148 square feet of office space pursuant to a lease dated January 9, 2018, which continues through April 30, 2021. In addition, we lease approximately 5,043 square feet of office space in Research Triangle Park, North Carolina pursuant to a lease dated August 1, 2019, which continues through July 31, 2022. We believe these facilities are sufficient for our near-term needs, and expect to expand to new and/or additional space as we grow. We believe the biotechnology environment in the South San Francisco area offers suitable additional space on commercially reasonable terms to enable our expansion.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been listed on the Nasdaq Global Market under the symbol "STSA" since September 12, 2019. Prior to this date, there was no public market for our common stock.

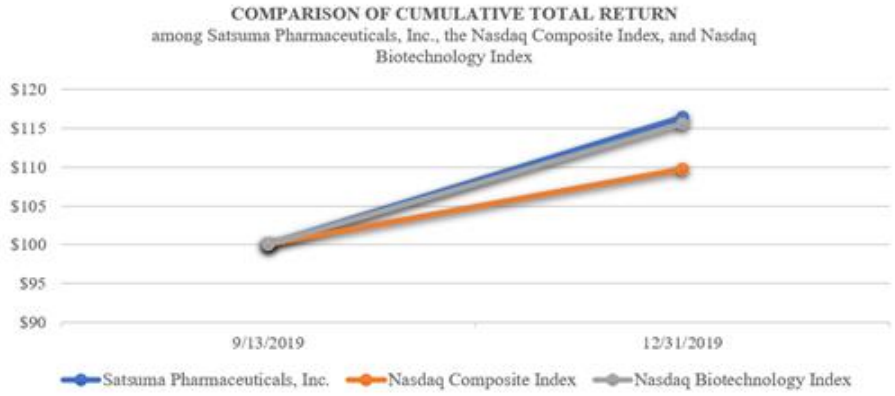
Holders of Common Stock

As of February 29, 2020, there were approximately 23 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Stock Performance Graph

The following graph is not "soliciting material" or deemed "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to liabilities under that Section, and shall not be deemed incorporated by reference into any filing of Satsuma Pharmaceuticals Inc. under the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total return of the Nasdaq Composite Index and the Nasdaq Biotechnology Index for an investment of $100, between September 12, 2019 (the date of our initial public offering) and December 31, 2019. The stockholder returns shown in the graph below are based on historical results and are not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.



Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, we are currently subject to covenants under our loan agreement with Silicon Valley Bank that place restrictions on our ability to pay dividends. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

From January 1, 2019 through December 31, 2019, we sold and issued the following unregistered securities, which share numbers have been adjusted, as appropriate, for the 1-for-4.7 reverse stock split that occurred on September 11, 2019:

1. In April 2019, we issued an aggregate of 6,889,986 shares of our Series B convertible preferred stock to sixteen accredited investors at $8.95444 per share for aggregate proceeds to us of approximately $61.7 million.
2. Prior to filing our registration statement on Form S-8 in September 2019, we granted stock options and stock awards to employees, directors and consultants under our 2016 Equity Incentive plan, covering an aggregate of 904,886 shares of common stock, at a weighted average exercise price of $4.13 per share.
3. Prior to filing our registration statement on Form S-8 in September 2019, we issued an aggregate of 267,210 shares of common stock at a weighted-average purchase price of $1.12 per share to employees, directors and consultants for aggregate proceeds to us of approximately $299,500 upon the exercise of stock options.

Use of Proceeds from Initial Public Offering

On September 12, 2019, the U.S. Securities and Exchange Commission declared effective our registration statement on Form S-1 (File No. 333-233347), as amended, filed in connection with our initial public offering ("IPO"). The IPO closed on September 17, 2019 and we issued and sold 5,500,000 shares of our common stock at a price to the public of $15.00 per share, which did not include the issuance of any shares in connection with the exercise by the underwriters of their option to purchase up to 825,000 additional shares. We received gross proceeds from the IPO of approximately $82.5 million, before deducting underwriting discounts and commissions, and estimated offering expenses payable by us. In October 2019, we sold and issued an additional 552,116 shares of common stock at $15.00 per share to the underwriters of the IPO following the partial exercise of their option to purchase additional shares for gross proceeds of $8.3 million before underwriting discounts, commissions and offering costs. The managing underwriters of the offering were Credit Suisse Securities (USA) LLC, SVB Leerink LLC and Evercore Group L.L.C. No offering expenses were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities or to any of our affiliates.

There has been no material change in our planned use of the net proceeds from our IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 5, 2018.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected historical financial data below should be read in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected financial data set forth below is derived from our audited financial statements and may not be indicative of future operating results.

	Year Ended December 31,		
	2019	2018	2017
	(in thousands, except share and per share data)		
Statements of Operations Data:			
Operating expenses			
Research and development	$ 24,196	$ 6,433	$ 4,193
General and administrative	4,685	1,082	754
Total operating expenses	$ 28,881	7,515	4,947
Loss from operations	$ (28,881)	(7,515)	(4,947)
Interest income	1,189	72	30
Interest expense	(482)	(90)	(15)
Other income (expense), net	(1)	187	(240)
Net loss	$ (28,175)	$ (7,346)	$ (5,172)
Unrealized gains on marketable securities	17	—	—
Comprehensive loss	(28,158)	(7,346)	(5,172)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.80)	$ (7.15)	$ (9.26)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	5,863,950	1,026,905	558,597

	As of December 31,		
	2019	2018	2017
	(in thousands)		
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 117,900	$ 5,205	$ 1,658
Working capital	106,773	3,439	214
Total assets	126,276	6,381	1,984
Long-term debt	4,930	4,965	—
Convertible preferred stock	—	11,648	5,528
Accumulated deficit	(43,001)	(14,826)	(7,480)
Total stockholders' equity (deficit)	115,335	(12,132)	(5,432)

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 together with the section titled "Selected Financial Data" and our financial statements and the related notes included elsewhere in this report. This discussion and analysis and other parts of this report contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Risk Factors" and elsewhere in this report.

Overview

We are a clinical-stage biopharmaceutical company developing a novel therapeutic product for the acute treatment of migraine. Our product candidate, STS101, is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate, or DHE, which can be quickly and easily self-administered with a proprietary pre-filled, single-use, nasal delivery device. DHE products have long been recommended as a first-line therapeutic option for the acute treatment of migraine and have significant advantages over other therapeutics for many patients. However, broad use has been limited by invasive and burdensome administration and/or sub-optimal clinical performance of available injectable and liquid nasal spray products. STS101 is specifically designed to deliver the clinical advantages of DHE while overcoming these shortcomings. We have completed a Phase 1 clinical trial in 42 healthy volunteers, in which STS101 demonstrated rapid and sustained DHE plasma concentrations within ranges previously associated with efficacy and safety in controlled studies of other DHE products, low pharmacokinetic variability, and a favorable safety and tolerability profile. In July 2019, we initiated our Phase 3 EMERGE efficacy trial of STS101 and expect to report topline data in the second half of 2020.

Since our inception in June 2016, we have invested substantially all of our efforts and financial resources in the development of STS101 for the acute treatment of migraine. We have incurred significant operating losses to date and expect that our operating expenses will increase significantly as we advance STS101 through clinical development, manufacturing and regulatory approval, and as we prepare for commercialization of STS101, if approved; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. In addition, we expect to incur additional costs associated with operating as a public company.

Our net losses were $28.2 million, $7.3 million and $5.2 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $43.0 million.

We do not have any products approved for sale and have not generated any product revenue since our inception. Prior to the completion of our IPO in September 2019, we have funded our operations primarily with an aggregate of $78.8 million in gross cash proceeds from the sale and issuance of convertible preferred stock, a convertible promissory note, and long-term debt.

In April 2019, we received gross cash proceeds of $61.7 million from the sale and issuance of Series B convertible preferred stock.

In September 2019, we sold and issued 5,500,000 shares of common stock at $15.00 per share for gross proceeds of $82.5 million. In October 2019, we sold and issued an additional 552,116 shares of common stock at $15.00 per share for gross proceeds of $8.3 million as a result of the partial exercise by the underwriters of their option to purchase additional shares. These gross proceeds are before underwriting discounts, commissions and offering costs. Upon the closing of our IPO, all redeemable convertible preferred shares then outstanding automatically converted into 9,936,341 shares of common stock, 5,116 warrants were net exercised immediately after the IPO resulting issuance of 4,801 shares of common stock.

Our ability to generate product revenue will depend on the successful development and eventual commercialization of STS101. Until such time as we can generate significant revenue from sales of STS101, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of STS101.

As of December 31, 2019, we had cash, cash equivalents and marketable securities of $117.9 million. We believe that those cash, cash equivalents and marketable securities will be sufficient to fund our projected operations for at least 12 months from the issuance of our financial statements as of and for the year ended December 31, 2019.

Components of Operating Results

Operating Expenses

Research and Development Expenses

All of our research and development expenses consist of expenses incurred in connection with the development of STS101 for the acute treatment of migraine. These expenses include:

- payroll and personnel-related expenses, including salaries, annual cash bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees;
- fees paid to third parties to conduct preclinical and clinical studies and other research and development activities, including contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and other service providers; and
- costs for licenses and allocated overhead, including rent, equipment, depreciation, information technology costs and utilities.

We expense both internal and external research and development expenses as they are incurred. We have entered into various agreements with CROs and CMOs. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events or tasks, and contracted costs. The estimated costs of research and development provided, but not yet invoiced, are included in accrued and other current liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we adjust the accrual accordingly. Payments made to CROs and CMOs under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. Nonrefundable payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as prepaid expenses and other current assets on our balance sheet. The capitalized amounts are recognized as expense as the goods are delivered or the related services are performed.

We expect our research and development expenses to increase substantially, as we advance STS101 through clinical development, manufacturing and regulatory approval, and as we prepare for commercialization of STS101, if approved. Predicting the timing or the cost to complete our clinical program or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, if we experience significant delays in enrollment in any of our clinical trials or if we experience delays in manufacturing with any of our CMOs, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if STS101 will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, directors and officers insurance, allocated overhead, including rent, debt service, equipment, depreciation, information technology costs, and utilities, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, including salaries, benefits and stock-based compensation expenses, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with stock exchange listing and Securities and Exchange Commission, or SEC, requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income

Interest income consists primarily of interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists primarily of interest related to our long-term debt, convertible note, and accretion of debt discount and debt issuance costs.

Other Income (Expense), Net

Other income (expense), net primarily consists of changes in the fair value of convertible preferred stock tranche liability and the obligation to issue additional shares of common stock.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

	2019	2018	Change	% Change
Operating expenses:				
Research and development	$ 24,196	$ 6,433	$ 17,763	276%
General and administrative	4,685	1,082	3,603	333%
Loss from operations	(28,881)	(7,515)	(21,366)	284%
Interest income	1,189	72	1,117	1551%
Interest expense	(482)	(90)	(392)	436%
Other income (expense), net	(1)	187	(188)	-101%
Net loss	$ (28,175)	$ (7,346)	$ (20,829)	284%

Research and Development Expenses

Research and development expenses increased by $17.8 million, or 276%, from the year ended December 31, 2018 to the year ended December 31, 2019. The increase in research and development expenses was primarily due to an increase of $15.9 million in fees paid to CROs and CMOs as a result of increased clinical and non-clinical trial activities, an increase of $1.0 million in payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, due to increases in headcount partially offset with payroll tax credit, an increase of $0.8 million in allocated overhead, including depreciation and travel expenses and an increase of $0.1 million of other research and development related expenses.

General and Administrative Expenses

General and administrative expenses increased by $3.6 million, or 333%, from the year ended December 31, 2018 to the year ended December 31, 2019. The increase in general and administrative expenses was primarily due to an increase of $1.1 million of payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, due to increases in headcount, and an increase of $2.5 million of professional fees for legal, consulting, accounting, tax and other services.

Interest Income

Interest income increased by $1.1 million from the year ended December 31, 2018 to the year ended December 31, 2019, which was primarily due to an increase in interest income on our cash, cash equivalents and marketable securities balances, which increased as a result of the net proceeds from our Series B convertible preferred stock in April 2019 and IPO in September 2019.

Interest Expense

Interest expense increased by $0.4 million from the year ended December 31, 2018 to the year ended December 31, 2019, which was primarily attributable to interest expense related to our long-term debt, including accretion of debt discount and debt issuance costs.

