UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 001-38293

SCPHARMACEUTICALS INC.

(Exact name of registrant as specified in its Charter)

Delaware	**46-5184075**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2400 District Avenue, Suite 310 Burlington, Massachusetts	**01803**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 517-0730

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	SCPH	The Nasdaq Global Select Market

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

None
(Title of class)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 registrant's voting and non-voting common equity held by non-affiliates of the registrant computed by reference to the price at which the common equity was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (June 28, 2019) was $27,492,179. The number of shares of registrant's Common Stock outstanding as of March 23, 2020 was 20,981,880.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the registrant's Definitive Proxy Statement for the 2020 Annual Meeting of Shareholders.

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PART I

This Annual Report on Form 10-K contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the completion of device validation, drug stability testing and other activities required for the resubmission of the FUROSCIX® NDA with the Smart Dose drug delivery system on our current projected timelines and subsequent review and potential approval by the U.S. Food and Drug Administration, or FDA, including any delays in submission or approval related to COVID-19;
- the likelihood of approval by the FDA of our regulatory filings for FUROSCIX using our next generation delivery device;
- the timing or likelihood of other regulatory filings and approvals, including any approval to market and sell subcutaneous ceftriaxone;
- the outcome of any bridging studies, clinical trials or human factors studies that may be required by the FDA for approval of any of our product candidates;
- the commercialization, marketing and manufacturing of FUROSCIX or any other of our product candidates, if approved;
- the pricing and reimbursement of FUROSCIX or any other of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of FUROSCIX or any other of our product candidates for which we receive marketing approval;
- the initiation, timing, progress and results of our research and development programs, including subcutaneous ceftriaxone and future preclinical and clinical studies;
- our ability to advance any other product candidates into, and successfully complete, clinical studies and obtain regulatory approval for them;
- our ability to identify additional product candidates;
- the implementation of our strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering FUROSCIX or any other of our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of components and drug product for commercialization of FUROSCIX or any other of our product candidates;
- our ability to maintain and establish collaborations;
- our financial performance;
- developments relating to our competitors and our industry, including the impact of government regulation; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement

is a guarantee of future performance. While we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

Item 1. Business.

OVERVIEW

We are a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. Our strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or IV, delivery. By moving delivery away from the high-cost healthcare settings typically required for IV administration, we believe our technology has the potential to reduce overall healthcare costs and advance the quality and convenience of care. Our lead product candidate, FUROSCIX, consists of our proprietary buffered formulation of furosemide delivered subcutaneously via an on-body infusor and is under development for treatment of congestion due to volume overload in patients with worsening heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization.

We filed a new drug application, or NDA, for FUROSCIX with the U.S. Food and Drug Administration, or FDA, in August 2017. On June 11, 2018 we received a Complete Response Letter, or CRL, from the FDA for our NDA, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required clarification on an additional dose validation study and device modifications necessary to advance FUROSCIX using our previous delivery technology, the sc2Wear Infusor, we decided to transition to our next generation device. Our next generation device is being developed through a partnership with West Pharmaceutical Services, Inc., or West, using its proprietary, wearable, SmartDose® drug delivery system (SmartDose is a registered trademark of West Pharma. Services IL, Ltd., a subsidiary of West, in the United States and other jurisdictions). We held a Type C meeting with the FDA on June 18, 2019 and based on the results of that meeting we anticipate resubmission of the FUROSCIX NDA with the SmartDose drug delivery system by mid-year 2020.

Heart failure affects 6.5 million adults in the United States and this population is expected to grow to greater than 8.0 million by 2030. Our proprietary formulation of furosemide administered subcutaneously via the next generation SmartDose drug delivery system, which we refer to together as FUROSCIX, is intended to help alleviate the signs and symptoms associated with congestion due to fluid retention in heart failure patients, such as fatigue and shortness of breath. FUROSCIX is designed to offer alternative outpatient intervention for heart failure patients who display reduced responsiveness to oral diuretics in non-emergency situations and do not require hospitalization.

We believe FUROSCIX, if approved by the FDA, would allow heart failure patients to receive IV-strength diuresis outside the high-cost hospital setting. Prevention of hospital admission and reduced readmission rates would result in reducing the estimated 15 million days patients with heart failure spend in the hospital each year. By decreasing the number of admissions and readmissions to hospitals, we believe we can drive significant cost savings to payers and hospitals.

We are leveraging our subcutaneous formulation expertise to develop additional product candidates that we believe can significantly decrease the cost of treatment by moving treatment away from the hospital setting and can improve patient quality of life by eliminating the need for IV catheters. In this area, we have conducted additional development work to deliver ceftriaxone, a parenteral cephalosporin that is typically administered intravenously or intramuscularly. Based on IMS Health data, each year in the United States, there are 15 million outpatient days of ceftriaxone therapy to treat various types of infections, including pneumonia, urinary tract infections, and Lyme Disease. The current outpatient treatment option for these patients, Outpatient Parenteral Antimicrobial Therapy, or OPAT, requires the placement of a long-term venous access device, known as a peripherally inserted central catheter, or PICC, and coordination of home infusion or office-based infusion services for patients to receive antibiotics outside of the hospital, which places significant burdens on the patients. Subcutaneous administration of ceftriaxone represents an opportunity to reduce costs to the overall health care system and improve the quality of care by reducing the complications and serious health risks associated with IV catheters and increasing patient mobility and convenience. We have conducted a pharmacokinetic study with subcutaneous ceftriaxone and intend to conduct additional clinical trials to advance its development.

Beyond furosemide and ceftriaxone, we aim to leverage our subcutaneous formulation expertise to develop and seek approval of additional drug candidates. We intend to conduct feasibility work on additional product candidates.

OUR PLATFORM AND OTHER PIPELINE PROGRAMS

FUROSCIX to Treat Decompensated Heart Failure

Heart failure is a chronic disease resulting from impairment of the heart's ability to pump blood and can be caused by a number of factors, including congenital conditions, history of heart attack, arrhythmias and complications of other chronic conditions such as diabetes and hypertension. Patients with heart failure are prone to retain water and salt, or fluid, in their blood stream and other tissues. As fluid accumulates, heart pumping efficiency begins to diminish, and congestion ensues. Congestion can lead to extra fluid in the lungs, ankles and abdomen causing symptoms ranging from weight gain, mild swelling and shortness of breath while walking to more severe symptoms, such as weakness, severe fatigue and difficulty breathing when sitting or lying down. Congestion is the most common symptom experienced in patients with heart failure and is a common trigger for heart failure patients to seek medical attention. This state of worsening of heart failure symptoms due to excessive fluid retention, or congestion, is referred to as decompensated heart failure.

Oral diuretics, in particular loop diuretics, are the mainstay for the management and prevention of congestion in patients with heart failure. Diuretics, such as furosemide, work by promoting the removal of excess salt and water via the kidneys. However, during periods of decompensation or worsening heart failure due to congestion, the absorption of oral furosemide decreases and it becomes less effective. Since symptoms of congestion generally worsen over several days or weeks, there is a window of opportunity to intervene. In the face of decreased absorption and efficacy of oral furosemide and worsening symptoms, doses of oral diuretics are typically increased or synergistic diuretics are added in an attempt to overcome the reduced absorption and to facilitate diuresis. When this fails, clinicians have to rely on hospitalization for the administration of IV diuretics to relieve the symptoms of congestion, or decongestion.

Even when following a regular oral loop diuretic regimen, patients with heart failure regularly experience episodes of decompensated heart failure. These episodes can be triggered by various physiological factors, some as simple as salty meals or a patient missing or skipping doses of oral furosemide. Patients and physicians aim to prevent these episodes by monitoring for early signs of congestion, such as swelling ankles, weight gain, breathing difficulty or decreased urination. At the onset of a decompensated heart failure event, physicians commonly increase the dose of the patient's oral diuretic or add another oral diuretic in an effort to eliminate excess fluid. If this dosing strategy fails and the progressive accumulation of fluid overwhelms the failing heart, the patient is eventually admitted to the hospital for treatment of the decompensated heart failure with IV diuretics.

Congestion due to sodium retention leading to decompensation is the primary cause for patient admission to the acute care setting among adult patients with heart failure. An analysis of 585 heart failure admissions published in the American Journal of Critical Care found that 59% of admissions are attributed to excessive sodium retention leading to volume overload. Patients suffering from an acute-decompensation event can develop worsening symptoms rapidly and a multi-day hospital admission for a more aggressive and predictable diuretic treatment regimen with IV furosemide is required.

FUROSCIX is our novel formulation of furosemide contained in a pre-filled, Crystal Zenith® cartridge and self- administered subcutaneously via a single-use, disposable and wearable on-body delivery system. The user inserts the pre-filled cartridge into the wearable device, applies it to the abdomen via a medical-grade adhesive, and a subcutaneous infusion of FUROSCIX is administered through a pre-programmed, biphasic delivery profile with 30 mg administered over the first hour, followed by 12.5 mg per hour for the subsequent 4 hours (a total dose of 80 mg (10 mL) over 5 hours).

We believe that, if approved, FUROSCIX has the potential to provide a safe and effective solution that will enable IV-strength diuresis outside of the high-cost hospital setting. We believe we can reduce the estimated 15 million days per year that heart failure patients spend in the hospital and thus reduce overall health care costs by decreasing both admissions and readmissions.

Subcutaneous delivery has the potential to:

- *Reduce hospital admission rates*: We believe FUROSCIX, if approved, could in certain instances avoid a hospitalization altogether, by providing IV-strength diuresis in an outpatient setting such as the physician's office, a heart failure clinic or at home. Since symptoms of congestion generally worsen over several days or weeks, there is a window of opportunity to intervene. It is estimated that 90% of patients presenting to the emergency department with decompensated heart failure are admitted to the hospital and approximately 50% of those patients could be safely discharged after a brief period of observation.
- *Reduce patient readmission*: We believe FUROSCIX, if approved, could reduce the incidence of readmission for heart failure patients by continuing IV-strength diuresis in the home environment upon discharge. It is estimated that 30-50% of patients that are hospitalized for acute decompensated heart failure that are transitioned to oral furosemide prior to being discharged from the hospital have persistent symptoms of congestion at discharge. Persistent congestion may reduce the absorption of oral furosemide reducing the diuretic effect. As a result, patients are often readmitted to the hospital to receive IV furosemide. We believe FUROSCIX can break this cycle by providing IV-strength diuresis to patients shortly after discharge to reduce the rate of readmissions for decompensated heart failure.

FUROSCIX is designed to offer an outpatient intervention to deliver IV-strength furosemide. We believe this approach can improve patients' quality of life by providing treatment with minimal interruption of daily living. The wearable design of the SmartDose drug delivery system to administer FUROSCIX could promote patient mobility by delivering the required dose while the patient resumes their normal daily activities outside of the hospital. Evidence also supports that in-home care for patients with heart failure may prolong life expectancy and improve quality of life by facilitating access to the patient's care support system. Based on our market research, we believe that patients and physicians would embrace FUROSCIX, if approved, if it would improve patient outcomes and quality of life.

Clinical Development of FUROSCIX

Our Subcutaneous Formulation of Furosemide

To date, 127 subjects with heart failure have received FUROSCIX via subcutaneous administration in our clinical studies, where 101 subjects received FUROSCIX via our previous delivery device, the sc2Wear Infusor, and 26 subjects received FUROSCIX via the B. Braun Perfusor Space Infusion Pump, or B. Braun Pump, a large, three-pound commercial pump used in operating rooms and emergency care settings. Based on the overall observations and outcomes of these studies, we believe that FUROSCIX has the potential to be used to treat congestion, with comparable pharmacokinetics, diuresis and natriuresis to IV furosemide, when administered by patients and their caregivers in clinical and home environments. To date, no clinical studies have been conducted using the next generation SmartDose drug delivery system with FUROSCIX.

We held a pre-NDA meeting with the FDA on June 1, 2017, and in August 2017 we submitted an NDA for our lead product candidate, FUROSCIX, incorporating our previous delivery device, the sc2Wear Infusor. The FDA notified us in October 2017 that it had accepted our NDA for review and assigned us a June 23, 2018 Prescription Drug User Fee Act, or PDUFA, date. On June 11, 2018 we received a CRL from the FDA, which indicated that, among other things, certain device modifications to the sc2Wear Infusor were required. We conducted a post-action meeting with the FDA on September 24, 2018 and a Type C meeting with the FDA on January 9, 2019. Based on our interactions with the FDA, which required clarification on an additional dose validation study and device modifications necessary to advance FUROSCIX using the sc2Wear Infusor, we decided to transition to our next generation infusor for FUROSCIX, which is being developed through a partnership with West with their proprietary, wearable, SmartDose subcutaneous drug delivery system. We plan to resubmit an NDA for FUROSCIX incorporating the next generation SmartDose drug delivery system and to support our application for marketing approval using the data from our clinical studies from FUROSCIX administered via the sc2Wear Infusor and the B. Braun Pump, data from human factors studies using the SmartDose delivery system and full device validation, verification and stability data in the new Crystal Zenith® cartridge.

Pharmacokinetic/Pharmacodynamic (PK/PD) Study

We conducted a pivotal, randomized, open-label crossover study from April to September 2015 to assess the relative bioavailability of our novel formulation of furosemide and IV furosemide in 17 patients with heart failure who were experiencing decompensation. In this study, FUROSCIX was delivered subcutaneously via the B. Braun Pump. This study also evaluated diuresis and the excretion of sodium over eight hours and 24 hours post-dosing as the pharmacodynamic endpoints.

Treatment arms

In this study, our reference treatment was IV furosemide with two bolus injections of 40 mg dosed over two minutes, two hours apart. Our test treatment was FUROSCIX with 80 mg infused subcutaneously, with 30 mg over the first hour followed by 12.5 mg per hour over the subsequent four hours.

Comparative pharmacokinetic results

This study demonstrated bioequivalence in the concentration of drug delivered over time based upon the area under the curve, or AUC, between our subcutaneous formulation of furosemide and IV furosemide. Although the maximum concentration, or Cmax, of furosemide achieved was four-fold higher with IV injection compared to subcutaneous infusion, the bioavailability of subcutaneous infusion relative to intravenous injection was 99.6%, with a 90% confidence interval of 94.8% to 104.8%, thus meeting the FDA's defined bioequivalence criteria limit of 80% to 125%. We believe that the difference in Cmax between IV injection and subcutaneous furosemide is attributable to the two bolus IV injections administered at the initiation of IV therapy. Nevertheless, the longer period of administration for our subcutaneous formulation resulted in similar bioavailability profiles of the two routes of administration over time.

Comparative pharmacodynamic results

The total urine sodium excretion and urine output were comparable between our subcutaneous formulation of furosemide and IV furosemide.

Phase 3 Product Design Clinical Validation (PDCV) Study

In October 2016, we conducted a Phase 3, open-label, single-arm, single-dose study as a clinical validation of the use of FUROSCIX with the sc2Wear Infusor in 74 adult heart failure patients at five clinical sites in the United States. Six of these patients were ultimately excluded from the study due to activator interruptions, and one patient was excluded due to truncated infusion, resulting in a modified intention to treat, or MITT, population of 67 patients that completed the five-hour infusion period.

In this study, FUROSCIX was subcutaneously administered using the sc2Wear Infusor with a preset dosage of 30 mg of FUROSCIX over the first hour, followed by 12.5 mg per hour for the subsequent four hours.

The primary endpoint of this study was defined as the absence of major product failures and free from major system-related failures of the sc2Wear Infusor leading to an under-infusion of 80 mg $\pm$ 10% with performance criteria of 95% passage rate with 95% confidence interval. The device that was evaluated in this study, the sc2Wear Infusor, is no longer being developed as the device constituent to administer FUROSCIX. However, the drug constituent is the same, albeit in a new-container closure system.

In the 67 subjects in the MITT population that completed the 5-hour infusion, 63 (94%), with confidence intervals of 85% to 98%, were free from major system-related failure. All four failures in the MITT population were a result of an under delivery of the intended dose, and the study failed to achieve the prespecified acceptance criteria. Unrecognized, under filling of the device resulted in 75% major product failure resulting in drug under delivery. In a post-hoc analysis, when the sc2Wear Infusor was adequately filled, the specified dose was delivered in 63/64, with a 98% success rate with confidence intervals of 92% - 100% of the infusions. One product failure was determined to be due to a dispensing failure, which resulted in the delivery of 67 mg of furosemide instead of the 72 mg minimum dose specification.

Throughout the study, the subjects reported pain using an 11-point numeric rating scale ranging from 0 (no pain) to 10 (worst pain imaginable). The average maximum pain experienced during device wear was 0.7, with a maximum of 5. All but three subjects completing the 5-hour infusion reported an overall maximum pain score of 3 or less.

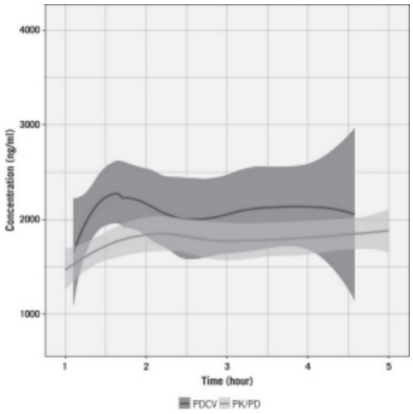
The most frequently observed adverse events were local skin effects, such as reddening, or erythema, bruising and pain, which were mild or moderate in severity. No patients reported infections at the infusion site. One serious adverse event was observed and determined by the investigator not to be related to FUROSCIX. The event was a single episode of ventricular tachycardia, or quickening of the patient's heart rate, that occurred five days after completion of the study. The event occurred in a patient with a history of prior episodes of ventricular tachycardia.

Our conclusions were that in patients with heart failure, the sc2Wear Infusor remained attached to the body for 5-hour wear, was well tolerated, had high patient acceptance and delivered a therapeutic dose of the diuretic. However, the primary endpoint of successful dose delivery was not achieved.