Other Income (Expense), Net

Other income (expense), net decreased by $0.2 million from the year ended December 31, 2018 to the year ended December 31, 2019, which was primarily due to a decrease in the fair value of the convertible preferred stock tranche liability of $0.3 million during the year ended December 31, 2018 partially offset with change in fair value of SNBL grant liability of $0.1 million.

Comparison of the Years Ended December 31, 2018 and 2017

	2018	2017	Change	% Change
Operating expenses:				
Research and development	$ 6,433	$ 4,193	$ 2,240	53%
General and administrative	1,082	754	328	44%
Loss from operations	(7,515)	(4,947)	(2,568)	52%
Interest income	72	30	42	140%
Interest expense	(90)	(15)	(75)	500%
Other income (expense), net	187	(240)	427	(178%)
Net loss	$ (7,346)	$ (5,172)	$ (2,174)	42%

Research and Development Expenses

Research and development expenses increased by $2.2 million, or 53%, from the year ended December 31, 2017 to the year ended December 31, 2018. The increase in research and development expenses was primarily due to an increase of $1.3 million in fees paid to CROs and CMOs, and an increase of $0.9 million in payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, due to increases in headcount.

General and Administrative Expenses

General and administrative expenses increased by $0.3 million, or 44%, from the year ended December 31, 2017 to the year ended December 31, 2018. The increase in general and administrative expenses was primarily due to an increase of $0.1 million of payroll and personnel expenses, including salaries, benefits and stock-based compensation expenses, and an increase of $0.1 million of professional fees for legal, consulting, accounting, tax and other services.

Interest Income

Interest income increased by less than $0.1 million from the year ended December 31, 2017 to the year ended December 31, 2018, which was primarily attributable to interest income from cash and cash equivalents.

Interest Expense

Interest expense increased by $0.1 million from the year ended December 31, 2017 to the year ended December 31, 2018, which was primarily attributable to interest expense related to our long-term debt, including accretion of debt discount and debt issuance costs.

Other Income (Expense), Net

Other income (expense), net increased by $0.4 million from the year ended December 31, 2017 to the year ended December 31, 2018, which was primarily due to a decrease in the fair value of the convertible preferred stock tranche liability of $0.3 million during the year ended December 31, 2018.

Liquidity and Capital Resources; Plan of Operations

Sources of Liquidity

Prior to the completion of our IPO in September 2019, we had funded our operations since our inception primarily through private placements of convertible preferred stock, a convertible promissory note, and long-term debt. We do not have any products approved for sale and have never generated any revenue. In August 2016, we received $0.1 million under a convertible promissory note. We received gross cash proceeds of $6.0 million from the sale and issuance of Series A convertible preferred stock during the year ended December 31, 2016, and gross cash proceeds of $6.0 million from the sale and issuance of Series A convertible preferred stock during the year ended December 31, 2018. In April 2019, we received gross cash proceeds of $61.7 million from the sale and issuance of Series B convertible preferred stock. We also entered into the credit facility described below with Silicon Valley Bank.

In September 2019, we sold and issued 5,500,000 shares of common stock at $15.00 per share for gross proceeds of $82.5 million. In October 2019, we sold and issued an additional 552,116 shares at $15.00 per share for gross proceeds of $8.3 million as a result of the partial exercise by the underwriters of their option to purchase additional shares. These gross proceeds are before underwriting discounts, commissions and offering costs.

Credit Facility

In October 2018, we entered into the Loan Agreement with Silicon Valley Bank. The Loan Agreement provides for loan advances of up to $10.0 million. We drew down the first advance of $5.0 million as of the effective date of the Loan Agreement. The remaining $5.0 million is available for draw down in $1.0 million increments. The Loan Agreement contains customary affirmative and negative covenants and events of default, including covenants and restrictions that among other things, restrict our ability to incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, engage in asset sales or sale and leaseback transactions, and declare dividends or redeem or repurchase capital stock. Interest on the loan advances is payable monthly at a floating per annum rate equal to the greater of 1.5% above the prime rate and 6.5%. Upon the occurrence of an event of default, interest will increase to 5.0% above the rate that is otherwise applicable. Principal on the outstanding loan advance is repayable commencing on December 1, 2019 in 30 monthly payments through maturity. The maturity date of the loan advances is May 1, 2022.

Future Funding Requirements

We have incurred net losses since our inception. Our net losses were $28.2 million, $7.3 million and $5.2 million for the years ended December 31, 2019, 2018 and 2017, respectively. Based on our current business plan, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our planned operations for at least 12 months from the issuance of our financial statements as of and for the year ended December 31, 2019.

We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize STS101 or enter into collaborative agreements with third parties, and we do not know when, or if, either will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, STS101 and begin to commercialize STS101, if approved. We are subject to the risks typically related to the development of new product

candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

We will continue to require additional capital to develop STS101 and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue the development and commercialization of STS101. We anticipate that we will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress, results and costs of our clinical trials for STS101;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the cost, timing and outcome of regulatory review of STS101;
- the cost of building a sales force in anticipation of commercialization of STS101;
- the cost and timing associated with commercializing STS101, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending
- intellectual property-related claims;
- any product liability or other lawsuits related to STS101;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the
- development and commercialization of STS101;
- the extent to which we acquire or in-license other product candidates or technologies;
- the payment of royalty payments owed under our existing license agreement;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the costs associated with being a public company; and
- the timing, receipt and amount of sales of STS101, if approved.

A change in the outcome of any of these or other variables with respect to the development of STS101 could significantly change the costs and timing associated with its development. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any debt financing into which we enter 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 or engage in certain merger, consolidation or asset sale transactions. For example, the Loan Agreement contains many of these restrictions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate our development program and clinical trials. We may also be required to sell or license to others rights to STS101 in certain territories or indications that we would prefer to develop and commercialize ourselves. Adequate additional funding may not be available to us on acceptable terms or at all. See “Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below:

	Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Net cash (used in) provided by:			
Operating activities	$ (29,637)	$ (6,981)	$ (4,321)
Investing activities	$ (95,876)	$ (402)	$ (58)
Financing activities	$ 143,063	$ 10,930	$ —
Net increase (decrease) in cash and cash equivalents	$ 17,550	$ 3,547	$ (4,379)

Cash Flows used in Operating Activities

Net cash used in operating activities was $29.6 million for the year ended December 31, 2019. Cash used in operating activities was primarily due to the use of funds in our operations to develop STS101, which resulted in a net loss of $28.2 million, adjusted for an increase in prepaid expenses and other assets of $6.5 million and a decrease of other non-current liabilities by $0.1 million, net amortization of premiums and discounts on marketable securities of $0.1 million, which amounts were partially offset by an increase in accounts payable of $4.0 million, an increase in accrued and other liabilities of $0.2 million, depreciation expense of $0.1 million, stock-based compensation expense of $0.7 million, non-cash interest expense and amortization of debt discount and issuance costs of $0.1 million. The increase in accounts payable resulted from the timing of payments to our service providers. The increase in accrued and other liabilities was primarily due to an increase in accrued research and development and accrued compensation.

Net cash used in operating activities was $7.0 million for the year ended December 31, 2018. Cash used in operating activities was primarily due to the use of funds in our operations to develop STS101, which resulted in a net loss of $7.3 million, adjusted for changes in fair value of convertible preferred stock tranche liability of $0.3 million, an increase in prepaid expenses and other assets of $0.5 million, a decrease in accounts payable of $0.2 million, which amounts were partially offset by depreciation expense of $0.1 million, change in the fair value of the obligation to issue additional common stock by $0.1 million, stock-based compensation expense of $0.2 million, and an increase in accrued and other liabilities of $0.9 million. The decrease in accounts payable resulted from the timing of payments to our service providers. The increase in accrued and other liabilities was primarily due to an increase in accrued research and development and accrued compensation.

Net cash used in operating activities was $4.3 million for the year ended December 31, 2017. Cash used in operating activities was primarily due to the use of funds to develop STS101, which resulted in a net loss of $5.2 million, adjusted for an increase in prepaid expenses and other assets of $0.3 million, which amounts were partially offset by a change in the fair value of the obligation to issue additional shares of common stock of $0.2 million, stock-based compensation expense of $0.1 million, an increase in accrued and other liabilities of $0.4 million, and an increase in accounts payable of $0.4 million. The increase in accrued and other liabilities was primarily due to an increase in accrued research and development and accrued compensation. The increase in accounts payable resulted from the timing of payments to our service providers.

Cash Flows used in Investing Activities

Net cash used in investing activities was $95.9 million for the year ended December 31, 2019, which consisted of purchases of marketable securities of $99.9 million, which amounts were partially offset by proceeds from maturities of marketable securities of $4.5 million and purchases of property and equipment of $0.5 million.

Net cash used in investing activities was $0.4 million for the year ended December 31, 2018, which consisted of $0.4 million used to purchase property and equipment.

Net cash used in investing activities was $0.1 million for the year ended December 31, 2017, which consisted of $0.1 million used to purchase property and equipment.

Cash Flows provided by Financing Activities

Net cash provided by financing activities was $143.1 million for the year ended December 31, 2019, which consisted of $61.5 million of net cash proceeds from our issuance of Series B convertible preferred stock, $81.4 million of net cash proceeds from our IPO and $0.3 million from exercise of stock options, partially offset by repayment of debt of 0.2 million.

Net cash provided by financing activities was $10.9 million for the year ended December 31, 2018, which consisted of $6.0 million of net cash proceeds from the issuance of Series A convertible preferred stock and borrowings of $4.9 million under our long-term debt facility with Silicon Valley Bank, net of issuance costs.

We did not undertake any financing activities in the year ended December 31, 2017.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019:

	Payments Due by Period (in thousands)				
	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years	Total
Operating lease obligations (1)	$ 299	$ 278	$ —	$ —	$ 577
Long-term debt obligations (2)	2,269	3,229	—	—	5,498
Total contractual obligations	$ 2,568	$ 3,507	$ —	$ —	$ 6,075

(1) We lease our office facilities in South San Francisco, California under non-cancelable operating leases through April 2021. There is an option to renew for an additional three years. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.

In July 2019, we entered into a lease agreement to lease another office space in North Carolina. The lease term is three years and the lease expires in July 2022.

(2) In October 2018, we entered into the Loan Agreement with Silicon Valley Bank. The Loan Agreement provides for loan advances of up to $10.0 million. The first advance of $5.0 million was drawn down during the year ended December 31, 2018. The loan is repayable commencing on December 1, 2019 in 30 monthly payments through maturity. In addition to regular monthly payments, a final payment equal to the original amount of the loan multiplied by 5.0% is due on the earliest to occur of (a) May 1, 2020 or (b) the prepayment in full of the loan. We repaid $0.2 million of the loan in December 2019.

We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, manufacturing and testing and providing other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Under the terms of our license agreement with Shin Nippon Biomedical Laboratories, Ltd., or SNBL, we have agreed to make royalty payments based on a low single-digit percentage of worldwide net sales of certain products covered thereby, payable on a product-by-product and country-by-country basis until the latest of the expiration of the last-to-expire patent covering such product and the ten-year anniversary of the first commercial sale of such product in such country. No upfront or milestone payments are otherwise owed pursuant to the license agreement.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates. For more detail on our critical accounting policies, refer to Note 1 to the financial statements included elsewhere in this Annual Report on Form 10-K.