We discussed this data with the FDA at a pre-NDA meeting, held on June 1, 2017. Although the PDCV study did not meet the prespecified endpoint, the FDA requested that our NDA submission include an assessment of the data generated from all of our studies. In addition, the FDA requested that a high-level safety assurance case be submitted just prior to the NDA submission and that certain updated risk analyses be submitted concurrently with our NDA. The NDA was filed on August 23, 2017 and we received a CRL on June 11, 2018. A Type A/End of Review, EOR, meeting between us and the Division of Cardiovascular and Renal Products was held on September 24, 2018 and a Type C meeting was held on January 9, 2019 to understand the requirements to support approval of our combination product. We explored multiple design modifications to the original device constituent but determined they would not be sufficient to meet the FDA's requirements for approval. Accordingly, we proposed a different device constituent, the SmartDose drug delivery system, which includes certain device features that address issues noted in the CRL (e.g. prefilled cartridge, less variable dose delivery performance, dose delivery notification and fault notification including in the case of an occlusion). With the new device constituent of the combination product, there is no change in drug formulation, delivery rate, delivery profile, dose or intended method of application, or user environment.

Post-Hoc Comparative Analysis to Bridge the Pharmacokinetics from the PK/PD Study and Plasma Concentrations from the PDCV Study

The B. Braun Pump was used for subcutaneous administration of our subcutaneous formulation of furosemide in the PK/PD study and the sc2Wear Infusor was used to administer our subcutaneous formulation of furosemide in the PDCV study. Both studies delivered FUROSCIX as a subcutaneous infusion whereby 30 mg were administered over the first hour followed by 12.5 mg per hour over the subsequent four hours. Mean furosemide concentrations and the representative 95% confidence intervals obtained during the five-hour infusion from the two studies are represented in the figure below:



Overall, between the first and fifth hours, the plasma furosemide concentrations were higher and more variable in the PDCV study compared to the PK/PD study, partly due to the unmatched timepoints. However, between the second and fifth hours the furosemide concentrations were similar between the two studies. The higher concentrations observed in the PDCV study were lower than the C_{max} observed in the IV doses in the PK/PD study, which we believe is relevant to regulatory safety assessments of FUROSCIX.

Based on a pharmacokinetic bridging analysis conducted between the PK/PD and PDCV studies, comparable furosemide systemic exposures and subsequently comparable diuresis would be expected to be achieved when FUROSCIX is administered via an on-body subcutaneous delivery system.

At the Type C Guidance Meeting held on June 18, 2019, the FDA confirmed that we are not required to conduct additional clinical safety, efficacy, or pharmacology studies to support the resubmission of the NDA for FUROSCIX incorporating the SmartDose drug delivery system.

Human Factors Summary

We conducted a human factors validation study for the next generation device from October 21, 2019 to November 14, 2019. The study included 60 subjects made up of 30 heart failure patients, 15 caregivers and 15 healthcare practitioners (HCPs). Half of the patients were trained, while the remaining patients, all caregivers and all HCPs were untrained.

Participants performed extremely well across all user groups and training conditions. All participants but one successfully setup and started the infusion without experiencing any use errors related to critical tasks which would delay dosing or harm the patient.

All participants successfully noticed, identified, and articulated how to respond to an alarm experienced during an infusion without any use errors.

All participants successfully allowed the infusion to carry out, noticed when it completed and performed all steps required to remove and dispose of the on-body infusor without any use errors.

Overall, the study, which was designed to measure eight observational use metrics, across 900 tasks including during setup, starting of the infusion, responding to the on-body infusor alarm and finishing the procedure after the infusion demonstrated a user success rate of 99%.

Participants also performed well during the knowledge and reading comprehension tasks. Thirty-seven knowledge and comprehension tasks related to critical information were evaluated. Overall, across all 2,220 knowledge and comprehension tasks, participants experienced a user success rate of over 99.5%.

Based on the results from the human factors program that culminated with this validation study, we conclude the following:

- The FUROSCIX On-Body Infusor and Instructions for Use (IFU) have been successfully validated with the intended user populations (congestive heart failure (CHF) patients, family caregivers, and HCPs) and use cases.
- The validation results demonstrate that the FUROSCIX On-Body Infusor and IFU can be safely and effectively used and that performance of critical tasks will not result in patterns of preventable use errors.
- After two suggested minor edits to the IFU, all use-related risks for the commercial product will either (a) have been eliminated or (b) consist of acceptable residual risks that cannot be mitigated.

We will continue to explore, evaluate and improve the safe and effective use of FUROSCIX.

Investigator Sponsored Studies

We intend to support investigator sponsored studies post-approval and to initiate Phase 4 studies with FUROSCIX, incorporating the SmartDose drug delivery system, to evaluate the efficacy, safety, patient acceptance and health economic outcomes.

Commercialization

If we successfully obtain regulatory approval, we plan to commercialize FUROSCIX in the United States by building and utilizing our own commercial infrastructure. We currently intend to focus our commercial efforts on the United States market, which we believe represents the largest market opportunity for FUROSCIX. In addition,

we plan to seek collaborations with third-party partners outside of the United States to distribute our products in foreign markets, if approved by the relevant foreign regulatory authorities.

If approved, we believe that we can effectively commercialize FUROSCIX in the United States with an initial specialty sales force of approximately 35-40 representatives. We intend to initially pursue a highly-concentrated target market, which consists of 400 hospitals, associated clinics and office-based practices that, collectively account for 40% of all IV furosemide administered to heart failure patients based on current IMS Drug Distribution Data. We also plan to target the top ten Medicare Part D plans, which cover 80% of Medicare Part D patients. We conducted payer research on 14 payers, representing 22 to 29 million total Medicare lives. We found that reducing readmissions, increasing patient comfort were ranked as important potential attributes of FUROSCIX by the health plans and pharmacy benefit managers that were surveyed.

We intend to build a highly concentrated commercial infrastructure focused on distribution, promotion and customer support to healthcare providers in our key hospital targets and in office-based practices. Our target call points within these hospitals and practices will include heart failure specialists, cardiologists, hospitalists, emergency room doctors and heart failure nurse practitioners. To date, our market research with 309 healthcare professionals has indicated that 93% of our target prescribers would adopt FUROSCIX, if approved, with 80% intending to adopt FUROSCIX in the first six months of product availability. Furthermore, within the prescriber group of heart failure specialists, cardiologists and nurse practitioners that we intend to target at launch, the intent to adopt is 93%, 96% and 94%, respectively, and 89%, 88% and 86%, respectively, of those prescribers intend to adopt in the first six months of product availability. Based on our market research, healthcare professionals perceive the top potential advantages of FUROSCIX, if approved, as the ability to treat in the home setting, prevention of hospitalization, and avoidance of IV placement, while the lowest perceived barriers to adoption identified in the survey were the preference to monitor in a hospital setting, sufficiency of current medications and hospital guidelines or protocols. In addition, based on a last two patient exercise conducted in our quantitative market research with healthcare professionals, when given the option to change their prior treatment choice to FUROSCIX, if approved, 65% of healthcare practitioners in a clinic setting and 40% in a hospital setting responded that they would prescribe our product candidate. We expect to supplement our sales force with representatives in the medical science, nursing and reimbursement fields to support the proper training and utilization of FUROSCIX.

As part of our commercialization strategy, we plan to educate hospitals, healthcare practitioners, patients and caregivers of the benefits of FUROSCIX and its proper use. We plan to work with national associations, such as the Heart Failure Society of America (HFSA) and the American Association of Heart Failure Nurses (AAHFN), hospital networks and individual hospitals to update treatment and issue guidelines to include subcutaneous furosemide in treatment plans. These guidelines are intended to provide information to hospitals and healthcare practitioners regarding treatment of heart failure patients with subcutaneous furosemide.

Patients with heart failure could receive FUROSCIX at the initial worsening signs and symptoms when the response to oral diuretics is not adequate. In addition, patients could receive FUROSCIX after discharge, if they still are exhibiting some signs and symptoms of congestion despite their oral diuretic regimen.

We expect to package FUROSCIX, if approved, as individual, single use only on-body infusor kits. In April 2016, we held a meeting with the Centers for Medicare and Medicaid Services, or CMS, at which CMS stated that coverage and reimbursement of FUROSCIX may be available under Medicare Part D as a transition of care drug.

By educating patients on the proper use of FUROSCIX shortly after discharge followed by a face-to-face visit, health care professionals can ensure proper training, initiate treatment at the point of care, and ensure that patients can receive additional days of treatment in the home setting.

Our Pipeline Programs

Beyond our initial focus on heart failure, our strategy is to identify and develop additional product candidates where, if approved, could provide effective and convenient subcutaneous therapy that may benefit patients, caregivers and payers.

- *FUROSCIX*: FUROSCIX is a proprietary furosemide formulation that is buffered to a neutral pH to enable subcutaneous administration via a proprietary wearable, pre-programmed on-body delivery system, based on the SmartDose drug delivery system. It is under development for the treatment of congestion due to volume overload in patients with worsening heart failure who display reduced

responsiveness to oral diuretics and do not require hospitalization. We plan to resubmit the NDA for FUROSCIX by mid-year 2020.

- *scCeftriaxone*: We have filed an investigational new drug application, or IND, for scCeftriaxone, an antibiotic currently used intravenously for the treatment of infections caused by gram-positive and gram-negative organisms. To date, we have completed a PK study for scCeftriaxone.
- *scCarbapenem*: We have completed several IND-enabling studies for our scCarbapenem program, an antibiotic currently used intravenously for the treatment of infections caused by gram-negative organisms.

Ceftriaxone

Many patients with an infection requiring IV antibiotics are admitted to the hospital, and a portion of these patients will require subsequent outpatient treatment with IV administration requiring insertion of a PICC line catheter. Ceftriaxone is a parenteral antibiotic commonly used to treat various types of infections, including pneumonia, bone and joint infections, blood stream infections, urinary tract infections and Lyme Disease. According to 2015 data from Arlington Medical Resources, ceftriaxone is the second most utilized antibiotic in the hospital setting and second most utilized IV antibiotic at hospital discharge. Based on Option Care data from August 2016, ceftriaxone represents the largest segment of antibiotics prescribed in the outpatient setting, accounting for 19% of all outpatient prescriptions. Each year, there are approximately 15 million outpatient days of ceftriaxone therapy in the United States based on IMS Health data, with 50% of outpatient ceftriaxone administered to Medicare patients who do not have coverage for home infusion services and frequently must drive to a hospital clinic, emergency room or physician's office or be admitted to a skilled nursing facility or hospital to receive IV antibiotics. Subcutaneous antibiotics, including ceftriaxone, have the potential to reduce the length of hospital stay by facilitating transition of care and eliminating the risks of complications from long term IV catheters. Such antibiotics could also enhance convenience and independence of patients and caregivers and potentially reduce the economic burden to payers, particularly in Medicare, by reducing payments for outpatient infusion services.

After the submission of the IND we conducted a randomized, partially blinded crossover study of 18 patients to evaluate the PK and bioavailability of a commercial formulation of ceftriaxone administered subcutaneously as compared to IV administration. In this study, we observed that the bioavailability of subcutaneous ceftriaxone was 108% of that of IV ceftriaxone. In a PD model based on subcutaneous pharmacokinetics observed in this study, the T>MIC for the first 24 hours for the ceftriaxone 1-gram subcutaneous infusion was observed to be not inferior to the 1-gram IV infusion (98.5% vs 100%). The most common adverse event observed with subcutaneous ceftriaxone administration was pain, with a median pain score of two on a scale of zero to ten (with zero being no pain and ten being the worst possible pain). There were no serious adverse events reported in this study.

We intend to identify a suitable on-body delivery system for the administration of ceftriaxone subcutaneously, conduct additional studies to evaluate optimal delivery for ceftriaxone and to evaluate the skin safety of subcutaneous administration of ceftriaxone.

Additional Product Programs

We are leveraging our know-how for use in other clinical settings where subcutaneous delivery can improve IV treatments to develop a suite of product candidates that, like FUROSCIX and ceftriaxone, we believe can decrease the cost of treatment by moving treatment out of the hospital setting and eliminating the need for IV catheters. We expect to pursue the development of a subcutaneous carbapenem to treat infections caused by gram-negative infections and have completed initial feasibility work on a potential candidate. We also intend to identify other opportunities where subcutaneous delivery can improve patient treatment and reduce healthcare costs. We intend to evaluate market criteria to systematically choose potential product programs for our pipeline. We plan to look for product candidates that we believe allow us to clearly demonstrate value to patients and the healthcare system and that have large market potential and a concentrated specialty physician prescribing base. We expect to leverage our FUROSCIX sales force to promote additional products that we develop and commercialize.

Our FUROSCIX On-Body Infusor

The FUROSCIX On-Body Infusor is a drug-device combination product consisting of FUROSCIX (furosemide injection, 80 mg per 10 mL), a novel, pH neutral furosemide formulation optimized for subcutaneous

administration and contained in a prefilled, Crystal Zenith® (CZ) cartridge, and a proprietary wearable, pre-programmed on-body delivery system, the FUROSCIX On-Body Infusor, based on the SmartDose drug delivery system. The FUROSCIX On-Body Infusor is applied to the abdomen via a medical grade adhesive and delivers a subcutaneous infusion of FUROSCIX through a pre-programmed, biphasic delivery profile over 5 hours.

MANUFACTURE OF OUR PRODUCT CANDIDATES

We use a network of qualified suppliers or contract manufacturing organizations, or CMOs, to produce, manufacture, sterilize and assemble the component parts of our product candidates, including FUROSCIX. Our suppliers produce these component parts to our designs and specifications. Certain processes utilized in the manufacture and test of our product candidates have been verified and validated as required by the FDA and other regulatory bodies. The manufacturing facilities of our suppliers are subject to periodic inspection by the FDA and certain corresponding state agencies, and we regularly audit our suppliers' processes to ensure conformity with the specifications, policies and procedures for our product candidates.

We have produced FUROSCIX for use in our clinical trials and stability studies only. We believe that our current third-party manufacturers have capacity for potential commercialization of FUROSCIX, if approved, in quantities sufficient to meet our expected commercial needs, and to accommodate the manufacturing of materials for future clinical trials of other potential product programs that we may identify for our product pipeline.

In order to meet projected global demand for FUROSCIX, if approved, we plan to support an increase in production capacity at West's facilities.

INTELLECTUAL PROPERTY

Proprietary protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We and our partners have been building and continue to build our intellectual property portfolio relating to our product candidates and technology. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us or our partners in the future will be commercially useful in protecting our technology.

Patent rights

Patent life determination depends on the date of filing of the application and other factors as promulgated under the patent laws. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country.

Furosemide 8 mg/mL formulation

As of February 1, 2020, we own a patent family directed to the composition of matter of our subcutaneous formulation of furosemide and methods of treating congestion, hypertension and heart failure using the formulation of furosemide. This patent family includes U.S. Patent No. 9,884,039, directed to methods of treatment, U.S. Patent No. 10,272,064 directed to liquid pharmaceutical formulations, one pending U.S. patent application directed to methods of treatment and pharmaceutical formulations, one granted patent in each of China and Japan, one pending patent application in each of Canada, Europe and Japan, and three granted patents and seven pending patent applications in other countries outside of the United States. Patents that issue from this patent family are generally expected to expire in 2034, excluding any additional term in the United States for patent term adjustment. U.S. Patent Nos. 9,884,039 and 10,272,064 are scheduled to expire in April 2034.

Other furosemide formulations

As of February 1, 2020, we also own an international patent application filed under the Patent Cooperation Treaty (PCT) directed to compositions of matter of liquid pharmaceutical formulations containing an increased concentration of furosemide and methods of treating congestion, fluid overload, or hypertension using these formulations of furosemide. An international PCT patent application is not eligible to become an issued patent until, among other things, we file a patent application in regional or national patent offices within 30 or 31 months of filing of the earliest-filed priority patent application. If we continue to pursue patent protection and file one or more patent applications with respect to our international PCT patent application, and if any patents issue based on the international PCT application, we expect such patents, if issued, to expire in 2040.

Trade secret and other protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know-how to protect our technology and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

Other intellectual property rights

We file trademark applications and pursue registrations in the United States and abroad when appropriate. We own trademark registrations in the U.S. and E.U. for the marks SCPHARMACEUTICALS and FUROSCIX.

From time to time, we may find it necessary or prudent to obtain licenses from third-party intellectual property holders.

COMPETITION

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the development and commercial success of our product candidates include ease of administration and convenience of dosing, therapeutic efficacy, safety and tolerability profiles and cost. Many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as more experience in the development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Consequently, our competitors may develop similar products for the treatment of heart failure or for other indications we may pursue in the future, and such competitors' products may be more effective, better tolerated and less costly than our product candidates. Our competitors may also be more successful in manufacturing and marketing their products than we are. We will also face competition in recruiting and retaining qualified personnel and establishing clinical trial sites and patient enrollment in clinical trials.

GOVERNMENT REGULATION

United States Drug Development

In the United States, the FDA regulates drugs, medical devices and combinations of drugs and devices, or combination products, under the federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, requests for voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts,

restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates are subject to regulation as combination products, which means that they are composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different Centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its 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 our product candidates, the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our product candidates. Accordingly, we plan to investigate our products through the IND framework and seek approval through the NDA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require a separate medical device authorization for the Infusor component of FUROSCIX, but this could change during the course of its review of any marketing application that we may submit. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive pre-clinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials in accordance with an applicable IND and other clinical study related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA which, for a combination product like FUROSCIX, is expected to include information and data regarding the drug delivery device technology;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with the FDA's current good manufacturing practice requirements, or cGMP;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing or sale.

Once a pharmaceutical product candidate is identified for development, it enters the pre-clinical testing stage. Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance, and may be imposed on all drug products within a certain class of drugs. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2. Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials. Companies that conduct certain clinical trials also are required to register them and post the results of completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov in the United States, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events, findings from other studies that suggest a significant risk to humans exposed to the product, findings from animal or in vitro testing that suggest a significant risk to human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether a trial may move forward at designated check points based on access to certain data from the study. The clinical trial sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and 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 candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product. The submission of an NDA is subject to the payment of a substantial user fee, and the sponsor of an approved NDA is also subject to an annual program user fee; although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA typically makes a decision on accepting an NDA for filing within 60 days of receipt. The decision to accept the NDA for filing means that the FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal to complete its substantive review of a standard NDA and respond to the applicant is ten months from the receipt of the NDA. The FDA does not always meet its PDUFA goal dates, and the review process is often extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. During its review, the FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product 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. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

505(b)(2) Approval Process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for the FDA to approve a new product and permits reliance for such approval on published literature or an FDA finding of safety and effectiveness for a previously approved drug product. Specifically, section 505(b)(2) permits the filing of an NDA where one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Typically, 505(b)(2) applicants must perform additional trials to support the change from the previously approved drug and to further demonstrate the new product's safety and effectiveness. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the section 505(b)(2) applicant.