Accrued Research and Development

We monitor the activity under its various agreements with CROs, CMOs and other service providers to the extent possible through communication with each service provider, detailed invoice and task completion review, analysis of actual expenses against budget, pre-approval of any changes in scope, and review of contractual terms. Our research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. These estimates may or may not match the actual services performed by the service providers. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly. Payments made to service providers under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Stock-Based Compensation

We use a fair value-based method to account for all stock-based compensation arrangements with employees and non-employees, including stock options and stock awards. Our determination of the fair value of stock options on the date of grant utilizes the Black-Scholes option pricing model. The fair value of the option granted is recognized on a straight-line basis over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period, which usually is the vesting period. We account for forfeitures as they occur. Estimates of the fair value of equity awards as of the grant date using valuation models such as the Black-Scholes option pricing model are affected by assumptions with a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately the amount of stock-based compensation expense recognized. These inputs are subjective and generally require significant analysis and judgment to develop. Changes in the following assumptions can materially affect the estimate of the fair value of stock-based compensation:

- *Expected Term* – The expected term is calculated using the simplified method, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- *Expected Volatility* – For all stock options granted to date, the volatility data was estimated based on a study of publicly traded industry peer companies as we did not have any trading history for our common stock. For purposes of identifying these peer companies, we considered the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, we measured historical volatility over a period equivalent to the expected term. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

- *Expected Dividend* – The Black-Scholes valuation model calls for a single expected dividend yield as an input. We currently have no history or expectation of paying cash dividends on our common stock. Accordingly, we have estimated the dividend yield to be zero.
- *Risk-Free Interest Rate* – The risk-free interest rate is based on the yield available on U.S. Treasury instruments whose term is similar in duration to the expected term of the respective stock option.

Common Stock Valuations

Prior to our IPO, the estimated fair value of the common stock underlying our stock options and stock awards was determined at each grant date by our board of directors, with assistance from management and external appraisers. All options to purchase shares of our common stock were intended to be exercisable at a price per share not less than the per-share fair value of our common stock underlying those options on the date of grant. The approach to estimate the fair value of the Company's common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or Practice Aid. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

JOBS Act Accounting Election

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use this extended transition period under the JOBS Act. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

Recent Accounting Pronouncements See "Organization and Summary of Significant Accounting Policies—Recent Accounting Pronouncements" in Note 1 to our financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates or exchange rates. As of December 31, 2019, we had cash, cash equivalents and marketable securities of $117.9 million, consisting of interest-bearing money market funds, investments in corporate bonds, overnight repurchase agreements, and asset-backed securities for which the fair value would be affected by changes in the general level of U.S. interest rates. However, due to the short-term maturities and the low-risk profile of our cash equivalents and marketable securities, an immediate 10% change in interest rates would not have a material effect on the fair value of our cash equivalents and marketable securities.

We do not believe that inflation, interest rate changes or exchange rate fluctuations have had a significant impact on our results of operations for any periods presented herein.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Satsuma Pharmaceuticals, Inc.:

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Satsuma Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2019.

San Diego, California
March 10, 2020

SATSUMA PHARMACEUTICALS, INC.

Balance Sheets
(in thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 22,755	$ 5,205
Short-term marketable securities	84,942	—
Prepaid expenses and other current assets	7,047	199
Total current assets	114,744	5,404
Property and equipment, net	832	445
Long-term marketable securities	10,203	—
Other non-current assets	497	532
Total assets	$ 126,276	$ 6,381
Liabilities		
Accounts payable	$ 4,282	$ 327
Accrued and other current liabilities	1,710	1,497
Current portion of long-term debt	1,979	141
Total current liabilities	7,971	1,965
Long-term debt	2,951	4,824
Other noncurrent liabilities	19	76
Total liabilities	10,941	6,865
Commitments and Contingencies (Note 8)		
Series A convertible preferred stock, $0.0001 par value, 10,000,000 shares authorized as of December 31, 2019 and 3,191,489 shares authorized as of December 31, 2018; no shares issued and outstanding as of December 31, 2019 and 3,046,355 shares issued and outstanding as of December 31, 2018; liquidation value of $0 as of December 31, 2019 and $12,134 as of December 31, 2018	—	11,648
Stockholders' equity (deficit)		
Common stock, $0.0001 par value, 300,000,000 shares and 5,319,148 shares authorized as of December 31, 2019 and December 31, 2018, respectively; 17,382,047 shares and 1,083,280 shares issued and outstanding as of December 31, 2019 and December 31, 2018	2	1
Additional paid-in-capital	158,317	2,693
Accumulated other comprehensive income	17	—
Accumulated deficit	(43,001)	(14,826)
Total stockholders' equity (deficit)	115,335	(12,132)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 126,276	$ 6,381

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

SATSUMA PHARMACEUTICALS, INC.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Operating expenses			
Research and development	$ 24,196	$ 6,433	$ 4,193
General and administrative	4,685	1,082	754
Total operating expenses	$ 28,881	$ 7,515	$ 4,947
Loss from operations	(28,881)	(7,515)	(4,947)
Interest income	1,189	72	30
Interest expense	(482)	(90)	(15)
Other income (expense), net	(1)	187	(240)
Net loss	$ (28,175)	$ (7,346)	$ (5,172)
Unrealized gains on marketable securities	17	—	—
Comprehensive loss	$ (28,158)	$ (7,346)	(5,172)
Net loss per share attributable to common stockholders, basic and diluted	$ (4.80)	$ (7.15)	$ (9.26)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	5,863,950	1,026,905	558,597

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

SATSUMA PHARMACEUTICALS, INC.
Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at January 1, 2017	1,506,307	$ 5,528	542,553	$ —	$ 1,982	$ (2,308)	$ —	$ (326)
Vesting of restricted stock	—	—	31,915	—	—	—	—	—
Stock-based compensation	—	—	—	—	66	—	—	66
Net loss	—	—	—	—	—	(5,172)	—	(5,172)
Balances at December 31, 2017	1,506,307	5,528	574,468	—	2,048	(7,480)	—	(5,432)
Vesting of restricted stock	—	—	31,915	—	—	—	—	—
Issuance of common stock on settlement of obligation to issue additional common stock	—	—	476,897	1	471	—	—	472
Common stock warrants issued in connection with long-term debt	—	—	—	—	4	—	—	4
Issuance of Series A convertible preferred stock for cash, net of issuance costs of $14	1,506,307	5,986	—	—	—	—	—	—
Conversion of convertible note into Series A convertible preferred stock, including interest of $8 adjusted for derivative liability of $27	33,741	134	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	170	—	—	170
Net loss	—	—	—	—	—	(7,346)	—	(7,346)
Balances at December 31, 2018	3,046,355	11,648	1,083,280	1	2,693	(14,826)	—	(12,132)
Issuance of Series B convertible preferred stock for cash, net of issuance costs of $206	6,889,986	61,490	—	—	—	—	—	—
Conversion of redeemable convertible preferred stock into common stock	(9,936,341)	(73,138)	9,936,341	1	73,137	—	—	73,138
Issuance of common stock upon initial public offering, net of issuance cost	—	—	6,052,116	—	81,435	—	—	81,435
Vesting of restricted stock	—	—	31,914	—	—	—	—	—
Stock-based compensation	—	—	—	—	747	—	—	747
Issuance of common stock upon exercise of stock options	—	—	273,595	—	305	—	—	305
Other comprehensive income	—	—	—	—	—	—	17	17
Issuance of common stock upon net exercise of common stock warrants	—	—	4,801	—	—	—	—	—
Net loss	—	—	—	—	—	(28,175)	—	(28,175)
Balances at December 31, 2019	—	$ —	17,382,047	$ 2	$ 158,317	$ (43,001)	$ 17	$ 115,335

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

SATSUMA PHARMACEUTICALS, INC.
Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2019	Year Ended December 31, 2018	Year Ended December 31, 2017
Cash flows from operating activities			
Net loss	$ (28,175)	$ (7,346)	$ (5,172)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation	141	57	10
Non-cash interest expense, and amortization of debt discount and issuance costs	132	28	15
Net amortization of premiums and accretion of discounts on marketable securities	(127)	—	—
Stock-based compensation	747	170	66
Loss on disposal of assets	3	—	—
Change in fair value of derivative liability	—	1	7
Change in fair value of obligation to issue additional common stock	—	101	232
Change in fair value of convertible preferred stock tranche liability	—	(291)	—
Loss on extinguishment of convertible note	—	4	—
Changes in assets and liabilities			
Prepaid expenses and other assets	(6,489)	(475)	(254)
Accounts payable	3,984	(177)	363
Accrued and other current liabilities	203	924	412
Other non-current liabilities	(56)	23	—
Net cash used in operating activities	(29,637)	(6,981)	(4,321)
Cash flows from investing activities			
Purchases of marketable securities	(99,855)	—	—
Proceeds from maturities of available-for-sale securities	4,530	—	—
Purchases of property and equipment	(551)	(402)	(58)
Net cash used in investing activities	(95,876)	(402)	(58)
Cash flows from financing activities			
Borrowings, net of issuance costs	—	4,944	—
Repayment of debt	(167)	—	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	61,490	5,986	—
Proceeds from initial public offering	81,435	—	—
Proceeds from exercise of common stock options	305	—	—
Net cash provided by financing activities	143,063	10,930	—
Net increase (decrease) in cash and cash equivalents	17,550	3,547	(4,379)
Cash and cash equivalents			
Cash and cash equivalents, at beginning of period	5,205	1,658	6,037
Cash and cash equivalents, at end of period	$ 22,755	$ 5,205	$ 1,658
Supplemental disclosure of cash flow information:			
Cash paid for income taxes	$ 10	$ 4	$ 1
Cash paid for interest	$ 347	$ 34	$ —
Supplemental non-cash investing and financing activities:			
Purchases of property and equipment in accounts payable and accrued and other current liabilities	$ 9	$ 29	$ 22
Issuance of common stock warrants in connection with long-term debt	$ —	$ 4	$ —
Conversion of redeemable convertible preferred stock into common stock	$ 73,138	$ —	$ —
Conversion of convertible note and accrued interest into preferred stock	$ —	$ 134	$ —
Issuance of common stock to settle liability for obligation to issue additional common stock	$ —	$ 471	$ —

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

1. Organization and Summary of Significant Accounting Policies

Description of the Business

Satsuma Pharmaceuticals, Inc. (the "Company") is a clinical-stage biopharmaceutical company developing a novel therapeutic for the acute treatment of migraine. The Company's product candidate, STS101, is a drug-device combination of a proprietary dry-powder formulation of dihydroergotamine mesylate, or DHE, which can be quickly and easily self-administered by a proprietary pre-filled, single-use, nasal delivery device. The Company, headquartered in South San Francisco, was incorporated in 2016 in the state of Delaware.

Initial Public Offering

On September 12, 2019, the Company's registration statement on Form S-1 (File No. 333-233347) relating to its initial public offering ("IPO") of common stock became effective. The IPO closed on September 17, 2019 at which time the Company issued 5,500,000 shares of its common stock at a price of $15.00 per share, which did not include the issuance of any shares in connection with the exercise by the underwriters of their option to purchase up to 825,000 additional shares. The Company received an aggregate of $82.5 million gross proceeds, before underwriting discounts, commissions and offering costs. In addition, upon closing the IPO, all outstanding shares of the Company's redeemable convertible preferred stock converted into 9,936,341 shares of common stock. In connection with the completion of its IPO, on September 12, 2019, the Company's certificate of incorporation was amended and restated to provide for 300,000,000 authorized shares of common stock with a par value of $0.0001 per share and 10,000,000 authorized shares of preferred stock with a par value of $0.0001 per share. In October 2019, the Company sold and issued an additional 552,116 shares of common stock at $15.00 per share to the underwriters of the IPO following the partial exercise of their option to purchase additional shares for gross proceeds of $8.3 million before underwriting discounts, commissions and offering costs.

Liquidity

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, risks of clinical delays or failure, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, reliance on contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), compliance with government regulations and the need to obtain additional financing to fund operations. STS101 is currently under development and will require significant additional development efforts as the Company continues the development of, and seek regulatory approvals for, STS101 and begin to commercialize it, if approved. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting.

There can be no assurance that the Company's development of STS101 will be successfully completed, that adequate protection for the Company's intellectual property will be obtained or maintained, that STS101 will obtain necessary government regulatory approval or that STS101 will be commercially viable, if approved. Even if STS101 development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from other pharmaceutical and biopharmaceutical companies. In addition, the Company is dependent upon the services of its employees, consultants and other third parties.

The Company has incurred significant losses and negative cash flows from operations in all periods since its inception and had an accumulated deficit of $43.0 million as of December 31, 2019. The Company has historically financed its operations primarily through private placements of convertible preferred stock, a convertible promissory note, long-term debt, and sale of common stock in the IPO. The Company has no products approved for sale, and the Company has not generated any revenue since its inception. The Company expects to incur significant additional operating losses over at least the next several years. There can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

As of December 31, 2019, the Company had cash, cash equivalents and marketable securities of $117.9 million. The Company's management believes that the Company's current cash, cash equivalents and marketable securities will be sufficient to fund its planned operations for at least 12 months from the date of the issuance of these annual financial statements.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP").