Our subcutaneous formulation of furosemide is based upon an already approved version of furosemide in oral and IV formulations, rather than a new chemical entity product candidate. Accordingly, we submitted a 505(b)(2) application that relied on FDA's prior findings of safety and effectiveness for previously-approved oral and/or IV furosemide in our clinical development plans and our NDA submission. We plan to use the 505(b)(2) pathway as well for other product candidates that we may develop.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the

FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of the FDA. The determination of which center will be the lead center is based on the “primary mode of action” of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the FDCA. In reviewing the NDA or 505(b)(2) application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System Regulations, or QSRs, applicable to medical devices.

Drug-device combination products present unique challenges for competitors seeking approval of Abbreviated New Drug Applications, or ANDA, for generic versions of combination products. Generally, the FDA reviews both the drug and device constituents of a proposed generic product to determine whether it is the same as the innovator product, including whether the basic design and operating principles of the device component are the same and whether minor differences require significant differences in labeling for safe and effective use. If the FDA determines that the device component of the proposed generic product is not the same in terms of performance and critical design, or that the labeling is not the same, it generally will not approve the ANDA. Likewise, if the FDA determines that certain clinical studies, such as clinical usability or human factors studies, are necessary to demonstrate the safety and/or effectiveness of the device component, the FDA generally will not accept or approve an ANDA for a combination product and will instead require the submission of a full NDA or 505(b)(2) application.

Post-Marketing Requirements

Any products for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse events with the product, providing the regulatory authorities with updated safety and efficacy information, and product sampling and distribution requirements in accordance with the Prescription Drug Marketing Act, a part of the FDCA. Moreover, each component of a combination product retains its regulatory status (as a drug or device, for example) and is subject to the requirements established by the FDA for that type of component. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion and advertising, including direct-to-consumer advertising. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. In addition, a pharmaceutical company must comply with restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers and their agents may not market or promote such off-label uses or provide off-label information in the promotion of drug products that is not consistent with the approved labeling for those products. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to corrective advertising in addition to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that combination products be manufactured in specific approved facilities and in accordance with cGMPs applicable to drugs and devices, including certain QSR requirements. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-marketing testing, known as Phase 4 testing, a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development and impact approved products already on the market.

Other Regulatory Matters

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

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, voluntary recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, exclusion from federal healthcare programs, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

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

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States. Alternatively, orphan drug designation may be available if the disease or the condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product is the first to receive FDA approval of the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same orphan indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity, which may permit off-label use for the orphan indication. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA for the same orphan indication or if our product candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

U.S. Marketing Exclusivity

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications, including 505(b)(2) applications. The FDA provides three years of marketing exclusivity for an NDA (including a 505(b)(2) application), or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Three-year exclusivity is typically awarded to innovative changes to a previously-approved drug product, such as new indications, dosage forms or strengths. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving applications for drugs that do not have the innovative change, such as generic copies of the original, unmodified drug product. Three-year exclusivity blocks approval of 505(b)(2) applications and ANDAs but will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including exclusivity attaching to certain patent certifications. This six-month exclusivity, which runs from the end of other exclusivity protection and patent terms, may be granted based on the voluntary completion within certain timeframes of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

European Orphan Designation and Exclusivity

In the European Union, the European Medicines Agency's, or EMA's, Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect not more than five in 10,000 persons in the European Union Community, or when, without incentives, it is unlikely that sales of such products in the European Union would be sufficient to justify the necessary investment in developing the products. Additionally, orphan drug designation is only available where no satisfactory method of diagnosis, prevention, or treatment of the condition has been authorized (or the product would be a significant benefit to those affected).

In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and 10 years of market exclusivity is granted following medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that

the product is sufficiently profitable not to justify maintenance of market exclusivity. Market exclusivity would not prevent the approval of a similar drug that is shown to be safer, more effective or otherwise clinically superior.

Other Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and similar state laws, each as amended, as applicable:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it 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 federal False Claims Act, or FCA, or federal civil money penalties statute;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a federal or state governmental program;
- HIPAA, which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; similar to the federal Anti-Kickback Statute, 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- the federal transparency requirements under the Affordable Care Act, or ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payer. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payers, including private insurers. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties. Finally, there are state and non-U.S. laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

We may develop products that, if approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Neither the U.S. government nor the U.S. courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom received stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. 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, including, without limitation, the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, individual imprisonment, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our drug candidates outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers’ outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies’ share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; created 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 the Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision repealing, effective January 1, 2019, 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS announced that it is suspending further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. 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 Act, the remaining provisions of the ACA are invalid as well. The Texas District Court Judge, as well as the Trump Administration and CMS, have stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal. It is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to legislation amendments to the statute, including the BBA, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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 Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains 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. Further, the Trump administration released a "Blueprint", or plan, 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. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. While a number of these and other proposed measures will require authorization through additional legislation 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. Individual states in the United States have also

increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we obtain regulatory approval. In the United States and markets in other countries, sales of any product candidates for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payers. Third-party payers include government authorities, managed care providers, private health insurers and other organizations. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payers. Third-party payers decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that use of a therapeutic is:

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

The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payer will pay for the product. Third-party payers may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payer not to cover our product candidates could reduce physician utilization of our products if approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

In addition, coverage and reimbursement for products can differ significantly from payer to payer. One third-party payer's decision to cover a particular medical product or service does not ensure that other payers will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately and will be a time-consuming process.

Third-party payers are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our product on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. A third-party payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payers. Private third-party payers tend to follow Medicare coverage and reimbursement limitations to a substantial degree, but also have their own methods and approval process apart from Medicare determinations. Therefore, one payer's determination to provide coverage for a product does not assure that other payers will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not

available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Outside of the United States, the pricing of pharmaceutical products and medical devices is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products and medical devices will likely continue as countries attempt to manage healthcare expenditures.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if third-party payers fail to provide coverage and adequate reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of December 31, 2019, we had 17 employees, including four in research and development, six in clinical and medical affairs, regulatory affairs and quality assurance and seven in finance, general administrative and executive administration, of which 15 were full-time employees and two of which were part- time employees. None of our employees are represented by a labor union or are parties to a collective bargaining agreement and we believe that our employee relations are good.

Facilities

Our principal executive offices are located in a 13,066 square foot facility in Burlington, Massachusetts. The term of the lease for our facility extends through November 2022. Our facility houses our research and development, sales, marketing, finance and administrative activities. We believe that our current facilities are adequate to meet our needs for the foreseeable future and that suitable additional space will be available as and when needed.

Corporate Information

We were formed as a limited liability company under the laws of the State of Delaware in February 2013 under the name scPharmaceuticals LLC and we converted to a corporation under the laws of the State of Delaware in March 2014 under the name scPharmaceuticals Inc. Our website address is www.scpharmaceuticals.com.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See "Forward-Looking Statements" in this Annual Report on Form 10-K.

Risks Related to Our Business, Financial Position and Need for Additional Capital

We have a history of significant operating losses and expect to incur significant and increasing losses for the foreseeable future; we may never achieve or maintain profitability.

We do not expect to generate revenue or profitability that is necessary to finance our operations in the short term. We incurred net losses of $29.4 million and $33.0 million for the years ended December 31, 2018 and 2019, respectively. In addition, our accumulated deficit as of December 31, 2019 was $129.5 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, if any, of our current or future product candidates, if approved, we may never attain profitability in the future. We have devoted substantially all of our financial resources and efforts to date to research and development, including preclinical studies and our clinical trials, and preparation for commercialization of our lead product candidate, FUROSCIX, if approved.

We anticipate that our expenses will increase substantially if and as we:

- pursue regulatory approval of FUROSCIX incorporating the SmartDose drug delivery system;
- establish sales, marketing, distribution and other commercial infrastructure and manufacture commercial inventory in anticipation of the potential regulatory approval of FUROSCIX;
- initiate and continue research, preclinical and clinical development efforts for FUROSCIX and any additional or future product candidates, including subcutaneous ceftriaxone;
- seek to identify additional product candidates;
- seek regulatory and marketing approvals for other product candidates that successfully complete clinical trials;
- manufacture larger quantities of product candidates for clinical development and, potentially, commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and
- add equipment and physical infrastructure to support our research and development.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, FUROSCIX or any other product candidates that we may develop. Successful commercialization will require achievement of key milestones, including completing clinical trials of our product candidates that are under clinical development, obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We have not generated any revenue from FUROSCIX and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from FUROSCIX, and we do not know when, or if, we will generate any revenue. There can be no guarantee that the FDA will accept our resubmitted NDA for FUROSCIX incorporating the next generation SmartDose drug delivery system or approve FUROSCIX in a timely fashion, if at all.

We do not expect to generate significant revenue unless or until we obtain marketing approval of, and begin to sell, FUROSCIX. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- resubmit an NDA for FUROSCIX incorporating the SmartDose drug delivery system;
- obtain marketing approval for FUROSCIX;
- set an acceptable price for FUROSCIX, if approved;
- obtain commercial quantities of FUROSCIX, if FUROSCIX is approved, at acceptable cost levels;
- commercialize FUROSCIX, if approved, by developing our own sales force for commercialization in the United States or in other key territories by entering into partnership or co-promotion arrangements with third parties;
- obtain third-party coverage or adequate reimbursement for FUROSCIX, if approved;
- achieve market acceptance of FUROSCIX, if approved, in the medical community and with third-party payers, including placement in accepted clinical guidelines for the conditions for which FUROSCIX is intended to target; and
- delay the introduction by third parties of alternate versions of FUROSCIX, if approved.

If FUROSCIX is approved for commercial sale, we expect to incur significant sales and marketing costs as we prepare for its commercialization. Even if we receive marketing approval and expend these costs, FUROSCIX may not be a commercially successful device-drug combination. We may not achieve profitability soon after generating product sales, if ever. If we are unable to generate product revenue, we will not become profitable and may be unable to continue operations without continued funding.

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing our product programs is a time-consuming, expensive and uncertain process that takes years to complete. We filed an NDA for FUROSCIX to be administered via the sc2Wear Infusor with the FDA in August 2017. In February 2019 we discontinued our use of the sc2Wear Infusor and refocused our development of FUROSCIX to incorporate the next generation SmartDose drug delivery system. Resubmitting an NDA, and our ability to obtain regulatory approval, for FUROSCIX incorporating the SmartDose drug delivery system may require significant capital for the preparation and presentation of data related to the SmartDose drug delivery system. In addition, if FUROSCIX or any of our other product candidates are approved, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We plan to continue to use our existing unrestricted cash primarily for development activities related to the advancement of FUROSCIX, pre-commercial planning and commercialization of FUROSCIX, if approved, automation necessary to increase capacity for our delivery technology, research and development, including for our infectious diseases program and for working capital and other general corporate purposes. We will be required to expend significant funds in order to commercialize FUROSCIX, as well as other product candidates we may seek to develop. In any event, our existing unrestricted cash may not be sufficient to fund all of the efforts that we plan to undertake, including the development of any of our product candidates. Accordingly, we may be required to obtain further funding through public or private equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional financing 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 our business strategy.

Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the time and expense required to resubmit an NDA for FUROSCIX incorporating the next generation SmartDose drug delivery system;
- the outcome, timing and costs of completing development and seeking regulatory approvals for FUROSCIX and other product candidates that we may develop;
- the costs of commercialization activities for FUROSCIX and any other of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of FUROSCIX or any other of our current and future product candidates;
- the pricing and reimbursement of FUROSCIX, if approved, and of other product candidates that may be approved;
- the number of future product candidates that we pursue and their development requirements;
- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, our other product candidates;
- our ability to enter into, and the terms and timing of, any collaborations, licensing or other arrangements;
- our headcount growth and associated costs as we establish a commercial infrastructure and continue our research and development activities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We expect our expenses to increase in connection with our planned operations. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership percentages of all our stockholders may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of our stockholders. In addition, royalty-based financing or debt financing, if available, may result in our relinquishing rights to valuable future revenue streams or fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the commercialization of FUROSCIX, if approved, and the development of our other product candidates.

If we raise additional funds through collaborations or marketing, distribution or licensing, or royalty-based financing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We commenced operations in 2013. Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and clinical trials for our product candidates. We submitted a new drug application, or NDA, for FUROSCIX incorporating the sc2Wear Infusor in August 2017. The FDA notified us in October 2017 that it had accepted our NDA for review. On June 11, 2018 we received a CRL from the FDA, which indicated that, among other things, certain device modifications to the sc2Wear Infusor were required. We conducted a post-action meeting with the FDA on September 24, 2018 and a Type C meeting with the FDA on January 9, 2019. Based on the outcome of our interactions with the FDA, we have transitioned to the SmartDose drug delivery system. Based on the outcome of our Type C meeting with the FDA on June 18, 2019, we will not have to conduct additional clinical safety, efficacy, or pharmacology studies as part of the resubmitted NDA for FUROSCIX. We plan to resubmit the NDA for FUROSCIX incorporating the SmartDose drug delivery system by mid-year 2020.

There can be no assurance that our NDA for FUROSCIX incorporating the SmartDose drug delivery system will be approved by the FDA. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

In addition, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

In September 2019, we restructured our loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank, providing for term loans of $20.0 million. All obligations under our secured loan are secured by substantially all of our existing property and assets (including our intellectual property assets), subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under our secured credit facility could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under our secured credit facility as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

We may become involved in litigation or other proceedings with third parties, which may be time consuming, costly and could result in delays in our development and commercialization efforts.

In connection with our decision to discontinue use of the sc2Wear Infusor and refocus our development efforts on FUROSCIX incorporating the next generation SmartDose drug delivery system, we eliminated our partnership with Sensile and other third parties, including contract manufacturers of the first generation device. Any disputes with such third parties that lead to litigation or similar proceedings may result in us incurring legal expenses, as well as facing potential legal liability. Such disputes, litigation or other proceedings are also time consuming and may cause delays in our development and commercialization efforts. If we fail to resolve these disputes quickly and on favorable terms, our business, results of operations, and financial condition may be harmed.

Risks Related to the Regulatory Approval and Commercialization of Our Lead Product Candidate, FUROSCIX

We are heavily dependent on the success of our product candidates and, in particular, our lead product candidate, FUROSCIX. We cannot give any assurance that we will receive regulatory approval for this product candidate or any other product candidates, which is necessary before they can be commercialized.

To date, we have expended significant time, resources and effort on the development of our product candidates, and a substantial majority of our resources are now focused on seeking marketing approval for and planning for potential commercialization of our most advanced product candidate, FUROSCIX, in the United States. Our business and future success are substantially dependent on our ability to successfully and timely obtain regulatory approval for and commercialize FUROSCIX for the treatment of decompensated heart failure. All of our other product candidates are in earlier stages of development and subject to the risks of failure inherent in developing drug products. Accordingly, our ability to generate significant product revenues in the near term will depend almost entirely on our ability to successfully obtain marketing approval for and commercialize FUROSCIX.

We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. In June 2018 we received a CRL from the FDA with respect to the NDA that we previously submitted in August 2017. The CRL indicated that, among other things, certain device modifications to the sc2Wear Infusor were required. We conducted a post-action meeting with the FDA on September 24, 2018 and a Type C meeting with the FDA on January 9, 2019. Based on the outcome of our interactions with the FDA, we have transitioned to the SmartDose drug delivery system. After conducting a Type C meeting with the FDA on June 18, 2019, we plan to resubmit the NDA for FUROSCIX incorporating the SmartDose drug delivery system by mid-year 2020.

There can be no assurance that the FDA will approve FUROSCIX and, unless it obtains regulatory approval, it may never be commercialized. Satisfaction of regulatory requirements can be protracted, is dependent upon the type, complexity and novelty of the product candidate and requires the expenditure of substantial resources. For example, FUROSCIX is considered to be a drug-device combination product by the FDA, and its NDA thus will require review and coordination by the FDA's drug and device centers prior to approval. We cannot predict whether we will obtain regulatory approval to commercialize FUROSCIX or any of our other product candidates, and we cannot, therefore, predict the timing of any future revenues from these product candidates, if any. Any further delay or setback in the regulatory approval or commercialization of any of these product candidates will adversely affect our business.

Our ability to successfully commercialize any of our products candidates will depend, among other things, on our ability to:

- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- establish and maintain commercial manufacturing arrangements with third-party manufacturers;
- build and maintain sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates;
- successfully complete our clinical trials for our product candidates under clinical development;
- establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States and such collaborators' ability to obtain regulatory and reimbursement approvals in such countries;
- secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and
- manage our spending as costs and expenses increase due to clinical trials, regulatory approvals and commercialization.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize FUROSCIX or any of our other product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize FUROSCIX, and our ability to generate revenue will be materially impaired.

FUROSCIX and the activities associated with its development and commercialization, including its design, research, testing, manufacture, safety, efficacy, recordkeeping, labeling, packaging, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and similar regulatory authorities outside the United States. Failure to obtain marketing approval for FUROSCIX will prevent us from commercializing it.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not received approval from regulatory authorities to market any product candidate in any jurisdiction, and it is possible that neither FUROSCIX nor any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales.

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA has already delayed our timeline to commercialization of FUROSCIX by issuing a CRL in June 2018 with respect to our NDA for FUROSCIX. In addition, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway for FUROSCIX;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of FUROSCIX or any of our product candidates for any indication;
- could determine that additional clinical, human factors or other studies are required to evaluate FUROSCIX incorporating the next generation SmartDose drug delivery system;
- may not find the data from bioequivalence studies and/or clinical trials sufficient to support the submission of an NDA or to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that there are unacceptable risks associated with the device component of FUROSCIX or that there are deficiencies with the information submitted to demonstrate the safety, effectiveness and reliability of the device component;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for FUROSCIX or any of our other product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously-approved drugs with the same conditions of approval as FUROSCIX (e.g., subcutaneous injection);
- may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

To date, most patients who have been evaluated in studies of our product candidates have been treated with versions of our product candidates incorporating the sc2Wear Infusor. As of February 2019, we have discontinued use of the sc2Wear Infusor in our product candidates and have pivoted to incorporate the next generation SmartDose drug delivery system. We plan to resubmit the NDA for FUROSCIX to reflect our transition to the SmartDose drug delivery system by mid-year 2020. If we are required to conduct additional testing or additional clinical studies, in addition to the summative human factors validation study completed in December 2019 and the ongoing device validation and drug stability testing, it could adversely affect the commercial viability of our product candidates and may adversely affect our ability to generate revenue, as a result of which our business, prospects, financial condition and results of operations may suffer.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may impose distribution or use restrictions, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory authorities. The FDA or other regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or other regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval or rejection of our marketing applications by the FDA or other regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

We have supported and continue to support investigator sponsored clinical trials evaluating novel approaches utilizing FUROSCIX to manage patients with worsening heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization. We do not control the design or administration of investigator-sponsored trials, and the investigator-sponsored trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant concerns with respect to FUROSCIX that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities.

All completed and ongoing studies are registered at www.clinicaltrials.gov. To the extent the results of these or other investigator-sponsored trials are inconsistent with, or different from, the results of our company-sponsored trials or raise concerns regarding FUROSCIX, the FDA or a foreign regulatory authority may question the results of the company-sponsored trials or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of FUROSCIX.

We expect to rely on third-party consultants to assist us in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish FUROSCIX's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. If we cannot successfully obtain approval of or commercialize FUROSCIX, our business will be materially harmed and the price of our common stock will be adversely affected.

We intend to utilize the 505(b)(2) pathway for the regulatory approval of FUROSCIX. Final marketing approval of FUROSCIX or any of our other product candidates by the FDA or other regulatory authorities may be delayed, limited, or denied, any of which would adversely affect our ability to generate operating revenues.

We are pursuing a regulatory pathway pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, for the approval of FUROSCIX, which allows us to rely on existing clinical data for the drug. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, and permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies or clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and efficacy for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, such as published data or new studies conducted by the applicant or clinical trials demonstrating safety and efficacy. The FDA could refuse to file our NDA submissions, request additional information before accepting our submissions for filing or require additional information to sufficiently demonstrate safety and efficacy to support approval.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and the complications and risks associated with these product candidates, would likely substantially increase. Moreover, an inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) application that we submit. Moreover, the FDA adopted an interpretation of the three-year exclusivity provisions whereby a 505(b)(2) application can be blocked by exclusivity even if does not rely on the previously-approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA's interpretation, the approval of FUROSCIX may be blocked by exclusivity awarded to a previously-approved drug product that shares certain innovative features with FUROSCIX, even if our 505(b)(2) application does not identify the previously-approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

Because our product candidates are designed to be self-administered subcutaneously by patients, they are drug-device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. For example, in June 2018, the FDA issued a CRL with respect to our NDA for FUROSCIX, indicating, among other things, that certain device modifications may be required to our sc2Wear Infusor device. In February 2019, we discontinued use of the sc2Wear Infusor and transitioned to the next generation SmartDose drug delivery system. We cannot assure you that the FDA will not require device modifications with respect to this next generation device following its review of any regulatory submission that we make. Any such findings could further delay regulatory approval for FUROSCIX or any of our other product candidates that incorporate our next generation device.

The commercial success of FUROSCIX and any other product candidates, if approved, depends upon attaining market acceptance by hospital networks, physicians, patients, third-party payers and the medical community.

Even if our current and future product candidates are approved for commercialization by the appropriate regulatory authorities, physicians may not prescribe our approved product candidates, in which case we would not generate the revenues we anticipate. Market acceptance of any of our product candidates by physicians, patients, third-party payers and the medical community depends on, among other things:

- our ability to provide acceptable evidence of safety and efficacy, at least equivalent to IV-level treatments;
- perceived advantages of our product candidates over alternative treatments, such as oral and IV formulations;
- relative convenience as well as ease of administration of our product candidates compared to existing treatments;
- any labeling restrictions placed upon each product candidate in connection with its approval;
- the prevalence and severity of the adverse side effects of each of our product candidates;
- the clinical indications for which each of our product candidates is approved, including any potential additional restrictions placed upon each product candidate in connection with its approval;
- prevalence of the disease or condition for which each product candidate is approved;
- the cost of treatment in relation to alternative treatments, including generic products;
- the extent to which each product is approved for use at, or included on formularies of, hospitals and managed care organizations;
- any negative publicity related to our or our competitors' products or other formulations of products that we administer subcutaneously, including as a result of any related adverse side effects;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness; and
- the availability of coverage and adequate reimbursement by third parties.

Additionally, if FUROSCIX or any of our other product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products, require us to take our approved product off the market or ask us to voluntarily remove the product from the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may impose conditions under a risk evaluation and mitigation strategy, or REMS, including distribution of a medication guide to patients outlining the risks of such side effects or imposing distribution or use restrictions;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

Successful commercialization will also depend on whether we can adequately protect against and effectively respond to any claims by holders of patents and other intellectual property rights that our products infringe upon their rights, whether any unanticipated adverse effects or unfavorable publicity develops in respect of our products, as well as the emergence of new or existing products as competition, which may be proven to be more clinically effective and cost-effective.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our lead product candidate, FUROSCIX, if approved, we may be unable to generate any revenue.

We do not have sufficient infrastructure for the sales, marketing or distribution of our product candidates, and the cost of establishing and maintaining such an organization may exceed the benefits of doing so. In order to market FUROSCIX, if approved by the FDA, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services.

We intend to establish a sales force to promote FUROSCIX to hospital networks, healthcare providers and third-party payers in the United States, if we obtain FDA approval. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately 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 could delay any product launch, which would adversely impact the commercialization of FUROSCIX. For example, if we recruit any sales representatives or establish marketing capabilities prior to the commercial launch of FUROSCIX and the commercial launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We cannot be sure that we will be able to hire a sufficient number of sales representatives or that they will be effective at promoting FUROSCIX. In addition, we will need to commit significant additional management and other resources to establish and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a positive return on our investment. We will also have to compete with other companies to recruit, hire, train and retain sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or attain adequate numbers of physicians to prescribe any drugs; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, our business, results of operations, financial condition and prospects will be materially adversely impacted.

Beyond FUROSCIX, we intend to leverage the sales and marketing capabilities that we establish for FUROSCIX to commercialize additional product candidates, if approved by the FDA, in the United States. If we are unable to do so for any reason, we would need to expend additional resources to establish commercialization capabilities for those product candidates, if approved.

In addition, we intend to establish collaborations to commercialize our product candidates, if approved by the relevant regulatory authorities, outside of the United States. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such efforts, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We cannot assure you that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If we fail to produce FUROSCIX in the volumes that we require on a timely basis, we may face delays in our commercialization efforts, if it is approved.

We do not currently own or operate manufacturing facilities for the production of any of our product candidates, including FUROSCIX. We currently depend on third parties to manufacture our product candidates, including the drug formulation and device components for FUROSCIX, and expect to continue to rely on such third parties to produce the final commercial product, if approved. Any future curtailment in the availability of materials could result in production or other delays with consequent adverse effects on us. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Pharmaceutical companies often encounter difficulties in production, particularly in scaling up production, of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our bioequivalence and/or clinical trials, increase the costs associated with conducting our bioequivalence and/or clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial.

Manufacturers of combination products need to comply with both pharmaceutical current good manufacturing practice requirements, or cGMPs, and medical device Quality System Regulations, or QSRs, enforced by the FDA through its facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP and QSR requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize such product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in the commercialization of our product candidates, entail higher costs or even prevent us from effectively commercializing our product candidates.

Even if we successfully obtain approval for, produce and distribute FUROSCIX, its success will be dependent on the proper use of FUROSCIX by patients, healthcare professionals and caregivers.

While we believe FUROSCIX can be self-administered by patients, caregivers and healthcare practitioners in a clinic and home environment, we cannot control the successful use of the product by patients, caregivers and healthcare professionals. We make use of packaging and instructions for use to provide guidance to users of FUROSCIX, but we cannot ensure that the product will be used properly.

For example, in our Phase 3 PDCV study, there were four cases in which the FUROSCIX administered doses fell below the predefined criteria. One case was determined to be a dispensing failure, and the remaining three cases were determined to be caused by an undetected incomplete filling of the sc2Wear Infusor, likely due to user errors. As a result, the study did not meet its specified primary endpoints. If we are not successful in promoting the proper use of FUROSCIX, if approved, by patients, healthcare professionals and caregivers, we may not be able to achieve market acceptance or effectively commercialize FUROSCIX.

Even in the event of proper use of FUROSCIX by patients, healthcare professionals and caregivers, individual devices may fail.

We have increased manufacturing capabilities for production of FUROSCIX, but increasing scale of production inherently creates increased risk of manufacturing errors. We may not be able to adequately inspect every device that is produced, and it is possible that individual devices may fail to perform as designed. Manufacturing errors could negatively impact market acceptance of FUROSCIX, result in negative press coverage, or increase the risk that we may be sued.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.

The risk that we may be sued on product liability claims is inherent in the development drug formulation and device products. We face a risk of product liability exposure related to the testing of our current and future product candidates in clinical trials and will face even greater risks upon any commercialization by us of our product candidates. Product liability claims might be brought against us by consumers, healthcare providers or others coming into contact with our product candidates. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of one or more of our products which could adversely affect our stock price and our operations.

Even if we obtain FDA approval for FUROSCIX in the United States, we may never obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize its full market potential.

In order to market products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, the clinical standards of care may differ significantly such that clinical trials conducted in one country may not be accepted by healthcare providers, third-party payers or regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional drug testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any drug we develop will be unrealized.

If we are unable to achieve and maintain coverage and adequate levels of reimbursement for our product or product candidates, if approved, their commercial success may be severely hindered.

Successful sales of FUROSCIX and any other product candidates that receive regulatory approval depend on the availability of adequate coverage and reimbursement from third-party payers, including governmental healthcare programs, such as Medicare and Medicaid, commercial payers, and health maintenance organizations. Patients who are prescribed medications for the treatment of their conditions generally rely on third-party payers to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payers is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate enough to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for FUROSCIX and any other product candidates that we attempt to commercialize will depend significantly on access to third-party payers' drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug in their formularies or otherwise restrict patient access through formulary controls or otherwise to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy requirement for coverage and reimbursement for products exists among third-party payers. Therefore, coverage and reimbursement for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific, clinical, and cost effectiveness data for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do, or limit the market potential of our product candidates, if approved.

We face and will continue to face competition from other companies in the pharmaceutical and medical device industries. We believe our technology and approach of developing proprietary formulations of medicines to be delivered subcutaneously will compete with the efforts of other companies seeking to develop similar therapies. These and other pharmaceutical companies are applying significant resources and expertise to the challenges of drug delivery. Some of these current and potential future competitors may be addressing the same therapeutic areas or indications as we are. Many of our current and potential future competitors have significantly greater research and development capabilities than we do, have substantially more marketing, manufacturing, financial, technical, human and managerial resources than we do, and have more institutional experience than we do.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that allow them to develop and commercialize their products before us and limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs or devices that are more effective, more widely used and less costly than ours, and they may also be more successful than us in manufacturing and marketing their products.

If the FDA approves a competitor's application for a product candidate or drug-device combination product before our application for a similar product candidate or drug-device combination product, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for FUROSCIX is approved first, we may still be subject to competition from other producers of heart failure and infectious disease therapies with approved products or approved 505(b)(2) NDAs for different conditions of use that would not be restricted by any grant of exclusivity to us.

The widespread acceptance of currently available therapies with which our product candidates will compete may limit market acceptance of our product candidates even if commercialized. Oral medication and IV drug delivery are currently available treatments for heart failure and are widely accepted in the medical community and have a long history of use. For example, the use of IV furosemide to treat decompensation in heart failure patients is well-established and has received widespread market acceptance. These treatments will compete with our FUROSCIX product candidate, if approved, and the established use of IV furosemide may limit the potential for FUROSCIX to receive widespread acceptance if commercialized.

Risks Related to the Ongoing Legal Requirements to Which Our Product Candidates are Subject

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

Once an NDA, including a Section 505(b)(2) application, is approved, the product covered becomes a "listed drug" which can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified versions of a drug to facilitate the approval of an ANDA or other application for similar substitutes. If these manufacturers demonstrate that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling, as our product candidate, they might only be required to conduct a relatively inexpensive study to show that their generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product candidate (and in some cases even this limited bioequivalence testing can be waived by the FDA). Competition from generic equivalents to our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our product candidates.

An NDA submitted under 505(b)(2) may subject us to a patent infringement lawsuit that would delay or prevent the review or approval of FUROSCIX.

Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from preclinical studies and/or clinical trials that were not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. An NDA under 505(b)(2) would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for a previously approved drug.

For NDAs submitted under section 505(b)(2), the patent certification and related provisions of the Hatch-Waxman Act apply. Accordingly, if we rely for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, we will be required to include patent certifications in our 505(b)(2) application regarding any patents covering the listed drug. If there are patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and we seek to obtain approval prior to the expiration of one or more of those patents, we will be required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of our 505(b)(2) application. Otherwise, our 505(b)(2) application cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. In connection with our NDA for FUROSCIX that we submitted to the FDA in August 2017, we certified that there were no unexpired patents for furosemide contained in the Orange Book.

If we submit a Paragraph IV certification, we will be required to provide notice of that certification to the NDA holder and patent owner shortly after our 505(b)(2) application is accepted for filing. Under the Hatch-Waxman Act, the patent owner may file a patent infringement lawsuit after receiving such notice. If a patent infringement lawsuit is filed within 45 days of the patent owner's or NDA holder's receipt of notice (whichever is later), a one-time, automatic stay of the FDA's ability to approve the 505(b)(2) NDA is triggered, which typically extends for 30 months unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity listed in the Orange Book for the listed drug, or for any other drug with the same, protected conditions of approval as our product, has expired. The FDA also may require us to perform one or more additional clinical trials or measurements to support the change from the listed drug, which could be time consuming and could substantially delay our achievement of regulatory approval. The FDA also may reject any future 505(b)(2) submissions and require us to submit traditional NDAs under 505(b)(1), which would require extensive data to establish safety and effectiveness of the product for the proposed use and could cause delay and additional costs. Or the FDA could reject any future 505(b)(2) application and require us to submit an ANDA if, before the submission of our 505(b)(2) application, the FDA approves an application for a product that is pharmaceutically equivalent to ours. These factors, among others, may limit our ability to commercialize our product candidates successfully.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

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

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

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

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

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

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

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

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

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, such as the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

Any of our product candidates for which we obtain marketing approval in the future will be subject to ongoing requirements and continued regulatory review, could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products following approval.

Any of our product candidates for which we, or any future collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA, the European Medicines Agency, or EMA, and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidates is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy.

The FDA or the EMA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or any future collaborators, do not market any of our products for which we, or they, receive marketing approval in a manner consistent with the approved labeling, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the marketing or manufacturing of such products;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- restrictions on coverage by third-party payers;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize FUROSCIX and affect the prices we may obtain.

In the United States and many foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of FUROSCIX, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively referred to as the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- 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;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;

- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include, among other things, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (70% as of January 1, 2019 due to the Bipartisan Budget Act of 2018, or the BBA) 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;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the requirements under the federal open payments program and its implementing regulations;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payers who argued were owed to them. The effects of this gap in reimbursement on third-party payers, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year or pay a penalty, which is commonly known as the "individual mandate." However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA -mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."

In July 2018, the Centers for Medicare and Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. In addition, CMS has recently published a final rule that would give states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. 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 of 2017, the remaining provisions of the ACA are invalid as well. While the Trump Administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the Texas District Court Judge issued an order staying the judgment pending appeal, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year through 2025. These reductions were extended through 2027 under the BBA. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers (including hospitals and cancer treatment centers), and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains 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. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase 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. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. On December 18, 2019, the FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. The FDA also issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and draft guidance are unknown at this time. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot be sure whether additional legislative changes will be enacted or what the impact of such changes on the marketing approvals of FUROSCIX, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent labeling and post-marketing testing and other requirements.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our relationships with customers and payers will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with investigators, healthcare professionals, consultants, third-party payers and customers, if any, will subject us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws and regulations may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. These include the following:

- *Anti-Kickback Statute.* The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity can be found guilty of violating the federal Anti-Kickback Statute without actual knowledge of the statute or specific intent to violate it. 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 federal False Claims Act or federal civil money penalties statute.
- *False Claims Laws.* The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery.
- *Anti-Inducement Law*. The anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a federal or state governmental program.
- *HIPAA.* The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, 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 making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, 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. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, also imposes obligations on

covered healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. Such obligations include mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- *Transparency Requirements.* 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 the Centers for Medicare & Medicaid Services, or CMS, information related to payments or transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members.
- *Analogous State and Foreign Laws.* Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can 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 non-governmental third-party payers, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. Some state laws 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; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom received stock options as compensation for services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and 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. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Even if we, or any future collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could impair our ability to generate revenue.

Once marketing approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. 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 labeling. Thus, we and any future collaborators will face restrictions on how we promote any products we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs and QSRs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, any future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and QSRs.

Accordingly, assuming we receive marketing approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to the Clinical Development of Other Product Candidates in Our Pipeline

The commencement and completion of clinical trials can be delayed or prevented for a number of reasons.

Beyond FUROSCIX, we intend to identify, develop and market additional product candidates, including subcutaneous ceftriaxone. However, we may not be able to commence or complete the clinical trials that would support the submission of an NDA to the FDA or marketing authorization to any other regulatory agency. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Clinical trials can be delayed or prevented for a number of reasons, including:

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;
- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- difficulties maintaining contact with subjects after treatment, which results in incomplete data;
- receipt by a competitor of marketing approval for a product targeting an indication that our product targets, such that we are not “first to market” with our product candidate;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and
- varying interpretations of data by the FDA and similar foreign regulatory agencies.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities 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 sites by the FDA or other regulatory authorities;
- unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and
- lack of adequate funding to continue the clinical trial.

Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates.

We cannot be certain that existing clinical trial results will be sufficient to support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Moreover, success in clinical trials in a particular indication, does not ensure that a product candidate will be successful in other indications. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials or successful later-stage trials in other related indications. 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. The results of preclinical and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and initial clinical trials. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon a product candidate and may delay development of any other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of the NDA to the FDA, the marketing authorization application to the EMA or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate revenue.