Reverse Stock Split

On September 11, 2019, the Company effected a 1-for-4.7 reverse stock split of the Company's common stock and convertible preferred stock. All issued and outstanding common stock, convertible preferred stock, stock options and per share amounts contained in the accompanying financial statements and notes to the financial statements have been retroactively adjusted to give effect to the stock split for all periods presented.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. Such estimates include the accrual of research and development expenses, valuation of the convertible preferred stock tranche liability, obligation to issue additional common stock, deferred tax assets, useful lives of property and equipment and the fair value of stock-based awards. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjust those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates and assumptions.

Segments

The Company operates and manages its business as a single operating and reportable segment, which is the business of developing, seeking regulatory approval for and commercializing STS101 for the acute treatment of migraine. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. No product revenue has been generated since its inception and all of the Company's long-lived assets are located in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original or remaining maturity of three months or less at the date of purchase to be cash equivalents.

Marketable Debt Securities

The Company determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluate such designation at each balance sheet date. All marketable debt securities are considered available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term marketable securities or long-term marketable securities. Unrealized gains and losses on available-for-sale debt securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. Other income (expense), net, includes amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method. The Company regularly reviews all its investments for other-than-temporary declines in fair value. The review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss

position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its accounting basis and the decline is other-than-temporary, the Company reduces the carrying value of the security it holds and records a loss for the amount of such decline.

Concentration of Credit Risk

The Company has no significant off balance sheet concentrations of credit risk. Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and short-term marketable securities. Substantially all the Company's cash is held by one financial institution that management believes to be of high credit quality. Such deposits may, at times, exceed federally insured limits. The Company invests its cash equivalents in marketable securities and money market funds. The Company has not experienced any credit losses on its deposits of cash or cash equivalents.

Fair Value of Financial Instruments

The carrying amounts of certain of the Company's financial instruments, including cash equivalents, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities and market interest rates, if applicable. The carrying amounts of the convertible preferred stock tranche liability and the obligation to issue additional common stock represent their fair value.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which generally ranges from three to five years. Leasehold improvements are stated at cost and amortized over the shorter of the useful lives of the assets or the lease term. Maintenance and repairs are charged to expense as incurred. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations and comprehensive loss in the period realized.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable or that the useful life is shorter than the Company had originally estimated. Recoverability is measured by comparison of the carrying amount of the asset or asset group to the future undiscounted cash flows which the asset or asset group is expected to generate. If the asset or asset group is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset or asset group exceeds the fair value of the asset or asset group. If the useful life is shorter than originally estimated, the Company amortizes the remaining carrying value over the new shorter useful life. There have been no such impairments of long-lived assets during the years ended December 31, 2019 and December 31, 2018.

Convertible Preferred Stock

The Company records all shares of convertible preferred stock at their respective fair values on the dates of issuance, net of issuance costs, or residual value, if issued together with other instruments that are remeasured to fair value on a recurring basis. The convertible preferred stock is recorded outside of permanent equity because while it is not mandatorily redeemable, in certain events considered not solely within the Company's control, such as a merger or acquisition or sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"), the convertible preferred stock will become redeemable at the option of the holders of at least a majority of the then outstanding shares of such preferred stock. All outstanding shares of convertible preferred stock converted into common stock upon effectiveness of the IPO.

Convertible Preferred Stock Tranche Liability

The Company was obligated to issue additional shares of Series A convertible preferred stock at future dates pursuant to the Series A convertible preferred stock purchase agreement. This obligation was determined to be a freestanding instrument that should be accounted for as a liability. At initial recognition, the Company recorded the convertible preferred stock tranche liability on the balance sheet at its fair value. The liability was subject to remeasurement at each balance sheet date, with changes in fair value recognized as a component of other income (expense), net in the statements of operations and comprehensive loss until it was extinguished upon issuance of Series A convertible preferred stock in February 2018 (see Note 7).

Obligation to Issue Additional Common Stock

The obligation to issue additional common stock to Shin Nippon Biomedical Laboratories, Ltd., or SNBL, pursuant to the Series A convertible preferred stock financing documents (the "SNBL Grant"), was accounted and classified as a liability as it was not indexed to the Company's stock, specifically because the settlement amount of the SNBL Grant could be affected by future issuance of equity shares or potential equity shares. Therefore, the obligation to issue additional shares of common stock to SNBL was initially measured at fair value and subsequently remeasured at fair value at each reporting date until it was extinguished upon issuance of common stock in February 2018, with changes in fair value recognized as a component of other income (expense), net in the statements of operations and comprehensive loss.

Research and Development Expenses

The Company's research and development expenses consist primarily of payroll and personnel-related expenses, including salaries, employee benefit costs and stock-based compensation expenses for the Company's research and product development employees, fees paid to third parties to conduct preclinical and clinical studies and other research and development activities on behalf of the Company, including CROs, CMOs and other service providers, costs for licenses, and allocated overhead, including rent, equipment, depreciation, information technology costs and utilities. The Company charges all research and development costs, both internal and external, to research and development expenses within the statements of operations and comprehensive loss as incurred. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate commercial use are also expensed as incurred.

Accrued Research and Development

The Company monitors the activity under its various agreements with CROs, CMOs and other service providers to the extent possible through communication with each service provider, detailed invoice and task completion review, analysis of actual expenses against budget, pre-approval of any changes in scope, and review of contractual terms. The Company's research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. These estimates may or may not match the actual services performed by the service providers. The estimated costs of research and development provided, but not yet invoiced, are included in accrued liabilities on the balance sheet. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made to service providers under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets on the balance sheet until the services are rendered.

Stock-Based Compensation

The Company maintains incentive plans under which incentive stock options and nonqualified stock options may be granted to employees and non-employee service providers. The Company accounts for all shared-based awards granted to employees and non-employees based on the fair value on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures as they occur. Generally, the Company issues awards with only service-based vesting conditions. For share-based awards with service-based vesting conditions, the Company

recognizes compensation expense using the straight-line method. The Company recognizes expense for awards subject to performance-based milestones over the requisite service period, using the accelerated attribution method, once the performance condition becomes probable of being achieved. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date.

Estimating fair value of stock-based awards using an option pricing model requires input of subjective assumptions, including fair value of the Company's common stock, and, for stock options, expected term of options and stock price volatility. The Company uses the Black-Scholes option-pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's estimates, involve inherent uncertainties and require application of management's judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. In 2019, the Company recorded unrealized gains on marketable securities of less than $0.1 million in other comprehensive income (loss). In 2018 and 2017, there were no components of other comprehensive income (loss) or accumulated comprehensive income (loss) and the net loss was equal to the comprehensive loss.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, convertible preferred stock, convertible preferred stock tranche liability, obligation to issue additional common stock, convertible note, stock options and common stock subject to repurchase related to unvested restricted stock awards are considered to be potentially dilutive securities. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as the convertible preferred stock is considered a participating security because it participates in dividends with common stock. The holders of convertible preferred stock do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Income Taxes

Income taxes are recorded using an asset and liability approach. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company's tax positions are subject to income tax audits. The Company recognizes the tax benefit of an uncertain tax position only if it is more likely than not that the position is sustainable upon examination by the taxing authority, based on the technical merits. The tax benefit recognized is measured as the largest amount of benefit which is more likely than not to be realized upon settlement with the taxing authority. The Company recognizes interest accrued and penalties related to unrecognized tax benefits in its tax provision. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. The provision for income taxes includes the effects of any accruals that the Company believes are appropriate, as well as the related net interest and penalties.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") under its accounting standard codifications ("ASC") or other standard setting bodies and adopted by the Company as of the specified effective date, unless otherwise discussed below.

New Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASC 842"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. ASC 842 provides a lessee with an option to not account for leases with a term of 12 month or less as leases in the scope of the new standard. ASC 842 supersedes the previous leases standard, ASC 840 Leases. For public business entities, this ASU is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, and should be applied through a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. Early adoption is permitted. For all other entities, this ASU is effective for fiscal years beginning after December 15, 2020 and interim periods within fiscal years beginning after December 15, 2021. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU No. 2016-02 is effective for the Company for the year ended December 31, 2021, and all interim periods within. The Company will adopt this ASU on January 1, 2021. In July 2018, the FASB issued supplemental adoption guidance and clarification to ASC 842 within ASU No. 2018-10, Codification Improvements to Topic 842, Leases and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. ASU No. 2018-11 provides another transition method in addition to the existing modified retrospective transition method by allowing entities to initially apply the new leasing standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In March 2019, the FASB issued ASU 2019-01, Leases (Topic 842) Codification Improvements, which further clarifies the determination of fair value of the underlying asset by lessors that are not manufacturers or dealers and modifies transition disclosure requirements for changes in accounting principles and other technical updates. In November 2019, the FASB issued ASU 2019-10, which delays the adoption dates for ASU 2016-02 for non-public entities. The Company is currently evaluating the impact the adoption of these ASUs will have on its financial statements and related disclosures. The Company expects to recognize a right-of-use asset and corresponding lease liability for its real estate operating leases upon adoption. See Note 8 for more information related to the Company's lease obligations, which are presented on an undiscounted basis therein.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326), to provide financial statement users with more useful information about expected credit losses, which was subsequently updated by ASU 2019-04, Codification Improvements to Topic 326, Financial Instrument - Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments, and ASU 2019-05, Financial Instruments - Credit Losses (Topic 326): Targeted Transition Relief. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount

expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. In November 2019, the FASB issued ASU No. 2019-10, according to which, the new standard is effective for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies ("SRC") as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, the new standard is effective for fiscal years beginning after December 15, 2022, and interim periods within that fiscal year. Early adoption is permitted. The Company is a SRC for fiscal year 2019. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In August 2018, the FASB issued ASU No.2018-13 (Topic 820), Fair Value Measurement. ASU 2018-13 modifies the disclosure requirements on fair value measurement in Topic 820. For public entities, ASU 2018-013 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company will adopt this ASU on January 1, 2020. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

2. Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

As of December 31, 2019, financial assets measured and recognized at fair value were as follows (in thousands):

	Fair Value Measurements at December 31, 2019			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
U.S. government bonds	$ 10,062	$ —	$ —	$ 10,062
Overnight repurchase agreements (1)	14,000	—	—	14,000
Corporate bonds	—	64,285	—	64,285
Asset backed securities	—	20,781	—	20,781
Marketable securities	24,062	85,066	—	109,128
Money market funds (1)	8,730	—	—	8,730
Total fair value of assets	$ 32,792	$ 85,066	$ —	$ 117,858

	Fair Value Measurements at December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimate Fair Value
Assets				
U.S. government bonds	$ 10,062	$ 1	$ —	$ 10,063
Overnight repurchase agreements (1)	14,000	—	—	14,000
Corporate bonds	64,285	17	(7)	64,295
Asset backed securities	20,781	7	(1)	20,787
Marketable securities	109,128	25	(8)	109,145
Money market funds (1)	8,730	—	—	8,730
Total fair value of assets	$ 117,858	$ 25	$ (8)	$ 117,875

(1) Included in cash and cash equivalents on the balance sheet.

As of December 31, 2018, financial assets measured and recognized at fair value were as follows (in thousands):

	Fair Value Measurements at December 31, 2018			
	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds (1)	$ 5,184	$ —	$ —	$ 5,184
Total fair value of assets	$ 5,184	$ —	$ —	$ 5,184

(1) Included in cash and cash equivalents on the balance sheet.

The following tables set forth the changes in the fair value of Level 3 financial liabilities (in thousands):

	Convertible Preferred Stock Tranche Liability	Obligation to Issue Additional Common Stock
Fair value at January 1, 2017	$ 291	$ 138
Change in fair value included in other income (expense), net	—	232
Fair value as of December 31, 2017	$ 291	$ 370
Change in fair value included in other income (expense), net	(291)	102
Settlement of obligation	—	(472)
Fair value as of December 31, 2018	$ —	$ —

The Company used the Black-Scholes option pricing model to estimate the fair value of the convertible preferred stock tranche liability (see Note 7). The Company used the fair value of the Company's common stock to estimate the fair value of the obligation to issue additional common stock (see Note 14).

3. Balance Sheet Components

Property and Equipment, Net

Property and equipment consisted of the following (in thousands, except years):

	Useful Life (In Years)	December 31, 2019	December 31, 2018
Furniture and fixtures	3	$ 58	$ 13
Leasehold improvements	Shorter of useful life or lease term	62	7
Machinery and equipment	3-5	805	375
Tooling	3-5	102	117
		1,027	512
Less: Accumulated depreciation		(195)	(67)
		$ 832	$ 445

Depreciation is computed using the straight-line method. Depreciation expense was $0.1 million, $0.1 million and less than $0.1 million for the years ended December 31, 2019, 2018 and 2017, respectively.

4. Accrued Liabilities and Other Current Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Accrued salaries and benefits	$ 1,145	$ 553
Accrued research and development expenses	88	772
Accrued professional services	248	85
Accrued interest	27	29
Other	202	58
	$ 1,710	$ 1,497

5. Convertible Note

On August 1, 2016, the Company issued a $0.1 million convertible promissory note (the "Convertible Note") to one of its founders and existing shareholders (see Note 14) bearing simple interest at 5.0% per annum. The outstanding amount was due and payable upon the earlier of (i) a demand made by the investor after the two-year anniversary of the initial issuance, or (ii) the continued occurrence of an event of default when declared due and payable by the investor.

The Convertible Note was amended on December 16, 2016 to redefine the automatic conversion trigger from a qualified financing before the maturity date of $7.0 million to the occurrence of the subsequent closing as defined in the Series A Preferred Stock Purchase Agreement dated December 16, 2016.

The Convertible Note included an embedded derivative that was required to be bifurcated and accounted for separately as a derivative liability. The derivative instrument was measured at fair value and recorded as a discount to the Convertible Note. The discount was amortized to interest expense over the term of the Convertible Note using the effective interest rate and the derivative liability was remeasured at each reporting period, with changes in value recorded to other income (expense), net on the Company's statements of operations and comprehensive loss. The estimated fair value of the derivative instrument was immaterial as of the issuance date and December 31, 2017, due to the probability of occurrence of the underlying events being remote.

Upon the subsequent financing, which occurred in February 2018 (see Note 9), the Convertible Note, including all accrued interest of less than $0.1 million at the date of the subsequent financing, converted into 33,741 shares of Series A preferred stock at $3.187 per share, which was equal to 80.0% of the price per share paid by the cash purchasers. The conversion of the Convertible Note was accounted for as an extinguishment with the loss on extinguishment of the Convertible Note of less than $0.1 million recorded in other income (expense), net on the Company's statements of operations and comprehensive loss. Total interest expense for each of the years ended December 31, 2017 and December 31, 2018 was less than $0.1 million. At December 31, 2017, accrued interest expense of less than $0.1 million was included in accrued liabilities on the Company's balance sheet. Amortization of debt discount for each of the years ended December 31, 2017 and December 31, 2018 was less than $0.1 million and was accounted for as interest expense on the Company's statements of operations and comprehensive loss. Loss on revaluation of derivative liability for each of the years ended December 31, 2017 and December 31, 2018 was less than $0.1 million.

6. Long-Term Debt

On October 26, 2018, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank. The Loan Agreement provides for loan advances of up to $10.0 million. The first advance (the "Term A Loan") of $5.0 million was available for draw down by the Company as of the effective date of the Loan Agreement. The remaining $5.0 million (the "Term B Loan" and together with the Term A Loan, the "Term Loans") is available for draw down by the Company in $1.0 million increments. Interest on the loan advances is payable monthly at a floating per annum rate equal to the greater of 1.5% above the prime rate or 6.5%. Upon the occurrence of an event of default, interest will increase to 5.0% above the rate that is otherwise applicable. The maturity date of the loan advances is May 1, 2022.

Principal on the Term A Loan is repayable commencing on December 1, 2019 in 30 monthly payments through maturity, however if a Term B Loan advance is made, then the Term A Loan will be repayable in 24 monthly payments commencing on June 1, 2020. The Term B Loan, if drawn, will be repayable in 24 monthly payments commencing on June 1, 2020. In addition to regular monthly payments, a final payment equal to the original principal amount of the Term Loans multiplied by 5.0% is due on the earliest to occur of (a) May 1, 2020 or (b) the prepayment in full of the term loan advances. The Company has the option to prepay the term loan advances with a prepayment premium of 3.0% of the outstanding principal if prepayment is made prior to October 26, 2019, 2.0% of the outstanding principal if prepayment is made after October 26, 2019 but before October 26, 2020, and 1.0% of the outstanding principal if prepayment is made after October 26, 2020 but before May 1, 2020. The repayment of term loan advances will be accelerated upon occurrence of an event of default. The Loan Agreement contains customary affirmative and negative covenants and events of default, including covenants and restrictions that among other things, restrict the ability of the Company to incur liens, incur additional indebtedness, make loans and investments, engage in mergers and acquisitions, engage in asset sales or sale and leaseback transactions, and declare dividends or redeem or repurchase capital stock.

As of December 31, 2019, the term loan advances, net of debt discount and debt issuance costs, were $4.9 million and are included in current portion of long-term debt and long-term debt on the Company's balance sheet. In December 2019, the Company repaid $0.2 million of term loan.

As of December 31, 2019, the future contractual maturities of debt by fiscal year are as follows (in thousands):

2020	$	2,000
2021		2,000
2022		833
Total future maturities of debt	$	4,833

In accordance with the terms of the Loan Agreement, on October 26, 2018, the Company issued warrants to purchase 10,232 shares of the Company's common stock at an exercise price of $1.04 per share with a term of 10 years. The Company will be obligated to issue additional warrants to purchase up to a maximum aggregate amount of shares of the Company's common stock equal to 0.15% of the Company's fully-diluted capitalization in connection with drawdowns of the Term B Loan at an exercise price equal to the latest valuation of the Company's common stock or if the Company's common stock is publicly traded, the lower of the trailing 10-day average closing share price of the Company's common stock prior to the first Term B Loan advance or the closing price per share on the day prior to the first Term B Loan advance ("Term B Warrants"). The Term B Warrants are considered issued and outstanding for accounting purposes on execution of the Loan Agreement. The warrants were accounted for and classified as equity at fair value using the following assumptions under the Option Pricing Model ("OPM"):

	Year Ended December 31, 2018
Expected term (years)	10.0
Expected volatility	74.8%
Risk-free interest rate	3.1%
Dividend yield	0%

The proceeds from the Term A Loan advance were allocated to the debt and the warrants based on their relative fair values. The resulting debt discount of less than $0.1 million is being recognized as interest expense over the term of the loan of 3.6 years using the effective interest method.

The Company incurred debt issuance costs of $0.1 million, which is presented as reduction of the Term A Loan advance, consistent with the presentation of debt discount. Debt issuance cost and final payment of $0.3 million is recognized as additional interest expense using the effective interest method over the term of the loan.

7. Convertible Preferred Stock Tranche Liability

In December 2016, the Company executed a Series A Preferred Stock Purchase Agreement to sell shares of Series A convertible preferred stock. The Series A convertible preferred stock issuance was structured in two tranches: (i) 1,506,307 shares at $3.9833 per share (the "First Tranche") and (ii) 1,506,307 shares at $3.9833 per share on achieving a certain development milestone by the Company or at the option of First Tranche investors at any time before such milestone is achieved (the "Second Tranche"). In December 2016, the Company recognized a convertible preferred stock tranche liability for the First Tranche investors' right to purchase from the Company, on the same terms, additional shares of Series A convertible preferred stock. The convertible preferred stock tranche liability was valued using the OPM, which resulted in an initial fair value of $0.3 million for the Company's obligation to sell the convertible preferred stock related to the Second Tranche. On December 31, 2017, the convertible preferred stock tranche liability was revalued, and the Company recorded a gain of less than $0.1 million in other income (expense), net for the year then ended.

On February 1, 2018, the Company issued an additional 1,506,307 shares of Series A convertible preferred stock at $3.9833 per share thereby extinguishing the convertible preferred stock tranche liability for the Second Tranche. Immediately prior to the closing of the Second Tranche, the Company remeasured the convertible preferred stock tranche liability to its then fair value of $0 and recorded a gain of $0.3 million in other income (expense), net.

8. Commitments and Contingencies

Operating Leases

The Company entered into a one-year lease agreement for office space in South San Francisco, California. Total rent payment under the agreement, which ran from January 1, 2017 to December 31, 2017, was $0.1 million.

On January 9, 2018, the Company entered into an office lease agreement for office space in South San Francisco, California. The lease term is through April 30, 2021. There is an option to renew for an additional three years.

On December 8, 2018, the Company entered into an office lease agreement for office space in North Carolina. The lease commenced on January 2, 2019 and the lease term was through June 30, 2019. There was an option to renew for two additional periods of three months each. On March 14, 2019, the Company entered into an amendment to the lease agreement for the office space in North Carolina to lease additional workspace at the same address over the same lease term. The lease was terminated on September 30, 2019.

In July 2019, the Company entered into a lease agreement to lease another office space in North Carolina. The lease term for this office space is three years and the lease expires in July 2022.

Rent expense was $0.2 million, $0.1 million and $0.1 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, less than $0.1 million of deferred rent representing future minimum rental payments for leases with scheduled rent escalations was included in accrued and other current liabilities and other noncurrent liabilities on the Company's balance sheet.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2019 were as follows (in thousands):

	Operating Leases
2020	$ 299
2021	195
2022	83
Total minimum lease payments	$ 577

Contingencies

From time to time, the Company may be involved in litigation related to claims that arise in the ordinary course of its business activities. The Company accrues for these matters when it is probable that future expenditures will be made, and these expenditures can be reasonably estimated. As of December 31, 2019, December 31, 2018 and December 31, 2017, the Company did not believe that any such matters, individually or in the aggregate, would have a material adverse effect on the Company's financial position, results of operations or cash flows.

Indemnification

The Company enters into standard indemnification arrangements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the fair value of these agreements is minimal.

9. Convertible Preferred Stock

The Company has authorized 10,000,000 shares of convertible preferred stock, $0.0001 par value.

In December 2016, the Company issued 1,506,307 shares of its Series A convertible preferred stock at $3.9833 per share to existing investors for proceeds of $5.8 million which was net of issuance costs of $0.2 million.

In February 2018, the Company issued 1,506,307 shares of its Series A convertible preferred stock at $3.9833 per share to existing investors for proceeds of $6.0 million, which was net of issuance costs of less than $0.1 million. The Convertible Note was exchanged for 33,741 shares of Series A convertible preferred stock at $3.187 per share, reflecting accrued interest of less than $0.1 million and a 20% discount to the purchase price per share paid by the cash investors.

In April 2019, the Company issued 6,889,986 shares of its Series B convertible preferred stock at $8.95444 per share to certain investors for gross proceeds of $61.7 million.

Upon the closing of the IPO in September 2019, all outstanding shares of the redeemable convertible preferred stock converted into 9,936,341 shares of common stock and the related carrying value was reclassified to common stock and additional paid-in capital. There was no issued and outstanding redeemable convertible preferred stock as of December 31, 2019.

Issued and outstanding redeemable convertible preferred stock and its principal terms as of December 31, 2018 were as follows (in thousands, except share and per share amounts):

	Redeemable Convertible Preferred Stock		Liquidation Value	Carrying Amount	Original Issue Price
	Authorized	Outstanding			
Series A convertible preferred stock	3,191,489	3,046,355	$ 12,134	$ 11,648	$ 3.9833
	3,191,489	3,046,355	$ 12,134	$ 11,648	

The holders of the convertible preferred stock have various rights and preferences as follows:

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or a deemed liquidation event, the holders of the convertible preferred stock were entitled to receive, prior and in preference to any distribution of any of the assets of the Company to the holders of the common stock by reason of their ownership of such stock, an amount per share for each share of convertible preferred stock held by them equal to the greater of (i) $3.9833 per share (subject to adjustment from time to time for recapitalization), plus all declared but unpaid dividends (if any) on such share of convertible preferred stock, or (ii) such amount per share as would have been payable had all shares of convertible preferred stock been converted into common stock immediately prior to such liquidation. If available assets were insufficient to pay the full liquidation preference of the series of convertible preferred stock, the assets available for distribution to holders of such preferred stock would be distributed among such holders on a pro rata basis. Any remaining funds and assets of the Company legally available for distribution would have been distributed pro rata to the common shareholders in proportion to the number of shares of common stock held by them. Shares of convertible preferred stock were not entitled to convert into shares of common stock in order to participate in any distribution, as shares of common stock, without first foregoing participation in the distribution as shares of convertible preferred stock.