Our product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. To date, patients treated with FUROSCIX have experienced drug-related side effects including local skin effects such as reddening, or erythema, bruising and pain, which were mild or moderate in severity. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. It is possible that there may be side effects associated with our other product candidates' use. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects.

Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow.

As part of our growth strategy, we intend to identify, develop and market additional product candidates beyond FUROSCIX. We are exploring various therapeutic opportunities for our pipeline and product programs for use with the next generation SmartDose drug delivery system. We may spend several years completing our development of any particular current or future internal product candidates, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license product candidates, approved products or the underlying technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising product candidates and products.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and other regulatory authorities.

Risks Related to Our Dependence on Third Parties

Use of third parties to manufacture our product candidates may increase the risk that we will not have sufficient quantities of our product candidates, products, or necessary quantities at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. As a result, we currently rely on third parties for supply of the active pharmaceutical ingredients, or API, in our product candidates, as well as the device components our of drug-device combination product candidates. Our current strategy is to outsource all manufacturing of our product candidates and products to third parties.

We currently engage third-party manufacturers to manufacture FUROSCIX. For example, we have engaged a third-party manufacturer for the manufacture of the furosemide formulation used in FUROSCIX and we have engaged a third party designer and manufacturer to develop and manufacture the on-body delivery system for FUROSCIX. There is no guarantee that we can maintain our relationships with these manufacturers and we may incur added costs and delays in identifying and qualifying any replacements for such manufacturers. There is no assurance that we will be able to timely secure further needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to commercialize FUROSCIX. There may be difficulties and delays in scaling up to commercial quantities of FUROSCIX and the costs of manufacturing could be prohibitive. Beyond FUROSCIX, third parties also manufacture the materials that we require for the development of our other product candidates, including subcutaneous ceftriaxone, and our reliance on these manufacturers for these activities carries similar risks as our reliance on third-party manufacturers in connection with FUROSCIX.

Reliance on third-party manufacturers entails additional risks, including:

- reliance on third parties for manufacturing process development, regulatory compliance and quality assurance;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control; and
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our products. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other foreign regulatory authorities.

Our lead product candidate, FUROSCIX, is a drug-device combination product that will be regulated under the drug regulations of the FDA based on its primary mode of action as a drug. Third-party manufacturers may not be able to comply with the regulatory requirements, known as current good manufacturing practice, or cGMP, applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the

ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

The FDA and other foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and corresponding foreign regulators also inspect these facilities to confirm compliance with applicable cGMPs and QSRs. Contract manufacturers may face manufacturing or quality control problems causing drug substance or device component production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP or QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

If our third-party manufacturers of our product candidates are unable to increase the scale of their production of our product candidates, or increase the product yield of manufacturing, then our costs to manufacture the product may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and subsequent commercialization of FUROSCIX or any of our other product candidates in our pipeline or that we may develop, our third-party manufacturers will be required to increase their production and automate and otherwise optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to automate and otherwise optimize their manufacturing process to increase the product yield for the next generation SmartDose drug delivery system and other components of our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate revenues and have a material adverse impact on our business and results of operations.

We rely on third parties to conduct our preclinical studies and clinical trials. If they do not perform satisfactorily or fail to meet expected deadlines, our business could be harmed.

We do not independently conduct clinical trials of any of our product candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct these clinical trials and expect to rely on these third parties to conduct clinical trials of any other product candidate that we develop. Any of these third parties may terminate their engagements with us under certain circumstances. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, there is a natural transition period when a new CRO begins work. As a result, delays would likely occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition and prospects.

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as Good Clinical Practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and institutional review boards. If we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill and resources to our ongoing development programs. These contractors 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, which could impede their ability to devote appropriate time to our clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired or foreclosed.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We expect to seek one or more collaborators for the development and commercialization of one or more of our product candidates. For example, we started collaborating with West in 2019 for development of our next generation device. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain marketing approval for product candidates from foreign regulatory authorities, we intend to enter into strategic relationships with international biotechnology or pharmaceutical companies for the commercialization of such product candidates outside of the United States.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA, the EMA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential collaborations or to otherwise develop specified product candidates. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Risks Related to Our Intellectual Property

Our drug development strategy relies heavily upon the 505(b)(2) regulatory approval pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs that we rely upon for approval if we want to obtain approval prior to patent expiry. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which would be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory approval pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book for the listed drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. We can avoid certifying to a method-of-use patent if we do not seek approval of the patented condition of use. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner and NDA holder shortly after our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our 505(b)(2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our application will not be subject to the 30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit.

Our success depends on our ability to protect our intellectual property and proprietary technology, as well as the ability of our collaborators to protect their intellectual property and proprietary technology.

Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection in the United States and other countries with respect to our proprietary product candidates. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business; we also license or purchase patent applications filed by others. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license, and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We are reliant on patents and patent applications that we license for our product candidates and failure by owners of this intellectual property to enforce claims could have a negative impact on our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents.

If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our licensed patents have, or that any of our pending licensed patent applications that mature into issued patents will include, claims with a scope sufficient to protect our current and future product candidates or otherwise provide any competitive advantage, nor can we assure you that our licenses are or will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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 licensed patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar to our product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

Even if they are unchallenged, our owned and licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our or our licensors' patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection or license rights. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business. Similar risks would apply to any patents or patent applications that we may own or in-license in the future.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party preissuance submission of prior art to the USPTO or to other patent offices around the world.

Alternately or additionally, we may become involved in post-grant review procedures, oppositions, derivations proceedings, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Pending and future patent applications may not result in patents being issued which protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates 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. 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;
- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed 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 and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;
- 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 in such countries.

Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our or our licensors' patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors may seek to market generic versions of any approved products by submitting ANDAs to the FDA in which they claim that patents owned or licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Pursuant to the terms of potential license agreements with third parties, some of our third-party licensors may have the right, but not the obligation in certain circumstances to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents. Even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors, and cannot guarantee that we would receive it and on what terms. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. If we cannot obtain patent protection, or enforce existing or future patents against third parties, our competitive position and our financial condition could suffer.

In addition, we rely on the protection of our trade secrets and proprietary know-how. Although 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, we cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets or proprietary know-how, our business may be harmed.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend, in part, on obtaining and maintaining patent protection and trade secret protection for the use, formulation and structure of our product candidates, the methods used to manufacture them, the related therapeutic targets and associated methods of treatment as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Further, the determination that a patent application or patent claim meets all of the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. We have not conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our various patent applications and patents, so we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

We cannot provide assurances that any of our patent applications will be found to be patentable, including over our own prior art patents, or will issue as patents. Neither can we make assurances as to the scope of any claims that may issue from our pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patents and patent applications in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our products and product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products or (c) provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as not infringed, invalid or unenforceable under U.S. or foreign laws; or
- if issued, the patents under which we hold rights may not be valid or enforceable.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or products, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisers may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Under the terms of some of our licenses, we do not have the ability to maintain or prosecute patents in the portfolio, and must therefore rely on third parties to comply with these requirements.

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

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. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States, including the Leahy-Smith America Invents Act, or the America Invents Act, could increase those uncertainties and costs. The America Invents Act was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013. The America Invents Act reforms United States patent law in part by changing the U.S. patent system from a “first to invent” system to a “first inventor to file” system, expanding the definition of prior art, and developing a post-grant review system. This legislation changes United States patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013.

Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post-grant review and *inter partes* review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents. For a patent with an effective filing date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of invalidity, whereas *inter partes* review proceedings can only raise an invalidity challenge based on published prior art and patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and uses a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in litigation in a U.S. federal court. If any of our or our licensors' patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent rights to us.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, 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 that we might obtain in the future.

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

Filing, prosecuting, enforcing and defending patents on our product candidates 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. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our product candidates.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Agreements through which we license patent rights may not give us sufficient rights to permit us to pursue enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents (or control of enforcement or defense) of such patent rights in all relevant jurisdictions as requirements may vary.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings 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. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Others may claim an ownership interest in our intellectual property which could expose us to litigation and have a significant adverse effect on our prospects.

A third party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. While we are presently unaware of any claims or assertions by third parties with respect to our patents or other intellectual property, we cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights, Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may have U.S. and non-U.S. issued patents and pending patent applications relating to compounds, formulations, methods of manufacturing compounds and/or formulations, and/or methods of use for the treatment of the disease indications for which we are developing our product candidates. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, we may not be free to manufacture or market our product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the composition, use or manufacture of our product candidates. We cannot guarantee that any of our patent analyses including, but not limited to, the scope of patent claims or the expiration of relevant patents are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including some which may be competitors or potential competitors. Some of these employees, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during 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 adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Additionally, for certain of our in-licensed patent rights, we do not have the right to bring suit for infringement and must rely on third parties to enforce these rights for us. If we cannot or choose not to take action against those we believe infringe our intellectual property rights, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted and our business would be harmed.

In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating such trade secrets. Further, 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 third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

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

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Risks Related to Employee Matters, Managing Growth and Ongoing Operations

We only have a limited number of employees to manage and operate our business.

As of December 31, 2019, we had 17 full-time or part-time employees. Our focus on the development of FUROSCIX has required us to optimize cash utilization and to manage and operate our business in a lean manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to commercialize FUROSCIX or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

We depend heavily on our executive officers, directors, and principal consultants and the loss of their services would materially harm our business.

Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, directors, principal consultants and others. In addition, we have established relationships with universities and research institutions which have historically provided, and continue to provide, us with access to research laboratories, clinical trials, facilities and patients. Our ability to compete in the biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel.

Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Departed personnel have sought to compete with us historically and may continue to do so in the future. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

We rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. If we are unable to continue to attract and retain highly qualified personnel, our ability to develop and commercialize our product candidates will be limited.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, to provide accurate information to the FDA or comparable non-U.S. regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product materials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, 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, standards or regulations. Additionally, 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 results of operations, including the imposition of significant fines or other sanctions.

We expect to expand our organization and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug manufacturing, regulatory affairs and sales, marketing and distribution, as well as to support our public company operations. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to

managing these growth activities. Moreover, our expected growth could require us to relocate to a different geographic area of the country. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

As a public company, we must comply with public company reporting and other obligations. Continued compliance with these requirements will increase our costs and require additional management resources, and do not ensure that we will be able to satisfy them.

As a result of operating as a public company, compliance with the Sarbanes-Oxley Act of 2002, as well as other rules and regulations promulgated by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, results in significant legal, accounting, administrative and other costs and expenses, which will continue to increase after we are no longer an “emerging growth company.” The listing requirements of the Nasdaq Global Select Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we continue to comply with all of these requirements.

We are subject to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. 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 Jumpstart Our Business Startups Act of 2012, or 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 before 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 control over financial reporting.

During the course of our review and testing of our internal controls, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, 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 are required to timely file accurate quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. 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 Select Market or other adverse consequences.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of other third parties on which we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug 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. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

COVID-19 may materially and adversely affect our business and our financial results.

The recent outbreak of COVID-19 originated in Wuhan, China in December 2019 and has since spread globally, including to the United States and European countries. The continued spread of COVID-19 could adversely impact our device validation, drug stability testing and other operations, including our ability to recruit and retain patients, principal investigators, site staff, caregivers and healthcare providers as necessary. For instance, the COVID-19 outbreak may negatively affect the operations of third-party suppliers or contract research organizations that we rely upon to carry out our device validation, drug stability testing and clinical trials or the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. Furthermore, COVID-19 may delay enrollment in any future clinical trials due to prioritization of hospital resources toward the outbreak and restrictions in travel. Some patients may be unwilling to enroll in future clinical trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. Any negative impact COVID-19 has to patient enrollment or treatment or the timing and execution of our device validation and drug stability testing could cause us to delay the planned resubmission of the FUROSCIX NDA with the Smart Dose drug delivery system, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely. We have already suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers or contract research organizations operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

Risks Related to Our Common Stock

An active trading market for our common stock may not be sustainable. If an active trading market is not sustained, our ability to raise capital in the future may be impaired.

We completed our initial public offering in November 2017. Prior to this time, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on the Nasdaq Global Select Market, an active trading market for our shares may not be sustained. If an active market for our common stock is not sustained, it may be difficult for our stockholders to sell shares of our common stock without depressing the market price for the shares or at all. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

The trading price of our common stock may be highly volatile and fluctuate substantially.

Our stock price is likely to be highly volatile. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- the timing and results of applications for FDA approval of FUROSCIX and other regulatory actions with respect to our product candidates;
- the pricing and reimbursement of FUROSCIX, if approved, and of other product candidates that may be approved;
- regulatory actions with respect to our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- the timing and results of clinical trials of our pipeline product candidates;
- commencement or termination of collaborations for our development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights, including proprietary rights that we in-license from third parties;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

Additionally, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years following our completed initial public offering. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the consolidated financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute

payments not previously approved. We may choose to take advantage of some, but not all, of the available exemptions. We will continue to take advantage of these reduced reporting requirements for as long as we remain an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Future sales of our common stock into the market could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our IPO continue to hold a substantial number of shares of our common stock that many of them are now able to sell in the public market. If these pre-IPO shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Moreover, certain holders of securities issued prior to our IPO have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2019, we had federal net operating loss carryforwards of $17.5 million, which expire at various dates through 2038, and $18.9 million, which may be carried forward indefinitely. At December 31, 2019, the Company had available state net operating loss carryforwards of $33.5 million, which expire at various dates through 2039 and $0.1 million, which may be carried forward indefinitely. If not utilized, the net operating loss carryforwards will expire. At December 31, 2019, we had federal and state research and development tax credit carryforwards of $2.0 million and $0.5 million, respectively. If not utilized, the research and development credits expire at various dates through 2039. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited.

In 2017 we experienced an ownership change that we believe under Section 382 of the Code will result in limitations in our ability to utilize net operating losses and credits. In addition, we may experience future ownership changes as a result of future offerings or other changes in ownership of our stock. As a result, the amount of the net operating loss and tax credit carryforwards presented in our consolidated financial statements could be limited and may expire unutilized.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. Accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. In addition, the terms of any of our existing, and potentially future, debt or credit agreements will preclude us from paying dividends. For example, under our loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank, we are restricted from paying any dividends or making any distributions on account of our capital stock. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Based upon shares outstanding as of December 31, 2019, our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially own shares representing approximately 79.2% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management or the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Some of these persons or entities may have interests that are different than those of other stockholders. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares were sold in our initial public offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors or they may want us to pursue strategies that deviate from the interests of other stockholders.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management or hinder efforts to acquire a controlling interest in us.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. This could also have the effect of discouraging others from making tender offers for our common stock. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. In the event one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices are located in a 13,066 square foot facility in Burlington, Massachusetts. The term of the lease for our facility extends through November 2022.

Item 3. Legal Proceedings.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "SCPH".

As of March 23, 2020, there were 29 stockholders of record, which excludes stockholders whose shares were held in nominee or street name by brokers.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently 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. Any future determination to pay cash dividends will be made at the discretion of our board of directors. In addition, the terms of our outstanding indebtedness restrict our ability to pay cash dividends, and any future indebtedness that we may incur could preclude us from paying cash dividends.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans in Item 11 of Part III of this Annual Report on Form 10-K is incorporated herein by reference.

Recent Sales of Unregistered Securities

We deemed the grants and exercises of stock options issued under our equity compensation plans prior to the completion of our initial public offering in November 2017 to be exempt from registration in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data.

The selected statements of operations data for the years ended December 31, 2018 and 2019 and the balance sheet data as of December 31, 2018 and 2019 are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of our future results.

The following selected financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

	YEAR ENDED DECEMBER 31,	
(in thousands, except share and per share data)	**2018**	**2019**
Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	$ 15,948	$ 24,632
General and administrative	13,719	8,273
Total operating expenses	29,667	32,905
Loss from operations	(29,667)	(32,905)
Interest income (expense), net	280	(107)
Other (expense) income, net	(56)	16
Net loss and comprehensive loss	$ (29,443)	$ (32,996)
Net loss per share, basic and diluted (1)	$ (1.59)	$ (1.77)
Weighted-average common shares outstanding, basic and diluted (1)	18,556,126	18,600,718

(1) See Note 3 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for an explanation of the calculations of our basic and diluted net loss per share.

	AS OF DECEMBER 31,	
(in thousands)	**2018**	**2019**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and restricted cash (1)	$ 89,660	$ 72,806
Working capital (2)	85,220	70,410
Total assets	93,755	77,283
Term loan	9,637	18,915
Accumulated deficit	(96,459)	(129,455)
Total stockholders' equity	78,744	51,365

(1) Includes $182,000 of restricted cash related to a letter of credit issued as a security deposit in connection with our office lease in Burlington, Massachusetts.

(2) We define working capital as current assets less current liabilities.

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 our consolidated financial statements and the related notes appearing at the end of this Annual Report on Form 10-K. This discussion includes forward-looking statements that involve risks, uncertainties and assumptions such as our plans, objectives, expectations and intentions. You should read the "Forward-Looking Statements" and "Risk Factors" sections of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

We are a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. Our strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or IV, delivery. By moving delivery away from the high-cost healthcare settings typically required for IV administration, we believe our technology has the potential to reduce overall healthcare costs and advances the quality and convenience of care. Our lead product candidate, FUROSCIX, consists of our novel formulation of furosemide delivered subcutaneously via an on-body infusor and is under development for treatment of congestion in patients with worsening heart failure who display reduced responsiveness to oral diuretics and do not require hospitalization.

We filed a new drug application, or NDA, for FUROSCIX, with the U.S. Food and Drug Administration, or FDA, in August 2017. On June 11, 2018 we received a Complete Response Letter, or CRL, from the FDA for our NDA, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required clarification on an additional dose validation study and device modifications necessary to advance FUROSCIX using the existing technology, we decided to transition to our next generation device. Our next generation device is being developed through a partnership with West Pharmaceutical Services, Inc., or West, using its proprietary, wearable, SmartDose drug delivery system. We held a Type C meeting with the FDA on June 18, 2019 and based on the results of that meeting we anticipate resubmission of the FUROSCIX NDA with the SmartDose drug delivery system by mid-year 2020.

Since our inception in February 2013, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, planning for commercialization, and conducting discovery, research and development activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. From inception through December 31, 2019, we had received net cash proceeds of $92.7 million from our initial public offering in November 2017, net cash proceeds of $56.7 million from sales of our preferred stock, net cash proceeds of $18.8 million from borrowings under our term loan, net cash proceeds of $13.5 million from sales of convertible notes and net cash proceeds of $4.0 million from the sale of common stock in our 2019 at-the-market offering.

For the years ended December 31, 2018 and 2019, our net losses were $29.4 million and $33.0 million, respectively. We have not been profitable since inception, and as of December 31, 2019, our accumulated deficit was $129.5 million. We expect to continue to incur net losses for the foreseeable future as we develop the infrastructure to commercialize our products, if approved, in the United States, including building our sales and marketing organization, continuing research and development efforts, engaging in scale-up manufacturing and seeking regulatory approval for new product candidates and enhancements. We will need additional funding to pay expenses related to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Research and Development Expenses

Research and development, or R&D, expenses consist of the cost of engineering, clinical trials, regulatory and medical affairs and quality assurance associated with developing our proprietary technology and product candidates. R&D expenses consist primarily of:

- employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense;
- cost of outside consultants who assist with technology development, regulatory affairs, clinical trials and medical affairs, and quality assurance;
- cost of clinical trial activities performed by third parties; and
- cost of facilities and supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. Given the emphasis to date on our lead product candidate FUROSCIX, our R&D expenses have not been allocated on a program-specific basis. In the future, we expect R&D expenses to increase in absolute dollars as we continue to develop new products and enhance existing products and technologies. We anticipate that our expenses will increase significantly as we:

- pursue regulatory approval of FUROSCIX incorporating the SmartDose drug delivery system;
- continue to advance our pipeline programs beyond FUROSCIX; including ceftriaxone;
- continue our current research and development activity;
- seek to identify additional research programs and additional product candidates;
- initiate preclinical testing and clinical trials for any product candidates we identify and develop, maintain, expand and protect our intellectual property portfolio; and
- hire additional research, clinical and scientific personnel.

General and Administrative Expenses

General and administrative, or G&A, expenses consist of employee-related expenses, including salaries, benefits, travel expense and stock-based compensation expense for personnel in executive, finance, commercial, human resources, facility operations and administrative functions. Other G&A expenses include pre-approval promotional activities, marketing, conferences and trade shows, professional services fees, including legal, audit and tax fees, insurance costs, general corporate expenses and allocated facilities-related expenses.

If we receive FDA approval for FUROSCIX incorporating the next generation SmartDose drug delivery system, we anticipate that our G&A expenses will increase as we continue to build our corporate and commercial infrastructure to support the development and commercial launch of FUROSCIX in the United States.

RESULTS OF OPERATIONS

Comparison of Years Ended December 31, 2018 and 2019

The following table summarizes our results of operations for the years ended December 31, 2018 and 2019 (in thousands):

(in thousands)	YEAR ENDED DECEMBER 31, 2018	2019	INCREASE (DECREASE)
Operating expenses:			
Research and development	$ 15,948	$ 24,632	$ 8,684
General and administrative	13,719	8,273	(5,446)
Total operating expenses	29,667	32,905	3,238
Loss from operations	(29,667)	(32,905)	3,238
Other (expense) income	(56)	16	72
Interest income	1,712	1,660	(52)
Interest expense	(1,432)	(1,767)	335
Net loss	$ (29,443)	$ (32,996)	$ 3,553

Research and development expenses. R&D expenses increased $8.7 million to $24.6 million during the year ended December 31, 2019, compared to $15.9 million during the year ended December 31, 2018. This increase was primarily attributable to a $5.3 million increase in device development costs, a $5.0 million increase in pharmaceutical development costs, $1.7 million in unrecoverable component costs related to the sc2Wear Infusor, and a $0.8 million increase in severance costs. The increase was partially offset by a $2.0 million decrease in employee-related costs, a $1.5 million decrease in supplies and contract services for clinical and medical affairs, a $0.4 million decrease in quality and regulatory consulting and a $0.1 million decrease in facility costs.

General and administrative expenses. G&A expenses decreased $5.4 million to $8.3 million during the year ended December 31, 2019, compared to $13.7 million during the year ended December 31, 2018. This decrease was primarily attributable to a $2.9 million decrease in employee-related costs, a $2.0 million decrease in costs related to commercial preparation, a $0.3 million decrease in severance costs and a $0.4 million decrease in legal and professional service costs. The decrease was partially offset by an increase of $0.2 million in public company costs primarily related to directors & officers insurance.

Other (expense) income. Other income increased $72,000 to $16,000 in other income during the year ended December 31, 2019, compared to expense of $56,000 during the year ended December 31, 2018. This increase was primarily attributable to foreign exchange gains due to foreign currency fluctuations.

Interest income. Interest income decreased $52,000 to $1.7 million during the year ended December 31, 2019 compared to the year ended December 31, 2018. This decrease was primarily attributable to lower cash balances during the year ended December 31, 2019.

Interest expense. Interest expense increased $0.3 million from the year ended December 31, 2018 to $1.8 million during the year ended December 31, 2019. This increase was due to the restructuring of the term loan in September 2019 with Solar Capital Ltd. and Silicon Valley Bank which increased the principal from $10.0 million to $20.0 million.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through December 31, 2019 primarily through the sale of shares of our common stock and, prior to that, through the private placement of our preferred stock and the incurrence of debt. From inception through December 31, 2019, we had received net cash proceeds of $92.7 million from our initial public offering in November 2017, net cash proceeds of $56.7 million from sales of our preferred stock, net cash proceeds of $18.8 million from borrowings under our term loan, net cash proceeds of $13.5 million from

sales of convertible notes and net cash proceeds of $4.0 million from the sale of common stock in our at-the-market offering. As of December 31, 2019, we had cash, cash equivalents and restricted cash of $72.8 million.

We expect to incur substantial additional expenditures in the next 12 months to support our ongoing activities and our plans to obtain regulatory approval for FUROSCIX incorporating the next generation SmartDose drug delivery system. We believe our existing unrestricted cash is sufficient to fund these operations through at least the next 12 months from the date of this annual report. We expect our costs and expenses to increase in the future as we prepare for and, if approved, commence U.S. commercialization of FUROSCIX, including the development of a direct sales force, and as we continue to make substantial expenditures on research and development, including to increase our manufacturing capacity and for conducting clinical trials of our product candidates. Additionally, we will incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the time and expense required to resubmit the NDA for FUROSCIX incorporating the next generation SmartDose drug delivery system;
- the potential FDA approval of FUROSCIX;
- the costs and expenses of establishing our U.S. sales and marketing infrastructure;
- the degree of success we experience in commercializing FUROSCIX, if approved;
- the revenue generated by sales of FUROSCIX, if approved and other products that may be approved;
- the pricing and reimbursement of FUROSCIX, if approved, and of other product candidates that may be approved;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the emergence of competing or complementary technological developments;
- the extent to which FUROSCIX, if approved, is adopted by the healthcare community;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Additional financing may not be available on a timely basis on terms acceptable to us, or at all. We may raise funds in equity, royalty-based or debt financings or enter into additional credit facilities in order to access funds for our capital needs. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we raise additional funds through royalty-based financing arrangements, we will likely agree to relinquish rights to potentially valuable future revenue streams and may agree to covenants that restrict our operations or strategic flexibility. Any debt financing obtained by us in the future would cause us to incur additional debt service expenses and could include restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and pursue business opportunities. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment or expansion of sales and marketing capabilities or other activities necessary to commercialize our products.

Loan and Security Agreement

In May 2017, we entered into a $10.0 million loan and security agreement, or the 2017 Loan Agreement, with Solar Capital Ltd. and Silicon Valley Bank (the Lenders). In November 2018, December 2018 and May 2019, we entered into the First Amendment to the Loan and Security Agreement, the Second Amendment to the Loan and Security Agreement and the Third Amendment to the Loan and Security Agreement, respectively (collectively, the Amendments). Upon execution of the First Amendment to the Loan and Security Agreement and the Third Amendment to the Loan and Security Agreement, we paid the Lenders Amendment Fees of $35,000 and $30,000

respectively. Additional fees incurred by the Lenders for the Amendments, totaling $40,000, were paid subsequent to the execution of such Amendments.

The interest rate under the 2017 Loan Agreement was LIBOR plus 8.45%. The initial interest-only period was until November 30, 2018, followed by a 30-month principal and interest period. The First Amendment to the Loan and Security Agreement extended the interest-only period through May 2019. The Third Amendment to the Loan and Security Agreement extended the interest-only period through August 2019, with the ability to further extend the interest-only period to November 2019. Pursuant to the 2017 Loan Agreement, we provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property, owned by us.

The 2017 Loan Agreement allowed us to voluntarily prepay all, but not less than all, of the outstanding principal at any time with a prepayment premium of 1% of the outstanding principal. The 2017 Loan Agreement included a final payment fee of $250,000 upon the earlier of the maturity date or prepayment of such borrowings. The final payment fee was increased to $325,000 in the First Amendment to the 2017 Loan Agreement. For the year ended December 31, 2019, the Company recorded $80,000 related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

In September 2019, we restructured the 2017 Loan Agreement and entered into the 2019 Loan Agreement, which provided for a $20.0 million term loan with the Lenders. The restructured four-year term loan facility allowed for an expansion of the 2017 Loan Agreement. Some of the proceeds from the 2019 Loan Agreement were used to pay off the 2017 Loan Agreement, including the final fee of $325,000. The 2019 Loan Agreement extends the term of the credit facility until September 17, 2023.

The interest rate under the 2019 Loan Agreement is the higher of (i) LIBOR plus 7.95% or (ii) 10.18% and there is an interest-only period until September 30, 2021. The rate at December 31, 2019 was 10.18%. Pursuant to the 2019 Loan Agreement, we provided a first priority security interest in substantially all of our assets, including intellectual property, subject to certain exceptions.

As of December 31, 2019, unpaid borrowings under the 2019 Loan Agreement totaled $20.0 million. For the year ended December 31, 2019, we recorded $169,000 and $90,000 related to the amortization of debt discount associated with the 2017 Loan Agreement and the 2019 Loan Agreement, respectively.

Similar to the 2017 Loan Agreement, the 2019 Loan Agreement allows us to voluntarily prepay all, but not less than all, of the outstanding principal at any time. A prepayment premium of 3% or 1% through the one-year anniversary and the two-year anniversary, respectively, would be assessed on the outstanding principal. After the two-year anniversary, a 0.5% prepayment premium would be assessed on the outstanding principal. A final payment fee of $500,000 is due upon the earlier to occur of the maturity date or prepayment of such borrowings. For the year ended December 31, 2019, we recorded $46,000 related to the amortization of the final payment fee associated with the 2019 Loan Agreement.

In an event of default under the 2019 Loan Agreement, the interest rate will be increased by 5% and the balance under the loan may become immediately due and payable at the option of the lenders.

We entered into an exit fee agreement with the Lenders in connection with the 2019 Loan Agreement which provides for an aggregate payment of 4% of the loan commitment, or $800,000, to the Lenders upon the occurrence of an exit event, as defined in the agreement.

The 2019 Loan Agreement includes restrictions on, among other things, our ability to incur additional indebtedness, change the name or location of our business, merge with or acquire other entities, pay dividends or make other distributions to holders of our capital stock, make certain investments, engage in transactions with affiliates, create liens, sell assets or pay subordinated debt.

At-the-Market Issuance Sales Agreement

On August 23, 2019, we entered into an Open Market Sale Agreement℠, (the ATM Agreement), with Jefferies LLC, Jefferies, with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.0001 per share, or (the ATM Shares), up to an aggregate amount of $15.0 million through Jefferies as its sales agent. The offering and sale of ATM Shares by us under the ATM Agreement will be and is being made pursuant to our shelf registration

statement on Form S-3, which was declared effective by the SEC on February 11, 2019 (Registration Statement No. 333-229120).

Subject to the terms and conditions of the ATM Agreement, Jefferies will use its commercially reasonable efforts to sell the ATM Shares, based upon instructions from us, consistent with its normal trading and sales practices. We will pay Jefferies a commission equal to 3.0% of the gross sales proceeds of such ATM Shares.

During the year ended December 31, 2019, we sold a total of 827,525 ATM Shares under the ATM Agreement at an average gross selling price of $5.19 per share for proceeds of $4.2 million, net of commissions.

We incurred $189,000 of legal, accounting and other costs to establish and activate the ATM program. We charged $54,000 of these costs against additional paid in capital upon issuance of shares during the year ended December 31, 2019.

In the period beginning January 1, 2020 through the date of this Annual Report on Form 10-K, we issued and sold an additional 1,502,892 shares of our common stock under the ATM program, resulting in our receipt of $10.4 million in net proceeds. With the shares sold in 2020, the ATM program is complete.

CASH FLOWS

The following table summarizes our sources and uses of cash for each of the periods presented:

	YEAR ENDED DECEMBER 31,	
(in thousands)	2018	2019
Net cash (used in) provided by:		
Operating activities	$ (28,812)	$ (30,442)
Financing activities	(8)	13,588
Net decrease in cash, cash equivalents and restricted cash	$ (28,820)	$ (16,854)

Net Cash Used in Operating Activities

During the year ended December 31, 2019, net cash used in operating activities was $30.4 million, consisting primarily of a net loss of $33.0 million. This was offset by $0.4 million increase in net operating liabilities and non-cash charges of $2.2 million. The non-cash charges primarily consisted of depreciation, stock-based compensation expense, amortization of right-of-use leased assets and non-cash interest expense related to amortization of debt discount associated with the 2017 and 2019 Loan Agreements.

During the year ended December 31, 2018, net cash used in operating activities was $28.8 million, consisting primarily of a net loss of $29.4 million and $2.2 million increase in net operating assets. This was offset by non-cash charges of $2.8 million. The non-cash charges primarily consisted of depreciation, stock-based compensation expense, amortization of right-of-use leased assets and non-cash interest expense related to amortization of debt discount associated with the 2017 Loan Agreement.

Net Cash (Used in) Provided by Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities was $13.6 million, consisting primarily of $9.6 million in borrowings under the 2019 Loan Agreement, net proceeds of $4.0 million from the at-the-market offering, and $60,000 in proceeds from stock option exercises.

During the year ended December 31, 2018, net cash used by financing activities was $8,000, consisting of debt and equity issuance costs offset by proceeds from stock option exercises.

OFF-BALANCE SHEET ARRANGEMENTS

We currently have no off-balance sheet arrangements.

CONTRACTUAL OBLIGATIONS

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods.

	PAYMENTS DUE BY PERIOD				
(in thousands)	TOTAL	2020	2021 and 2022	2023 and 2024	After 2024
Operating lease obligations (1)	$ 1,561	$ 528	$ 1,033	$ —	$ —
Term loan	20,000	—	12,500	7,500	—
Total	$ 21,561	$ 528	$ 13,533	$ 7,500	$ —

(1) Consists of obligations under multi-year, non-cancelable building and equipment leases for our facilities in Burlington, Massachusetts and Lexington, Massachusetts. The building leases expire on November 30, 2022 and December 31, 2022, respectively.

We have drawn down an aggregate of $20.0 million from our 2019 Loan Agreement as of December 31, 2019. Our contractual commitments under the 2019 Loan Agreement as of December 31, 2019 consist of an aggregate of $27.1 million in repayment obligations, inclusive of related interest amounts and final and exit fees in the amounts of $500,000 and $800,000, respectively. See "—Loan and Security Agreement" for additional information regarding the 2019 Loan Agreement.

We enter into contracts in the normal course of business with clinical trial sites and manufacturing organizations and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

Due to the discontinuation of use of the Company's first generation product candidate, sc2Wear Infusor, we have received notice of termination costs from vendors related to the program. We have accrued all costs for which we either believe we are contractually liable or for which we have negotiated settlement agreements in good faith. However, certain of our vendors have claimed or billed for additional costs for which we believe we are not obligated. At this time, we estimate that additional termination costs, if any, will be immaterial to our financial statements.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. 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 and any such differences may be material.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following discussion addresses our most critical accounting policies, which are those that are most important to our financial condition and results of operations and require our most difficult, subjective and complex judgments.

Stock-Based Compensation Expense

We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards, including employee stock options and restricted stock units. We recognize this expense over the requisite service period. In addition, we recognize stock-based compensation expense in the statements of operations based on awards expected to vest and, therefore, the amount of expense has been reduced for estimated forfeitures. We use the ratable straight-line method for expense attribution.

The valuation model we used for calculating the fair value of stock options for stock-based compensation expense is the Black-Scholes option-pricing model, or the Black-Scholes model. The Black-Scholes model requires us to make assumptions and judgments about the variables used in the calculation, including:

- *Expected term.* We do not believe we are able to rely on our historical exercise and post-vesting termination activity to provide accurate data for estimating the expected term for use in determining the fair value-based measurement of our options. Therefore, we have opted to use the “simplified method” for estimating the expected term of options, which is the average of the weighted-average vesting period and contractual term of the option.
- *Expected volatility.* Due to the lack of a public market for the trading of our common stock prior to our IPO and a lack of company specific historical volatility, we have determined the share price volatility for options granted based on an analysis of the volatility of a peer group of publicly traded companies. In evaluating similarity, we consider factors such as stage of development, risk profile, enterprise value and position within the industry.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for zero-coupon U.S. Treasury notes with remaining terms similar to the expected term of the options.
- *Dividend rate.* We assumed the expected dividend to be zero as we have never paid dividends and have no current plans to do so.
- *Expected forfeiture rate.* We estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest.
- *Service period.* We amortize all stock-based compensation over the requisite service period of the awards, which is generally the same as the vesting period of the awards. We amortize the stock-based compensation cost on a straight-line basis over the expected service periods.

Restricted stock units are valued at the fair market value per share of our common stock on the date of grant.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued R&D expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued R&D expenses include the costs incurred for services performed by our vendors in connection with R&D activities for which we have not yet been invoiced.

We base our expenses related to R&D activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct R&D on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the R&D expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there has been no material differences between our estimates of such expenses and the amounts actually incurred.

JOBS ACT ACCOUNTING ELECTION

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. This election is irrevocable.

NEW ACCOUNTING PRONOUNCEMENTS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption.

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks related to changes in foreign currency exchange rates and interest rates.