Conversion

Each share of convertible preferred stock was convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder. The conversion price was determined by dividing the original issuance price applicable to each series of convertible preferred stock, adjusted for any anti-dilution adjustments, by the applicable conversion price for such series. The Company's convertible preferred stock was convertible into the Company's shares of common stock on a one-for-one basis.

The shares were to automatically convert into fully-paid non-assessable shares of common stock at the conversion rate (a) immediately prior to the closing of a firm commitment underwritten initial public offering pursuant to an effective registration statement filed under the Securities Act of 1933, as amended (the "Securities Act") provided that the aggregate gross proceeds to the Company are not less than $25.0 million and the per share price is at least three times the original issuance price (a "Qualified IPO"), or (b) at the time upon the receipt of a written request for conversion from the holders of at least a majority of the convertible preferred stock outstanding.

Dividends

In any calendar year, the holders of outstanding shares of convertible preferred stock were entitled to receive dividends, when, as and if declared by the Company's board of directors (the "Board of Directors"), at a rate of $0.32 per share, in preference and priority to any declaration, set aside or payment of any distribution on common stock of the Company. The right to receive dividends on shares of convertible preferred stock was not cumulative, and no right to dividends accrued to holders of preferred stock unless dividends were declared.

Voting

The holders of convertible preferred stock had one vote for each full share of common stock into which their respective shares of convertible preferred stock could then be converted.

Redemption and Balance Sheet Classification

The convertible preferred stock was recorded as temporary equity because while it was not mandatorily redeemable, it would become redeemable at the option of the stockholders upon the occurrence of certain deemed liquidation events that were considered not solely within the Company's control.

10. Common Stock

The Company has authorized 300,000,000 shares of common stock, $0.0001 par value per share.

Each holder of shares of common stock shall be entitled to one vote for each share thereof held.

The Company had reserved common stock, on an as-converted basis, for future issuance as follows:

	December 31,	
	2019	2018
Conversion of Series A convertible preferred stock	—	3,046,355
Exercise of common stock warrants	5,116	10,232
Exercise of outstanding options	1,568,874	829,775
Shares of common stock available for grant under the 2019 Plan	1,778,044	—
Shares of common stock available for grant under the 2016 Plan	—	114,905
Total	3,352,034	4,001,267

11. Stock-Based Compensation

2019 Incentive Award Plan

The Company's board of directors adopted and the Company's stockholders approved, effective on the day of effectiveness of the registration statement on Form S-1, the 2019 Incentive Award Plan (the "2019 Plan"). Awards granted under the 2019 Plan may be either incentive stock options ("ISOs"), nonqualified stock options ("NSOs"), stock appreciation rights ("SARs"), or restricted stock units ("RSUs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). Following the effectiveness of the 2019 Plan, the Company will not make any further grants under the 2016 Equity Incentive Plan. However, the 2016 Plan will continue to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2016 Plan that are forfeited or lapse unexercised and which following the effective date of the 2019 Plan are not issued under the 2016 Plan will be available for issuance under the 2019 Plan.

2016 Incentive Award Plan

In 2016, the Company established its 2016 Equity Incentive Plan (the "2016 Plan") which provides for the granting of stock options to employees and consultants of the Company. Awards granted under the 2016 Plan may be either incentive stock options ("ISOs"), nonqualified stock options ("NSOs"), stock appreciation rights ("SARs"), or restricted stock units ("RSUs"). ISOs may be granted only to Company employees (including officers and directors who are also employees). NSOs may be granted to Company employees and consultants.

The exercise price of ISOs and NSOs shall not be less than 100% of the estimated fair value of the shares on the date of grant. The exercise price of ISOs granted to an employee who, at the time of grant, owns stock representing more than 10% ("10% stockholder") of the voting power of all classes of stock of the Company shall be no less than 110% of the estimated fair value of the shares on the date of grant. The options usually have a term of 10 years (or no more than five years if granted to a 10% stockholder). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance and/or other conditions. Generally, options and restricted stock awards vest over a four-year period.

In January 2020, the number of shares of common stock available for issuance under the 2019 Plan was increased by 695,281 shares as a result of the automatic increase provision in the 2019 Plan.

Activity under the 2019 Plan and 2016 Plan is set forth below:

	Shares Available for Grant	Outstanding Options		
		Number of Shares	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)
Balance, January 1, 2017	408,510			
Additional shares authorized	127,659			
Options granted	(429,781)	429,781	$ 0.89	9.32
Balance, December 31, 2017	106,388	429,781	$ 0.89	
Additional shares authorized	408,511			
Options granted	(402,121)	402,121	$ 1.04	9.32
Options cancelled	2,127	(2,127)	$ 0.90	
Balance, December 31, 2018	114,905	829,775	$ 0.97	8.82
Additional shares authorized	2,675,833			
Options granted	(1,028,118)	1,028,118	$ 4.96	9.38
Options exercised	—	(273,595)	$ 1.13	
Options cancelled	15,424	(15,424)	$ 1.04	
Balance, December 31, 2019	1,778,044	1,568,874	$ 3.55	8.85
Exercisable as of December 31, 2019	433,396			
Vested and expected to vest, December 31, 2019	1,568,874			

The weighted-average grant-date fair value of options granted during the years ended December 31, 2019, December 2018 and December 31, 2017 was $3.44, $0.66 and $0.56 per share, respectively.

As of December 31, 2019, the total unrecognized stock-based compensation expense for stock options was $3.0 million, which is expected to be recognized over a weighted-average period of 2.8 years.

The total fair value of options vested for the years ended December 31, 2019, December 31, 2018 and December 31, 2017 was $0.7, $0.2 million and less than $0.1 million, respectively.

The Company accounts for forfeitures as they occur.

The following table summarizes information about stock options outstanding as of December 31, 2019 (in thousands, except share and per share data):

	Options Outstanding		Option Vested and Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Term (Years)	Number Exercisable	Aggregate Intrinsic Value	Weighted Average Exercise Price
$ 0.90	261,684	7.34	176,444	$ 3,314	$ 0.90
$ 1.04	402,920	8.55	165,016	$ 3,076	$ 1.04
$ 4.56	781,036	9.37	90,874	$ 1,374	$ 4.56
$ 5.55	51,278	9.60	—	$ —	$ —
$ 13.93	6,000	9.95	—	$ —	$ —
$ 15.00	65,956	9.69	1,062	$ 5	$ 15.00
	1,568,874		433,396	$ 7,769	$ 1.76

The following table summarizes information about stock options outstanding as of December 31, 2018 (in thousands, except share and per share data):

	Options Outstanding		Option Vested and Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Term (Years)	Number Exercisable	Aggregate Intrinsic Value	Weighted Average Exercise Price
$ 0.90	427,654	8.32	247,880	$ 709	$ 0.90
$ 1.04	402,121	9.36	134,438	$ 366	$ 1.04
	829,775		382,318	$ 1,075	$ 0.97

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money as of December 31, 2019 and December 31, 2018.

Stock-Based Compensation Associated with Awards to Employees and Non-employees

During the years ended December 31, 2019, December 31, 2018 and December 31, 2017, the Company granted stock options to employees to purchase 1,023,012, 402,121 and 427,654 shares of common stock, respectively. During the year ended December 31, 2019, December 31, 2018 and December 31, 2017 the Company granted 5,106, 0 and 2,127 stock options to its non-employees, respectively.

The fair value of stock options was valued using the following assumptions:

	December 31,		
	2019	2018	2017
Expected term (years)	6.0 - 6.1	5.5 - 6.1	5.5 - 6.3
Expected volatility	63.6% - 74.9%	77.2% - 78.6%	65.2% - 67.8%
Risk-free interest rate	1.4% - 2.5%	2.9%	1.8% - 2.3%
Dividend yield	0%	0%	0%

Expected Term. The expected term is calculated using the simplified method, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the periods from grant until the mid-point for each of the tranches are averaged to provide an overall expected term.

Expected Volatility. The Company used an average historical stock price volatility of a peer group of publicly traded companies to be representative of its expected future stock price volatility, as the Company did not have any trading history for its common stock. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies. For each grant, the Company measured historical volatility over a period equivalent to the expected term.

Risk-Free Interest Rate. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equivalent to the expected term of a stock award.

Expected Dividend Rate. The Company has not paid any dividends and does not anticipate paying any dividends in the near future. Accordingly, the Company has estimated the dividend yield to be zero.

Fair Value of Common Stock

Prior to the IPO the fair value of the Company's common stock underlying the stock options was determined by the Board of Directors with assistance from management and, in part, on input from an independent third-party valuation firm. The Board of Directors determined the fair value of common stock by considering a number of objective and subjective factors, including valuations of comparable companies, sales of convertible preferred stock, operating and financial performance, the lack of liquidity of the Company's common stock and the general and industry-specific economic outlook. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

Restricted Stock

Activity with respect to restricted stock awards ("RSAs") was as follows (in thousands, except share data):

	Number of Shares Underlying Outstanding RSAs	Weighted Average Grant Date Fair Value
Unvested, January 1, 2017	95,744	$ —
Vested	(31,915)	$ —
Unvested, December 31, 2017	63,829	$ —
Vested	(31,915)	$ —
Unvested, December 31, 2018	31,914	$ —
Vested	(31,914)	$ —
Unvested, December 31, 2019	—	$ —

2019 Employee Share Purchase Plan

In September 2019, the Company adopted the 2019 Employee Share Purchase Plan ("ESPP"), which became effective on the business day prior to the effectiveness of the registration statement relating to the IPO. A total of 160,000 shares of common stock were initially reserved for issuance under the ESPP. The offering period and purchase period will be determined by the board of directors. As of December 31, 2019, no offerings had been authorized.

In January 2020, the number of shares of common stock available for issuance under the ESPP was increased by 173,280 shares as a result of the automatic increase provision in the ESPP.

Stock-Based Compensation Expense

Total stock-based compensation expense recorded related to options granted to employees and non-employees was as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Research and development	$ 334	$ 69	$ 13
General and administrative	413	101	53
	$ 747	$ 170	$ 66

12. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net loss attributable to common stockholders	$ (28,175)	$ (7,346)	$ (5,172)
Denominator:			
Weighted-average shares outstanding	5,879,820	1,074,690	638,297
Less: weighted-average unvested restricted shares and shares subject to repurchase	(15,870)	(47,785)	(79,700)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	5,863,950	1,026,905	558,597
Net loss per share attributable to common stockholders, basic and diluted	$ (4.80)	$ (7.15)	$ (9.26)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the period presented because including them would have been antidilutive:

	Year Ended December 31,		
	2019	2018	2017
Convertible preferred stock	—	3,046,355	1,506,307
Convertible Note	—	—	33,603
Convertible preferred stock tranche liability	—	—	1,506,307
Options to purchase common stock	1,568,874	829,775	429,781
Unvested restricted common stock awards	—	31,914	63,829
Obligation to issue additional common stock	—	—	374,695
Warrants to purchase common stock	5,116	10,232	—
Total	1,573,990	3,918,276	3,914,522

13. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2019, December 31, 2018 and December 31, 2017. The Company has incurred net operating losses only in the United States since its inception. The Company has not reflected any benefit of such net operating loss carryforwards in the financial statements.