We contract with vendors in foreign countries. As such, we have exposure to adverse changes in exchange rates of foreign currencies, principally the Swiss franc and the EU euro, associated with our foreign transactions. We believe this exposure to be immaterial. We currently do not hedge against this exposure to fluctuations in exchange rates.

Our exposure to market risk also relates to interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2019, our aggregate outstanding indebtedness was $20.0 million, which bears interest at the higher of (i) LIBOR plus 7.95% or (ii) 10.18%. Due to the short-term duration of our indebtedness, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our debt instruments.

Item 8. Consolidated Financial Statements and Supplementary Data.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of scPharmaceuticals Inc.

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of scPharmaceuticals Inc. and its subsidiary (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (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 the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

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

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

/s/ RSM US LLP

We have served as the Company's auditor since 2015.

Boston, Massachusetts
March 24, 2020

SCPHARMACEUTICALS INC.

Consolidated Balance Sheets
(in thousands, except share and per share data)

	DECEMBER 31, 2018	DECEMBER 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 89,478	$ 72,624
Prepaid expenses	1,757	2,619
VAT receivable	479	310
Other current assets	179	94
Total current assets	91,893	75,647
Restricted cash	182	182
Property and equipment, net	164	127
Right-of-use lease assets - operating, net	1,506	1,179
Deposits and other assets	10	148
Total assets	$ 93,755	$ 77,283
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 587	$ 1,142
Accrued expenses	2,922	3,688
Term loan, short term	2,811	—
Current portion of lease obligation - operating	353	407
Total current liabilities	6,673	5,237
Term loan, long term	6,826	18,915
Long term lease obligation - operating	1,353	943
Derivative liability	—	765
Other liabilities	159	58
Total liabilities	15,011	25,918
Commitments and contingencies (Note 11)		
Stockholders' Equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding	—	—
Common stock; $0.0001 par value; 150,000,000 shares authorized at December 31, 2019; 18,569,289 and 19,418,955 shares issued and outstanding at December 31, 2018 and December 31, 2019, respectively	2	2
Additional paid-in capital	175,201	180,818
Accumulated deficit	(96,459)	(129,455)
Total stockholders' equity	78,744	51,365
Total liabilities and stockholders' equity	$ 93,755	$ 77,283

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

SCPHARMACEUTICALS INC.

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

	FOR THE YEAR ENDED DECEMBER 31,	
	2018	2019
Operating expenses:		
Research and development	$ 15,948	$ 24,632
General and administrative	13,719	8,273
Total operating expenses	29,667	32,905
Loss from operations	(29,667)	(32,905)
Other (expense) income	(56)	16
Interest income	1,712	1,660
Interest expense	(1,432)	(1,767)
Net loss and comprehensive loss	$ (29,443)	$ (32,996)
Net loss per share, basic and diluted	$ (1.59)	$ (1.77)
Weighted—average common shares outstanding, basic and diluted	18,556,126	18,600,718

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

SCPHARMACEUTICALS INC.

Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT			
At December 31, 2017	18,534,240	2	173,011	(67,016)	105,997
Net loss	—	—	—	(29,443)	(29,443)
Offering costs	—	—	(4)	—	(4)
Issuance of common stock upon exercise of stock options	34,561	—	58	—	58
Vesting of restricted stock	488	—	1	—	1
Stock-based compensation	—	—	2,135		2,135
At December 31, 2018	18,569,289	2	175,201	(96,459)	78,744
Net loss	—	—	—	(32,996)	(32,996)
Issuance of common stock under at-the-market offering, net of commissions and issuance costs (Note 10)	827,525	—	4,108	—	4,108
Issuance of common stock upon exercise of stock options	22,141	—	60	—	60
Stock-based compensation	—	—	1,449	—	1,449
At December 31, 2019	19,418,955	$ 2	$ 180,818	$ (129,455)	$ 51,365

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

SCPHARMACEUTICALS INC.

Consolidated Statements of Cash Flows
(in thousands)

	FOR THE YEAR ENDED DECEMBER 31,	
	2018	2019
Cash flows from operating activities		
Net loss	$ (29,443)	$ (32,996)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation expense	38	37
Amortization expense - right-of-use leased assets - operating	294	327
Stock-based compensation	2,135	1,449
Non-cash interest expense	374	385
Fair value adjustment to derivative liability	—	2
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(833)	(611)
Accounts payable, accrued expenses and other liabilities	(1,377)	965
Net cash flows used in operating activities	(28,812)	(30,442)
Cash flows from financing activities		
Proceeds from common stock offering, net of underwriter discounts and offering costs	(4)	—
Proceeds from term loan, net of costs	(62)	9,555
Proceeds from at-the-market offering, net	—	3,973
Proceeds from the exercise of stock options	58	60
Net cash flows (used in) provided by financing activities	(8)	13,588
Net decrease in cash	(28,820)	(16,854)
Cash, cash equivalents and restricted cash, beginning of year	118,480	89,660
Cash, cash equivalents and restricted cash, end of year	$ 89,660	$ 72,806
Supplemental cash flow information		
Interest paid	$ 1,059	$ 1,383
Taxes paid	298	337
Supplemental disclosure of non-cash activities		
Issuance of derivative in connection with modification of term loan	$ —	$ 763
Transfer of issuance costs from other noncurrent assets to equity	—	54
Vesting of restricted stock	(1)	—
Acquisition of right-of-use leased assets - operating, net of disposal	26	—

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

1. Description of Business and Basis of Presentation

Description of Business

scPharmaceuticals LLC was formed as a Limited Liability Company under the laws of the State of Delaware on February 19, 2013. On March 24, 2014, scPharmaceuticals LLC was converted to a Delaware Corporation and changed its name to scPharmaceuticals Inc. (“the Company”). The Company is a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. The Company’s strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous (“IV”) delivery. The Company’s headquarters and primary place of business is Burlington, Massachusetts.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) and have been prepared on a basis which assumes that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary, scPharmaceuticals Securities Corporation. All significant intercompany balances and transactions have been eliminated in consolidation.

At December 31, 2019, the Company had cash, cash equivalents and restricted cash of $72.8 million and working capital of $70.4 million. During the year ended December 31, 2019, the Company incurred a net loss totaling $33.0 million and used cash in operating activities totaling $30.4 million. The Company expects to continue to incur losses and use cash in operating activities in 2020.

In November 2017, the Company completed an initial public offering ("IPO"), in which the Company issued and sold 7,294,968 shares of common stock at a public offering price of $14.00 per share, resulting in net proceeds of $92.7 million after deducting underwriting discounts and commissions and offering costs. Prior to the IPO, the Company funded its operations primarily through convertible notes and the sale of equity in private placements. The Company believes that, based on its current development plans and activities, its cash balance of $72.6 million as of December 31, 2019 will be sufficient to satisfy its liquidity requirements for more than one year from the issuance date of these consolidated financial statements.

2. Significant Accounting Policies

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 the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant items subject to such estimates and assumptions include accruals related to development costs and clinical activities, and the establishment of the tax valuation allowance. Actual results could differ from those estimates.

Foreign Currency Transactions

The functional currency of the Company is the U.S. dollar. Accordingly, gains and losses resulting from translating transactions denominated in currencies and balances of assets and liabilities outstanding at the balance sheet date, other than U.S. dollars, are included in net loss in the Statements of Operations and Comprehensive Loss.

Cash, Cash Equivalents and Restricted Cash

Cash, cash equivalents and restricted cash consists of bank deposits, certificates of deposit and money market accounts with financial institutions. Cash equivalents are carried at cost which approximates fair value due to their

short-term nature and which the Company believes do not have a material exposure to credit risk. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company places its cash and cash equivalents with institutions with high credit quality. However, at certain times such cash and cash equivalents may be in excess of Federal Deposit Insurance Corporation and Securities Investor Protection Corporation insurance limits. The Company has not experienced any losses with respect to these accounts.

As of December 31, 2019, the Company classified $182,000 as restricted cash related to a letter of credit issued as a security deposit in connection with the Company's lease of its corporate office facilities (Note 11). Cash, cash equivalents and restricted cash consists of the following (in thousands):

	December 31, 2018	December 31, 2019
Cash and cash equivalents	$ 89,478	$ 72,624
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 89,660	$ 72,806

Research and Development Costs

Research and development costs are expensed as incurred. Nonrefundable advance payments, if any, for goods or services used in research and development are initially recorded as an asset and then recognized as an expense as the related goods are delivered or services are performed. Research and development expenses include contract services, consulting, salaries, materials and supplies and overhead.

Income Taxes

The Company accounts for income taxes in accordance with the ASC 740, *Income Taxes.* Deferred tax assets and liabilities are recorded to reflect the impact of temporary differences between amounts of assets and liabilities for financial reporting purposes and such amounts as measured under enacted tax laws. A valuation allowance is required to offset any net deferred tax assets if, based upon the available evidence, it is more likely than not that some or all of the deferred tax asset will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. The tax benefits recorded are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is "more likely than not" to be realized following resolution of any uncertainty related to the tax benefit, assuming that the matter in question will be raised by the tax authorities. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense. At December 31, 2018 and 2019, the Company had no such accruals.

Stock-Based Compensation

Stock-based compensation expense for stock options is recognized based on the grant-date fair value using the Black-Scholes valuation model. Restricted stock units are valued at the fair market value per share of the Company's common stock on the date of grant. The Company recognizes compensation expense only for those stock-based awards expected to vest after considering expected forfeitures. Cumulative compensation expense is at least equal to the compensation expense for vested awards. Stock-based compensation is recognized on a straight-line basis over the service period of each award. Stock compensation costs have not been capitalized by the Company.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's chief executive officer is the CODM, and he uses consolidated financial information in determining how to allocate resources and assess performance. The Company has determined that it operates in one segment. All of the Company's assets are located in the United States.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)* ("ASU 2018-13"). ASU 2018-13 modifies fair value disclosure requirements, specifically around level transfers and valuation of Level 3 assets and liabilities. ASU 2018-13 is effective for financial statements issued for annual and interim periods beginning after December 15, 2019 for all entities. Early adoption of all or part of ASU No. 2018-13 is permitted. The Company does not expect ASU 2018-13 to have a material impact on its financial statements.

3. Net Loss per Share

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period without consideration of dilutive common stock equivalents. Diluted net loss per share is the same as basic net loss per common share, since the effects of potentially dilutive securities are anti-dilutive.

Dilutive common stock equivalents are comprised of unexercised stock options outstanding under the Company's equity plan and unvested restricted stock.

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

	FOR THE YEAR ENDED	
	DECEMBER 31, 2018	DECEMBER 31, 2019
Net loss and comprehensive loss	$ (29,443)	$ (32,996)
Weighted—average common shares outstanding, basic and diluted	18,556,126	18,600,718
Net loss per share, basic and diluted	$ (1.59)	$ (1.77)

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because their inclusion would be anti-dilutive (in common stock equivalent shares):

	FOR THE YEAR ENDED	
	DECEMBER 31, 2018	DECEMBER 31, 2019
Stock options to purchase common stock	1,588,306	1,439,518
Unvested restricted stock	—	160,900
	1,588,306	1,600,418

4. Property and Equipment

Purchased property and equipment consist of the following as of December 31, 2018 and 2019 (in thousands):

	ESTIMATED USEFUL LIFE	2018	2019
Office equipment	5 years	$ 10	$ 10
Office furniture	7 years	116	116
Computer equipment	3 years	8	8
Leasehold improvements	Life of lease	95	95
		229	229
Less: Accumulated depreciation		(65)	(102)
Property and equipment, net		$ 164	$ 127

Depreciation expense for the years ended December 31, 2018 and 2019 was $38,000 and $37,000, respectively.

5. Accrued Expenses

Accrued expenses at December 31, 2018 and 2019 consist of (in thousands):

	2018	2019
Contract research and development	$ 1,492	$ 2,001
Employee compensation and related costs	860	1,250
Consulting and professional service fees	356	296
Interest	47	91
State taxes	165	49
Other	2	1
Total accrued expenses	$ 2,922	$ 3,688

6. Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* (“ASC 740”), which requires an asset and liability approach for measuring deferred taxes based on temporary differences between the financial statement and tax bases of assets and liabilities existing at each balance sheet date using enacted tax rates for the years in which taxes are expected to be paid or recovered. The tax benefit arising from the Company’s net loss has been offset by an increase in the valuation allowance.

Accordingly, the Company had no net income tax provision or benefit during the years ended December 31, 2018 and 2019. Components of the net deferred tax assets at December 31, 2018 and 2019 are as follows (in thousands):

	2018	2019
Deferred tax assets:		
Federal net operating loss carryforwards	$ 6,189	$ 7,638
State net operating loss carryforwards	1,670	2,117
Research and development tax credits	1,824	2,410
Accrued liabilities	257	407
Stock-based compensation	510	778
Depreciation and amortization	10	1,330
Capitalized research and development costs	14,227	19,294
Lease liabilities	—	359
Other	20	—
Total deferred tax assets	$ 24,707	$ 34,333
Deferred tax liabiities:		
Right-of-use lease assets	—	(314)
Other	—	(21)
Total deferred tax liabilities	$ —	$ (335)
Valuation allowance	$ (24,707)	$ (33,998)
Net deferred tax assets	$ —	$ —

At December 31, 2019, the Company had available federal net operating loss carryforwards of $17.5 million, which expire at various dates through 2038, and $18.9 million, which may be carried forward indefinitely. At December 31, 2019, the Company had available state net operating loss carryforwards of $33.5 million, which expire at various dates through 2039, and $0.1 million, which may be carried forward indefinitely. In assessing the realizability of net deferred tax assets, management considers whether it is more likely than not that the net deferred tax assets will be realized. The ultimate realization of net deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing future deductible amounts become deductible. Management has established a full valuation allowance against the net deferred tax assets at December 31, 2018 and 2019 since it is more likely than not that these future tax benefits will not be realized. During 2019, the valuation allowance increased by $9.3 million.

At December 31, 2019, the Company had federal and state research and development credit carryforwards of $2.0 million and $0.5 million, respectively. The net credit carryforwards may be used to offset future income taxes and expire at various dates through 2039. Changes in the Company's ownership, as defined in the U.S. Internal Revenue Code, may limit the Company's ability to utilize the tax credit and net operating loss carryforwards.

On December 22, 2017, the United States enacted new tax reform ("Tax Cuts and Jobs Act"). The Tax Cuts and Jobs Act contains provisions with separate effective dates but is generally effective for taxable years beginning after December 31, 2017. Beginning with the year ending December 31, 2018, the corporate statutory rates on U.S. earnings was reduced from 34% to 21%.

A reconciliation of income tax (expense) benefit at the statutory federal income tax rate and income taxes as reflected in the consolidated financial statements at December 31, 2018 and 2019 are as follows:

	2018	2019
Federal income tax at statutory rate	21.00%	21.00%
State income tax, net of federal benefit	5.45%	5.68%
Research and development credits	2.35%	2.16%
Book compensation related to stock options	(0.61)%	(0.27)%
Change in income tax rate	(0.38)%	(0.05)%
Other	(0.45)%	(0.34)%
Increase in valuation allowance	(27.36)%	(28.18)%
Effective tax rate	—%	—%

The Company files tax returns in the United States, Massachusetts and other states. The tax years 2015 through 2019 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily the United States federal and Massachusetts, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service or state tax authorities if they have or will be used in a future period. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company recognizes both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company has not recorded any interest or penalties on any unrecognized tax benefits since its inception.

A reconciliation of the beginning and ending amount of uncertain tax benefits is as follows (in thousands):

	2018	2019
Beginning uncertain tax benefits	$ 284	$ 476
Prior year - increases	46	—
Current year - decreases	—	—
Current year - increases	146	152
Ending uncertain tax benefits	$ 476	$ 628

7. Stock-Based Compensation

Stock Options

In October 2017, the board of directors approved the 2017 Stock Option and Incentive Plan (the “2017 Stock Plan”) which became effective in November 2017, upon the closing of the Company’s IPO. The 2017 Stock Plan will expire in October 2027. Under the 2017 Stock Plan, the Company may grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units (“RSUs”) and other stock-based awards. The Company’s 2014 Stock Incentive Plan (the “2014 Stock Plan”) terminated in November 2017 effective upon the completion of the Company’s IPO. No additional options will be granted under the 2014 Stock Plan. At December 31, 2019, there were 828,962 options outstanding under the 2014 Stock Plan.

There were 1,430,000 shares of the Company’s common stock initially reserved for issuance under the 2017 Stock Plan. In addition, the number of shares of common stock that may be issued under the 2017 Stock Plan automatically increases on each January 1, beginning on January 1, 2018 and ending on January 1, 2027, by a number of shares equal to 4% of the Company’s shares of common stock outstanding on the immediately preceding December 31, subject to limitation. On January 1, 2018, 2019 and 2020, the number of shares issuable under the 2017 Stock Plan increased by 741,389, 742,772 and 776,758 shares, respectively.

At December 31, 2019, there were 3,166,868 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 252,707 options that have been forfeited from the 2014 Stock Plan.

At December 31, 2019, there were 2,395,412 options available for issuance, 610,556 options outstanding and 160,900 restricted stock units outstanding under the 2017 Stock Plan. Options granted under the 2017 Stock Plan have a term of ten years. Vesting of options under the 2017 Stock Plan is determined by the compensation committee of the board of directors but is generally a four-year term.

The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	2018	2019
Risk-free interest rate	2.42%—2.86%	1.59%—2.51%
Expected dividend yield	0%	0%
Expected life	5.5—7.0 years	5.5—6.1 years
Expected volatility	76%—86%	72%—74%
Weighted-average grant date fair value	$ 7.57	$ 2.31

Due to the lack of a public market for the trading of the Company's common stock prior to its initial public offering and the lack of company-specific historical volatility, volatility was estimated using historical volatilities of similar companies. The expected life of the awards is estimated based on the simplified method, which calculates the expected life based upon the midpoint of the term of the award and the vesting period. The Company uses the simplified method because it does not have sufficient option exercise data to provide a reasonable basis upon which to estimate the expected term. The Company has no history of paying dividends nor does management expect to pay dividends over the contractual terms of these options. The risk-free interest rates are based on the United States Treasury yield curve in effect at the time of grant, with maturities approximating the expected life of the stock options.