The differences between the statutory tax expense (benefit) rate and the effective tax expense (benefit) rate, were as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Tax at federal statutory income tax rate	$ (5,917)	$ (1,542)	$ (1,758)
Change in valuation allowance	6,708	1,527	1,099
Permanent differences	124	84	105
Prior year true ups	6	—	(70)
Research and development credits	(873)	(69)	—
State income taxes	1	1	—
Federal tax rate change	—	—	625
Other	(48)	—	—
Tax at effective income tax rate	$ 1	$ 1	$ 1

Significant components of the Company's net deferred tax assets are summarized as follows (in thousands):

	December 31,		
	2019	2018	2017
Deferred tax assets:			
Net operating loss carryforwards	$ 8,250	$ 2,456	$ 995
Research and development credit carryforwards	1,118	188	54
Stock-based compensation	45	4	—
Accruals and other	236	134	61
Gross deferred tax assets	9,649	2,782	1,110
Less: Valuation allowance	(9,491)	(2,696)	(1,103)
Deferred tax assets, net of valuation allowance	158	86	7
Deferred tax liabilities:			
Property and equipment	(158)	(86)	(7)
Net deferred tax assets	$ —	$ —	$ —

As of December 31, 2019, the Company had federal and state net operating loss carryforwards ("NOLs") of $39.1 million and $0.4 million, respectively. The federal NOLs consist of: (1) $4.7 million generated before January 1, 2018, which will begin to expire in 2037 but are able to offset 100% of taxable income; and (2) $34.5 million generated after December 31, 2017 that will carryforward indefinitely, but are subject to an 80% taxable income limitation. The state NOLs will begin to expire in 2037 if unused.

The Company also has California state research and development ("R&D") credit carryforwards of $0.3 million, which do not expire and Federal R&D credit carryforwards of $1.1 million which will begin to expire in 2037.

The Company has not performed a formal study validating these credits claimed in the tax returns. Once a study is prepared, the amount of R&D tax credits available could vary from what was originally claimed on the tax returns.

As part of the Protecting Americans from Tax Hikes Act of 2015 (the "PATH Act"), certain eligible companies have the ability to convert a portion of their R&D tax credits to offset payroll tax liabilities. As of December 31, 2019, the Company had converted $0.7 million of its federal R&D credits to be utilized as an offset against future payroll taxes.

The utilization of NOLs and tax credit carryforwards to offset future taxable income may be subject to an annual limitation as a result of ownership changes that have occurred previously or may occur in the future. Under Sections 382 and 383 of the Internal Revenue Code ("IRC") a corporation that undergoes an ownership change may be subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes otherwise available to offset future taxable income and/or tax liability. An ownership change is defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three-year period. The Company has not completed a formal study to determine if any ownership changes within the meaning of IRC Section 382 and 383 have occurred. If an ownership change has occurred, the Company's ability to use its NOLs or tax credit carryforwards may be restricted, which could require the Company to pay federal or state income taxes earlier than would be required if such limitations were not in effect.

Uncertain Income Tax Positions

The total amount of unrecognized tax benefits as of December 31, 2019 was $0.2 million. If recognized, none of the unrecognized tax benefits would affect the Company's effective tax rate.

The following table summarizes the activity related to the Company's unrecognized tax benefits:

Balance as of January 1, 2017	$	—
Increase related to current year tax positions		23
Balance as of December 31, 2017	$	23
Increase related to current year tax positions		134
Balance as of December 31, 2018	$	157
Increase related to current year tax positions		196
Decrease related to prior year tax positions		(115)
Balance as of December 31, 2019	$	238

The Company's policy is to account for interest and penalties as income tax expense. As of December 31, 2019, the Company had no interest related to unrecognized tax benefits. No amounts of penalties related to unrecognized tax benefits were recognized in the provision for income taxes. The Company does not anticipate any significant change within twelve months following the date of the filing of this Annual Report on Form 10-K.

The Company files income tax returns in the U.S. federal jurisdiction and various state jurisdictions. The Company is subject to U.S. federal and state income tax examination for calendar tax years beginning in 2016 due to net operating losses that are being carried forward for tax purposes.

14. Related Party Transactions

Transactions with SNBL

In June 2016, the Company and SNBL, entered into a licensing and assignment agreement (the "SNBL License"), which was amended and restated in December 2016 and further amended in January 2017, April 2017, and October 2017. Under the SNBL License, SNBL assigned to the Company certain patent rights and know-how that are directed to SNBL's proprietary nasal drug delivery technology, including its proprietary nasal delivery device (the "Device"), and formulation technologies, for use with DHE (the "DHE Product"). SNBL granted to the Company an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights and know-how, other than the assigned patent rights and know-how, to develop, make, use, and commercialize DHE Products in the field of treatment, prevention or prophylaxis of all indications and human medical conditions, as well as the products consisting of the Device used to deliver a combination of DHE and one or more active pharmaceutical ingredients other than DHE ("DHE Combination Products"), in the field of treatment, prevention or prophylaxis of migraine and non-migraine headaches. The Company granted to SNBL a non-exclusive, royalty-free, sublicensable license, under the Company's rights in improvements to the Device, to develop, make, use, and commercialize products and devices other than DHE Products and DHE Combination Products. During the term of the SNBL License, the Company, SNBL, and the Company's and SNBL's affiliates are not permitted to develop or commercialize, or to enable third parties to develop or commercialize, a product containing DHE as an active ingredient for delivery through nasal tissues or the respiratory system, other than pursuant to the SNBL License. The Company will be responsible, at its cost, for the development, manufacture and commercialization of DHE Products and DHE Combination Products under the SNBL License. The Company is required to use commercially reasonable efforts to develop and commercialize at least one such product, initially in the United States.

Under the SNBL License, the Company reimbursed SNBL for costs relating to its incorporation and prosecution and maintenance of the product-specific patents. The Company also agreed to make royalty payments based on a low single-digit percentage of worldwide net sales of DHE Products and DHE Combination Products, payable on a product-by-product and country-by-country basis until the latest of the expiration of the last-to-expire patent covering such product and the ten year anniversary of the first commercial sale of such product in such country. The royalty payments are subject to reductions based on royalties paid to any third party under a license to such third party's patent rights.

The Company has the sole right to control the prosecution and maintenance of, and to enforce, the patent rights that SNBL assigned to the Company. SNBL has the first right to control the prosecution and maintenance of the patent rights that SNBL licensed to the Company. The Company has step in rights if SNBL does not continue such prosecution and maintenance. The Company also have the first right to enforce such licensed patent rights with respect to certain infringing products. If the Company does not bring an action to enforce such patents against infringing activities that involve such infringing products, SNBL has the right to bring such an action.

The SNBL License will continue on a country-by-country and product-by-product basis until the expiration of the obligation to pay royalties with respect such product and country. The Company may terminate the SNBL License in its entirety without cause on ninety days' prior written notice. SNBL may terminate the SNBL License for our material breach that remains uncured for ninety days. SNBL may also terminate the SNBL License if the Company challenges the licensed patents, or if the Company assists any third party in challenging such patents. In addition, SNBL has the right to terminate the SNBL License upon the Company's insolvency.

There were no sales of products under the SNBL License during the years ended December 31, 2019, December 31, 2018 and December 31, 2017. In connection with the SNBL License, in July 2016, SNBL entered into a Common Stock Purchase Agreement with the Company to purchase of 510,638 shares of the Company's common stock at its par price of $0.0001. The Company recorded the estimated fair value of the SNBL License of $0.7 million as of the SNBL License date as additional paid-in capital as contribution by SNBL for 510,638 shares of common stock purchased by SNBL.

In August 2016, the Company signed the Convertible Note with SNBL for $0.1 million, which was later amended in December 2016 (Note 5). In February 2018, the Convertible Note and related accrued interest of less than $0.1 million converted into 33,741 shares of Company's Series A convertible preferred stock.

In December 2016, as part of the Series A convertible preferred stock financing, the Company granted to SNBL a right to obtain shares of Common Stock for no additional paid-in capital upon the occurrence of subsequent closings of the Company's Series A convertible preferred stock financing such that SNBL's percentage ownership of the fully-diluted capitalization of the Company following the SNBL Grant would be equal to 20% following the final closing of the Series A convertible preferred stock financing. In return, SNBL assigned product-specific know-how and patents relating to STS101 to the Company. The Company recorded an additional fair value of the SNBL License of $1.4 million in December 2016.

The obligation to issue additional common stock to SNBL was accounted and classified for as a liability as it was not indexed to the Company's own stock, specifically because the settlement amount of the SNBL Grant could be affected by future issuance of equity shares or potential equity shares. Therefore, the obligation to issue additional common stock to SNBL was initially measured at fair value and subsequently remeasured at fair value at each reporting date until it expires or is exercised. Upon the initial issuance, the Company recorded the obligation to issue additional common stock to SNBL at its estimated fair value of $0.1 million based on the estimated fair value of the Company's common stock of $0.90 per share and estimated 0.3 million shares of the Company's common stock to be issued to settle such obligation adjusted for the probability or the occurrence of the subsequent closing of the Series A convertible preferred stock financing. The difference between the additional fair value of the SNBL License and the estimated fair value of the obligation to issue additional common stock to SNBL, of $1.3 million was accounted as additional paid-in capital. On December 31, 2017, the obligation to issue additional common stock to SNBL was remeasured to its estimated fair value of $0.4 million and $0.2 million was recorded as a loss in other income (expense), net for the year ended December 31, 2017. In February 2018, the Company issued 476,897 shares of common stock for no consideration. Upon extinguishment of the obligation to issue additional common stock to SNBL, the obligation to issue additional common stock to SNBL was remeasured to its estimated fair value of $0.5 million and $0.1 million was recorded as a loss in other income (expense), net for the year ended December 31, 2018, and the estimated fair value of $0.5 million of the obligation to issue additional common stock to SNBL was reclassified to additional paid-in capital on the balance sheet.

In April 2019, as part of the Company's Series B Financing, SNBL purchased 307,110 shares of Series B convertible preferred stock with an aggregate purchase price of $2.7 million.

In September 2019, SNBL purchased 233,333 shares of the common stock upon the IPO, in addition to the conversion of its 33,741 shares of outstanding Series A preferred stock into the common stock as discussed in Note 9.

The Company incurred expenses in connection with preclinical study services performed by SNBL of less than $0.1 million, less than $0.1 million and $0.2 million, which are included in research and development expenses on the statement of operations for the years ended December 31, 2019, 2018 and 2017, respectively. Amounts due to SNBL in connection with these expenses of less than $0.1 million are included in accrued liabilities on the balance sheets as of December 31, 2019 and 2018.

Transactions with Others

Upon the closing of the IPO in September 2019, 3,887,668 shares of outstanding Series A and Series B convertible preferred stock owed by two shareholders of the Company, each owning more than 10% of the Company's equity on an as-converted basis, converted into 3,887,668 shares of common stock (see Note 9). Upon the IPO these shareholders also purchased additional 2,633,333 shares of the Company's common stock, with an aggregate purchase price of $39.5 million.

15. Quarterly Results of Operations Data (unaudited)

The following table sets forth our unaudited statement of operations data for each of the eight quarters in the period ended December 31, 2019. The unaudited quarterly statement of operations data set forth below have been prepared on a basis consistent with our audited annual financial statements in this Annual Report on Form 10-K and include, in our opinion, all normal recurring adjustments necessary for a fair statement of the financial information contained in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future. The following quarterly financial data should be read in conjunction with our audited financial statements and the related notes included elsewhere in this Annual Report on Form 10-K.

	Three months ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(In thousands, except per share amounts)			
Loss from operations	$ (2,714)	$ (6,422)	$ (8,470)	$ (11,275)
Net loss	$ (2,815)	$ (6,291)	$ (8,260)	$ (10,809)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.51)	$ (5.48)	$ (2.26)	$ (0.62)

	Three months ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
	(In thousands, except per share amounts)			
Loss from operations	$ (1,409)	$ (2,222)	$ (1,600)	$ (2,284)
Net loss	$ (1,212)	$ (2,203)	$ (1,587)	$ (2,344)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.36)	$ (2.07)	$ (1.48)	$ (2.17)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Management's Evaluation of our Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive and principal financial and accounting officers, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their control objectives.

Our management, with the participation of our principal executive officer and principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures at the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of such date.

Changes in Internal Control over Financial Reporting

Except for the changes in connection with the remediation of the previously identified material weakness discussed below, there has been no change in our internal control over financial reporting during the quarter ended December 31, 2019, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

In connection with the audit of our financial statements for the years ended December 31, 2018 and 2017, we identified a material weakness in our internal control over financial reporting. 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 our financial statements will not be prevented or detected on a timely basis. The material weakness identified in our internal control over financial reporting related to a lack of appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations. During 2019, we took a number of actions to remediate this material weakness, including:

- engaging SEC compliance and technical accounting consultants;
- hiring additional finance and accounting personnel to augment accounting staff and to provide more resources for complex accounting matters and financial reporting; and
- we have strengthened our financial statement review procedures and the supervisory reviews by our management that are performed during the financial close process and which support the accurate and timely preparation of consolidated financial statements that are fairly presented in accordance with US generally acceptable accounting principles.

We believe that the implementation of the remediation measures outlined above were sufficient to remediate the previously identified material weakness in internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

ITEM 9B. OTHER INFORMATION

None.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the Annual Meeting of Stockholders within 120 days after December 31, 2019, or the Proxy Statement, and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item will be contained in the Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) FINANCIAL STATEMENTS

The financial statements required by Item 15(a) are filed as part of this Annual Report on Form 10-K under Item 8 “Financial Statements and Supplementary Data.”

(2) FINANCIAL STATEMENT SCHEDULES

All schedules to the financial statements are omitted as the required information is either inapplicable or presented in the financial statements.

(3) EXHIBITS

ITEM 16. FORM 10-K SUMMARY

None.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	9/17/2019	3.1	
3.2	Amended and Restated Bylaws.	8-K	9/17/2019	3.2	
4.1	Reference is made to exhibits 3.1 through 3.2.				
4.2	Form of Common Stock Certificate.	S-1/A	9/3/2019	4.2	
4.3	Amended and Restated Investors' Rights Agreement, dated as of April 23, 2019, by and among Satsuma Pharmaceuticals, Inc. and the investors party thereto.	S-1	8/16/2019	4.3	
4.4	Warrant by and between Satsuma Pharmaceuticals, Inc. and Silicon Valley Bank.	S-1	8/16/2019	4.4	
4.5	Warrant by and between Satsuma Pharmaceuticals, Inc. and Life Science Loans II, LLC.	S-1	8/16/2019	4.5	
4.6	Description of Capital Stock				X
10.1	Lease Agreement, dated January 9, 2018, by and between Satsuma Pharmaceuticals, Inc. and Kashiwa Fudosan America, Inc.	S-1	8/16/2019	10.1	
10.2(a)†	Amended and Restated Licensing and Assignment Agreement, dated December 16, 2016, by and between Satsuma Pharmaceuticals, Inc. and Shin Nippon Biomedical Laboratories, Ltd.	S-1	8/16/2019	10.2(a)	
10.2(b)†	First Amendment to Amended and Restated Licensing and Assignment Agreement, dated January 13, 2017, by and between Satsuma Pharmaceuticals, Inc. and Shin Nippon Biomedical Laboratories, Ltd.	S-1	8/16/2019	10.2(b)	
10.2(c)†	Second Amendment to Amended and Restated Licensing and Assignment Agreement, dated as of April 27, 2017, by and between Satsuma Pharmaceuticals, Inc. and Shin Nippon Biomedical Laboratories, Ltd.	S-1	8/16/2019	10.2(c)	
10.2(d)†	Third Amendment to the Amended and Restated Licensing and Assignment Agreement, dated October 6, 2017, by and between Satsuma Pharmaceuticals, Inc. and Shin Nippon Biomedical Laboratories, Ltd.	S-1	8/16/2019	10.2(d)	
10.3	Loan and Security Agreement, dated as of October 26, 2018, by and between Silicon Valley Bank and the Company.	S-1	8/16/2019	10.3	
10.4(a)#	2016 Equity Incentive Plan.	S-1	8/16/2019	10.4(a)#	
10.4(b)#	Form of Stock Option Agreement under 2016 Equity Incentive Plan.	S-1	8/16/2019	10.4(b)#	
10.5(a)#	2019 Incentive Award Plan.	S-1/A	9/3/2019	10.5(a)	

10.5(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2019 Incentive Award Plan.	S-1	8/16/2019	10.5(b)	
10.5(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2019 Incentive Award Plan.	S-1	8/16/2019	10.5(c)	
10.5(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2019 Incentive Award Plan.	S-1	8/16/2019	10.5(d)	
10.6#	2019 Employee Stock Purchase Plan.	S-1/A	9/3/2019	10.6	
10.7(a)#	Offer Letter, dated June 17, 2016, by and between Satsuma Pharmaceuticals, Inc. and John Kollins.	S-1	8/16/2019	10.7(a)#	
10.7(b)#	First Amendment to Offer Letter, dated June 17, 2016, by and between Satsuma Pharmaceuticals, Inc. and John Kollins.	S-1	8/16/2019	10.7(b)#	
10.8#	Offer Letter, dated June 12, 2017, by and between Satsuma Pharmaceuticals, Inc. and Detlef Albrecht.	S-1	8/16/2019	10.8#	
10.9#	Offer Letter, dated December 21, 2018, by and between Satsuma Pharmaceuticals, Inc. and Tom O'Neil.	S-1	8/16/2019	10.9#	
10.10#	Non-Employee Director Compensation Program.	S-1/A	9/3/2019	10.10	
10.11	Form of Indemnification Agreement for Directors and Officers	S-1	8/16/2019	10.11	
10.12#	Form Change in Control and Severance Agreement.	S-1/A	9/3/2019	10.12	
23.1	Consent of Independent Registered Public Accounting Firm.				X
24.1	Power of Attorney. Reference is made to the signature page to the Registration Statement.				X
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.				X
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.				X
32.1*	Certification by the Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification by the Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101.INS	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X

101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

# Indicates management contract or compensatory plan.

† Certain confidential portions (indicated by brackets and asterisks) have been omitted from this exhibit.

* The certifications attached as Exhibit 32.1 and 32.2 that accompanies this Annual Report on Form 10-K is not deemed filed with the SEC and is not to be incorporated by reference into any filing of Satsuma Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

Company Name

Date: March 10, 2020

By: /s/ John Kollins

Name: John Kollins

Title: President and Chief Executive Officer (Principal Executive Officer)

Date: March 10, 2020

By: /s/ Tom O’Neil

Name: Tom O’Neil

Title: Chief Financial Officer (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John Kollins and Tom O'Neil, jointly and severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ John Kollins John Kollins	President and Chief Executive Officer (Principal Executive Officer)	March 10, 2020
/s/ Tom O'Neil Tom O'Neil	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2020
/s/ Heath Lukatch Heath Lukatch	Director	March 10, 2020
/s/ Thomas B. King Thomas B. King	Director	March 10, 2020
/s/ Michael Riebe Michael Riebe	Director	March 10, 2020
/s/ Elisbaeth Sandoval Elisbaeth Sandoval	Director	March 10, 2020
/s/ Rajeev Shah Rajeev Shah	Director	March 10, 2020
/s/ Ken Takanashi Ken Takanashi	Director	March 10, 2020

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, the amended and restated investors' rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors' rights agreement, copies of which are incorporated by reference as Exhibits 3.1, 3.2 and 4.3, respectively, to our Annual Report on Form 10-K.

Common Stock

As of December 31, 2019, Satsuma Pharmaceuticals, Inc. ("Satsuma") had common stock, $0.0001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and listed on The Nasdaq Global Market under the trading symbol "STSA."

Shares Outstanding

We are authorized to issue up to 300,000,000 shares of Common Stock. As of December 31, 2019, there are 17,382,047 shares of Common Stock issued and outstanding, 1,568,874 shares are issuable upon the exercise of outstanding options to purchase common stock and 5,116 shares issuable upon the exercise of outstanding warrants.

As of December 31, 2019, there were approximately 23 holders of record of our Common Stock. This number does not include beneficial owners whose shares are held by nominees in street name.

The actual number of stockholders is greater than the number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66 2⁄3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, such as the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Fully Paid and Nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Convertible Preferred Stock

Our board of directors has the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. As of December 31, 2019, no shares of preferred stock were outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Under our amended and restated investors' rights agreement, based on the number of shares outstanding as of December 31, 2019, the holders of approximately 10.9 million shares of common stock, or their transferees, have the right to require us to register their shares under the Securities Act so that those shares may be publicly resold, and to include their shares in any registration statement we file, in each case as described below.

Demand Registration Rights

Based on the number of shares outstanding as of December 31, 2019, the holders of approximately 10.9 million shares of our common stock (on an as-converted basis), or their transferees, are entitled to certain demand registration rights. The holders of at least 20% of these shares can, on not more than two occasions, request that we register all or a portion of their shares if the aggregate price to the public of the shares offered is at least $10.0 million (before deductions of underwriters' commissions and expenses).

Piggyback Registration Rights

Based on the number of shares outstanding as of December 31, 2019, after the consummation of this offering, in the event that we determine to register any of our securities under the Securities Act (subject to certain exceptions), either for our own account or for the account of other security holders, the holders of approximately 10.9 million shares of our common stock (on an as-converted basis), or their transferees, are entitled to certain "piggyback" registration rights allowing the holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to a registration related to employee benefit plans, the offer and sale of debt securities, or corporate reorganizations or certain other transactions, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration. In an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to exclude or limit the number of shares such holders may include.

Form S-3 Registration Rights

Based on the number of shares outstanding as of December 31, 2019, the holders of approximately 10.9 million shares of our common stock (on an as-converted basis), or their transferees, are entitled to certain Form S-3 registration rights. The holders of at least 20% of these shares can make a written request that we register their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered is at least $1.0 million (before deductions of underwriters' commissions and expenses). These stockholders may make an unlimited number of requests for registration on Form S-3, but in no event shall we be required to file more than two registrations on Form S-3 in any given twelve-month period.

Expenses of Registration

We will pay the registration expenses of the holders of the shares registered pursuant to the demand and Form S-3 registration rights described above.

Expiration of Registration Rights

The demand, piggyback and Form S-3 registration rights described above will expire, with respect to any particular stockholder, upon the earlier of five years after the consummation of our initial public offering or when that stockholder can sell all of its shares under Rule 144 of the Securities Act during any 90-day period (and without the requirement for the Company to be in compliance with the current public information required under Section c(1) of Rule 144 of the Securities Act).

Anti-Takeover Effects of Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware Law

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated Preferred Stock

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called at any time by our board of directors, or our President or Chief Executive Officer, but such special meetings may not be called by the stockholders or any other person or persons.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws eliminate the right of stockholders to act by written consent without a meeting.

Classified Board; Election and Removal of Directors; Filling Vacancies

Our board of directors is divided into three classes. The directors in each class serve for a three-year term, with one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation will provide for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock. For more information on the classified board, see “Management—Board Composition.” Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of Forum

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws or (iv) any action asserting a claim against us governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Securities Act or the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This 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 us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Amendment of Charter and Bylaws Provisions

The amendment of any of the above provisions in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue undesignated preferred stock would require approval by a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations of Liability and Indemnification Matters

Our amended and restated certificate of incorporation contains provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors are not personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

Each of our amended and restated certificate of incorporation and amended and restated bylaws provide that we are required to indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. Our amended and restated bylaws also obligates us to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With specified exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors and officers for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and our stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damages.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, New York 11219.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Satsuma Pharmaceuticals, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-233808) on Form S-8 of Satsuma Pharmaceuticals, Inc. of our report dated March 10, 2020, with respect to the balance sheets of Satsuma Pharmaceuticals, Inc. as of December 31, 2019 and 2018, the related statements of operations and comprehensive loss, convertible preferred stock and stockholder's equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes, which report appears in the December 31, 2019 annual report on Form 10-K of Satsuma Pharmaceuticals, Inc.

/s/ KPMG LLP

San Diego, California
March 10, 2020

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, John Kollins, certify that:

1. I have reviewed this Annual Report on Form 10-K of Satsuma Pharmaceuticals, Inc. for the year ended December 31, 2019;

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 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)) 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) 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

   (c) 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 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 10, 2020

By: /s/ John Kollins
John Kollins
President and Chief Executive Officer and Director
(Principal 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, Tom O'Neil, certify that:

1. I have reviewed this Annual Report on Form 10-K of Satsuma Pharmaceuticals, Inc. for the year ended December 31, 2019;

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 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)) 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) 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

   (c) 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 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 10, 2020

By: /s/ Tom O'Neil
Tom O'Neil
Chief Financial Officer
(Principal Financial and Accounting 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 Satsuma Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 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 10, 2020

By: /s/ John Kollins
John Kollins
President and Chief Executive Officer and Director
(Principal 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 Satsuma Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 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 10, 2020

By: /s/ Tom O'Neil
Tom O'Neil
Chief Financial Officer
(Principal Financial and Accounting Officer)