The following table summarizes information about stock option activity during 2018 and 2019 (in thousands, except share and per share data):

	NUMBER OF SHARES	WEIGHTED-AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM	AGGREGATE INTRINSIC VALUE
Outstanding, December 31, 2017	1,195,495	$ 5.38		
Granted	939,296	10.54		
Exercised	(34,561)	1.69		
Forfeited	(511,924)	10.85		
Outstanding, December 31, 2018	1,588,306	$ 6.75		
Granted	162,522	3.56		
Exercised	(22,141)	2.73		
Forfeited	(289,169)	8.54		
Outstanding, December 31, 2019	1,439,518	$ 6.09	7.62	$ 1,642
Vested and exercisable, December 31, 2019	911,924	$ 6.20	7.22	$ 977
Vested and expected to vest, December 31, 2019	1,341,385	$ 6.13	7.54	$ 1,520

The following table summarizes information about RSU activity during the year ended December 31, 2019:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
RSUs outstanding, December 31, 2018	—	$ —
Granted	160,900	3.25
Exercised	—	—
Forfeited	—	—
RSUs outstanding, December 31, 2019	160,900	$ 3.25

During 2018 and 2019, the Company received $58,000 and $60,000, respectively, upon exercise of stock options. The intrinsic value of the options exercised in 2018 and 2019 was $270,000 and $47,000, respectively.

Unrecognized compensation expense related to unvested options as of December 31, 2019 was $1.6 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 1.8 years. Unrecognized compensation expense related to unvested RSUs as of December 31, 2019 was $237,000 and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 1.1 years.

During the year ended December 31, 2018, the Company extended the exercise period for 102,661 vested options with a weighted average exercise price of $7.33 pursuant to separation agreements. The Company recorded incremental stock-based compensation expense of $117,000.

During the year ended December 31, 2019, the Company extended the exercise period to one year for 55,677 vested options and for two years for 85,432 vested options with a weighted average exercise price of $8.41 pursuant to separation agreements. The Company recorded incremental stock-based compensation expense of $70,000.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying condensed consolidated statements of operations and comprehensive loss for employees, directors and non-employees during the years ended December 31, 2018 and 2019 as follows (in thousands):

	2018	2019
Research and development	$ 567	$ 327
General and administrative	1,568	1,122
Total	$ 2,135	$ 1,449

8. Fair Value of Financial Instruments

The Financial Accounting Standards Board (“FASB”) Accounting Standard Codification (“ASC”) Topic, *Fair Value Measurements and Disclosures (“ASC 820”),* provides a fair value hierarchy, which classifies fair value measurements based on the inputs used in measuring fair value. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and observable.

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

The carrying values of the Company's cash and restricted cash, prepaid expenses, value added tax, or VAT, receivable and deposits approximate their fair values due to their short-term nature. The carrying value of the Company's loan payable was considered a reasonable estimate of fair value because the Company's interest rate is near current market rates for instruments with similar characteristics.

The following table summarizes the Company's assets and liabilities as of December 31, 2019 that are measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash equivalents	$ 67,824	$ 67,824	$ —	$ —
Total	$ 67,824	$ 67,824	$ —	$ —
Liabilities:				
Derivative liability	$ 765	$ —	$ —	$ 765
Total	$ 765	$ —	$ —	$ 765

The fair value of the derivative liability recognized in connection with the Company's 2019 Loan Agreement (Note 9) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method, which considered as inputs the timing and probability of occurrence of an exit event, the amount of the payment, and the risk-free discount rate reflecting the expected risk profile for each of the potential settlement scenarios.

9. Term Loan

In May 2017, the Company entered into a loan and security agreement (the "2017 Loan Agreement"), with Solar Capital Ltd. and Silicon Valley Bank, (together, the "Lenders") for $10.0 million. The 2017 Loan Agreement had a maturity date of May 1, 2021. Debt issuance costs for the 2017 Loan Agreement were to be amortized to interest expense over the remaining term of the 2017 Loan Agreement using the effective-interest method.

The interest rate under the 2017 Loan Agreement was LIBOR plus 8.45%. The initial interest-only period was until November 30, 2018, followed by a 30-month principal and interest period. The First Amendment to the Loan and Security Agreement, entered into in November 2018, extended the interest-only period through May 2019. The Third Amendment to the Loan and Security Agreement, entered into in May 2019, extended the interest-only period through August 2019, with the ability to further extend the interest only period to November 2019. Pursuant to the 2017 Loan Agreement, the Company provided a first priority security interest in all existing and after-acquired assets, excluding intellectual property, owned by the Company.

For the year ended December 31, 2019, the Company recorded $169,000 related to the amortization of debt discount associated with the 2017 Loan Agreement. For the year ended December 31, 2018, the Company recorded $280,000 related to the amortization of debt discount associated with the 2017 Loan Agreement.

The 2017 Loan Agreement allowed the Company to voluntarily prepay all (but not less than all) of the outstanding principal at any time. A prepayment premium of 1% would be assessed on the outstanding principal. A final payment fee of $250,000 was due upon the earlier to occur of the maturity date or prepayment of such borrowings. The final payment fee was increased to $325,000 in the First Amendment to the 2017 Loan Agreement. For the year ended December 31, 2019, the Company recorded $80,000, related to the amortization of the final payment fee associated with the 2017 Loan Agreement. For the year ended December 31, 2018, the Company recorded $94,000, related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

In September 2019, the Company replaced the 2017 Loan Agreement with a new $20.0 million term loan with the Lenders, the 2019 Loan Agreement. The restructured four-year term loan facility allows for an expansion of the 2017 Loan Agreement. Some of the proceeds from the 2019 Loan Agreement were used to pay off the 2017 Loan Agreement including the final fee of $325,000. The 2019 Loan Agreement extends the term of the credit facility until September 17, 2023. The payoff of the 2017 Loan Agreement was treated as a modification of the debt. Debt issuance costs for the 2019 Loan Agreement, including unamortized issuance costs for the 2017 Loan Agreement, will be amortized to interest expense over the remaining term of the 2019 Loan Agreement using the effective-interest method.

The interest rate under the 2019 Loan Agreement is the higher of (i) LIBOR plus 7.95% or (ii) 10.18% and there is an interest-only period until September 30, 2021. The rate at December 31, 2019 was 10.18%. Pursuant to the 2019 Loan Agreement, the Company provided a first priority security interest in substantially all of the Company’s assets, including intellectual property, subject to certain exceptions.

The Company entered into the Exit Agreement in connection with the 2019 Loan Agreement which provides for an aggregate payment of 4% of the loan commitment, or $800,000, to the Lenders upon the occurrence of an exit event. The Company concluded that the exit payment obligation met the definition of a derivative that was required to be accounted for as a separate unit of accounting. The Company recorded the issuance-date fair value of the derivative liability of $763,000 as a debt discount and as a derivative liability in the Company’s balance sheet.

As of December 31, 2019, unpaid borrowings under the 2019 Loan Agreement totaled $20.0 million. For the year ended December 31, 2019, the Company recorded $90,000 related to the amortization of debt discount associated with the 2019 Loan Agreement.

The 2019 Loan Agreement allows the Company to voluntarily prepay all (but not less than all) of the outstanding principal at any time. A prepayment premium of 3% or 1% through the one-year anniversary and the two-year anniversary, respectively, would be assessed on the outstanding principal. After the two-year anniversary, a 0.5% prepayment premium would be assessed on the outstanding principal. A final payment fee of $500,000 is due upon the earlier to occur of the maturity date or prepayment of such borrowings. For the year ended December 31, 2019, the Company recorded $46,000 related to the amortization of the final payment fee associated with the 2019 Loan Agreement.

In an event of default under the 2019 Loan Agreement, the interest rate will be increased by 5% and the balance under the loan may become immediately due and payable at the option of the lenders.

The 2019 Loan Agreement includes restrictions on, among other things, the Company’s ability to incur additional indebtedness, change the name or location of the Company’s business, merge with or acquire other entities, pay dividends or make other distributions to holders of its capital stock, make certain investments, engage in transactions with affiliates, create liens, sell assets or pay subordinated debt.

Total term loan and unamortized debt discount balances are as follows (in thousands):

	DECEMBER 31, 2018	DECEMBER 31, 2019
Face value	$ 10,000	$ 20,000
Less: discount	(363)	(1,085)
Total	$ 9,637	$ 18,915
Less: current portion	(2,811)	—
Long-term portion	$ 6,826	$ 18,915

As of December 31, 2019, future principal payments due under the 2019 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2021	$ 2,500
December 31, 2022	10,000
December 31, 2023	7,500
Total minimum principal payments	$ 20,000

10. Stockholders' Equity

Common Stock

At December 31, 2018 and 2019, the Company had 150,000,000 shares of common stock authorized with a par value of $0.0001. There were 18,569,289 and 19,418,955 shares issued and outstanding at December 31, 2018 and 2019, respectively. Voting, dividend and liquidation rights of the holders of the common stock are subject to the Company's articles of incorporation, corporate bylaws and underlying shareholder agreements.

Reserved Shares

The Company has reserved 1,439,518 and 160,900 shares of common stock for the exercise of outstanding options to purchase common stock and for the vesting of RSUs, respectively.

At-the-Market Issuance Sales Agreement

On August 23, 2019, the Company entered into an Open Market Sale Agreement℠ ("ATM Agreement"), with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, par value $0.0001 per share (the "ATM Shares"), having an aggregate offering price of up to $15.0 million through Jefferies as its sales agent. The offering and sale of ATM Shares by the Company under the ATM Agreement will be and is being made pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on February 11, 2019.

Subject to the terms and conditions of the ATM Agreement, Jefferies will use its commercially reasonable efforts to sell the ATM Shares, based upon instructions from the Company, consistent with its normal trading and sales practices. The Company will pay Jefferies a commission equal to 3.0% of the gross sales proceeds of such ATM Shares.

During the year ended December 31, 2019, the Company sold a total of 827,525 ATM Shares under the ATM Agreement, in the open market, at an average gross selling price of $5.18 per share for proceeds of $4.2 million, net of commissions.

The Company incurred $189,000 of legal, accounting and other costs to establish and activate the ATM program. The Company charged $54,000 of these costs against additional paid in capital upon issuance of shares during the year ended December 31, 2019.

Preferred Stock

At December 31, 2018 and 2019, the Company had 10,000,000 shares of preferred stock authorized with a par value of $0.0001 and no shares of preferred stock were issued or outstanding.

11. Commitments and Contingencies

Operating Leases

The Company entered into noncancelable operating leases for office facilities located in Lexington, Massachusetts and Burlington, Massachusetts through December 31, 2022 and November 30, 2022, respectively. Rent expense under the operating leases totaled $0.5 million and $0.5 million for the years ended December 31, 2018 and 2019, respectively.

Certain leases provide for increases in future minimum annual rental payments as defined in the lease agreements. The leases generally also include real estate taxes and common area maintenance ("CAM") charges in the annual rental payments.

Pursuant to the terms of its lease agreement for the Company's headquarters in Burlington, Massachusetts, the Company obtained a letter of credit in the amount of approximately $182,000 as security on the lease obligation. The letter of credit is listed as restricted cash on the Company's consolidated balance sheets.

Short-term leases are leases having a term of twelve months or less. The Company recognizes short-term leases on a straight-line basis and does not record a related lease asset or liability for such leases.

The following is a maturity analysis of the annual undiscounted cash flows reconciled to the carrying value of the operating lease liabilities as of December 31, 2019 (in thousands):

Year ended:	
December 31, 2020	$ 528
December 31, 2021	537
December 31, 2022	496
Total minimum lease payments	1,561
Less imputed interest	(211)
Total	$ 1,350

	2018	2019
Lease cost:		
Operating lease cost	$ 483	$ 490
Short-term lease cost	8	8
Sublease income	(39)	(56)
Total lease cost	$ 452	$ 442
Other information		
Cash paid for amounts included in the measurement of liabilities	$ 429	$ 514
Operating cash flows from operating leases	$ 49	$ (30)
Weighted-average remaining lease term - operating leases	3.9 years	2.9 years
Weighted-average discount rate - operating leases	10.1%	10.1%

In February 2018, the Company signed a sublease agreement for its facility located in Lexington, Massachusetts. The sublease commenced on April 1, 2018 and has an initial term of three years with an extension term through December 2022. In February 2020, the sublease was extended until December 31, 2022.

Research and Development Agreements

As part of the Company's research and development efforts, the Company enters into research and development agreements with unrelated companies. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company. Some of these agreements also contain provisions which require the Company to make payments for exclusivity in the development of products in the area of loop diuretics.

Contingencies

The Company follows subtopic 450-20 of the FASB Accounting Standards Codification to report accounting for contingencies.

Certain conditions may exist as of the date the financial statements are issued, which may result in a loss to the Company but which will only be resolved when one or more future events occur or fail to occur. The Company assesses such contingent liabilities, and such assessment inherently involves an exercise of judgment.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability can be estimated, then the estimated liability would be accrued in the Company's financial statements. If the assessment indicates that a potential material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, then the nature of the contingent liability, and an estimate of the range of possible losses, if determinable and material, would be disclosed. Loss contingencies considered remote are generally not disclosed unless they involve guarantees, in which case the guarantees would be disclosed.

Due to the discontinuation of use of the Company's first generation product candidate, sc2Wear Infusor, the Company has received notice of termination costs from vendors related to the program. The Company has accrued all costs for which it either believes it is contractually liable or for which the Company has negotiated settlement agreements in good faith. However, certain of the Company's vendors have claimed or billed for additional costs for which the Company believes it is not obligated. At this time, the Company estimates that additional termination costs, if any, will be immaterial to the Company's financial statements.

12. 401(k) Savings Plan

In July 2014, the Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code covering all of its employees. Employees may make contributions by withholding a percentage of their salary. The plan includes an employer match equal to 100% on the first 3% of deferred compensation and an additional 50% on the next 2% of deferred compensation. During the years ended December 31, 2018 and 2019, the Company has recognized compensation expense of $225,000 and $104,000, respectively, for the employer match contribution.

13. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

In the period beginning January 1, 2020 through the date of this Annual Report on Form 10-K, the Company issued and sold an additional 1,502,892 shares of its common stock under the ATM program, resulting in the receipt of $10.4 million in net proceeds. With the shares sold in 2020, the ATM program is complete.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive and financial officer and our principal accounting officer, evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as of December 31, 2019, our principal executive and financial officer and our principal accounting officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means “controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is recorded, processed, summarized and reported within the time periods specified in the Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Act is accumulated and communicated to the issuer’s management, including its principal executive and principal financial officers or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.” 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.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the company’s principal executive and financial officer and principal accounting officer and effected by the company’s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company’s assets that could have a material effect on the financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on its assessment, management believes that, as of December 31, 2019, our internal control over financial reporting is effective based on those criteria.

Inherent Limitations of Internal Controls

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Not applicable.

PART III

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 the conclusion of our fiscal year ended 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 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 Form 10-K by reference.

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

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

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as a part of this Report:

(1) Consolidated Financial Statements—Included in Item 8 of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Index to Exhibits.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
3.2	Amended and Restated By-laws of the Registrant (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 22, 2016 (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) filed on October 23, 2017)
4.2*	Description of Registered Securities
10.1#	2014 Stock Incentive Plan, as amended, and forms of award agreements thereunder (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) on October 23, 2017)
10.2#	2017 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
10.3#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
10.4#	2017 Employee Stock Purchase Plan (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
10.5#	Form of Indemnification Agreement (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
10.6	Office Lease Agreement, dated as of June 2, 2017, by and between the Registrant and NEEP Investors Holdings LLC (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) filed on October 23, 2017)

10.7	Loan and Security Agreement, dated as of September 17, 2019, by and among the Registrant, Solar Capital Ltd., as collateral agent, and the lenders listed on Schedule 1.1 thereto or otherwise a party thereto from time to time, including Solar Capital Ltd., as a lender, and Silicon Valley Bank, as a lender (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-38293) filed on November 12, 2019)
10.8#	Amended and Restated Employment Agreement, by and between the Registrant and John H. Tucker (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017)
10.9#*	Employment Agreement, by and between the Registrant and Rachael Nokes
10.10	Development Agreement, by and between the Registrant and West Pharmaceutical Services, Inc., dated January 28, 2019 (incorporated by reference as Exhibit 10.2 to the Registrants Quarterly Report on Form 10-Q (File No. 00138293) filed on May 8, 2019)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of RSM US LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.
† The Securities and Exchange Commission has granted confidential treatment of certain provisions. Omitted material for which confidential treatment has been granted has been filed separately with the Securities and Exchange Commission.
# Indicates a management contract or any compensatory plan, contract or arrangement.
** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

Company Name

Date: March 24, 2020

By: /s/ John H. Tucker
John H. Tucker
President, Chief Executive Officer, Principal Executive Officer and Principal Financial Officer

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

Name	Title	Date
/s/ John H. Tucker **John H. Tucker**	Director, President, Chief Executive Officer, Principal Executive Officer and Principal Financial Officer	March 24, 2020
/s/ Rachael Nokes **Rachael Nokes**	Principal Accounting Officer	March 24, 2020
/s/ Mette Kirstine Agger **Mette Kirstine Agger**	Director	March 24, 2020
/s/ Dorothy Coleman **Dorothy Coleman**	Director	March 24, 2020
/s/ Minnie V. Baylor-Henry **Minnie V. Baylor-Henry**	Director	March 24, 2020
/s/ Jack A. Khattar **Jack A. Khattar**	Director	March 24, 2020
/s/ Mason Freeman, M.D. **Mason Freeman**	Director	March 24, 2020
/s/ Leonard D. Schaeffer **Leonard D. Schaeffer**	Director	March 24, 2020
/s/ Klaus Veitinger, M.D., Ph.D. **Klaus Veitinger, M.D., Ph.D.**	Director	March 24, 2020
/s/ Frederick Hudson **Frederick Hudson**	Director	March 24, 2020

Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended

The following summary of the general terms and provisions of the registered capital stock of scPharmaceuticals Inc. ("scPharma", "we", "our") does not purport to be complete and is subject to, and qualified in its entirety by, reference to our Second Amended and Restated Certificate of Incorporation, or certificate of incorporation, our Amended and Restated Bylaws, or bylaws, each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, and applicable provisions of the Delaware General Corporation Law, or the DGCL. Our common stock, par value $0.0001 per share is registered pursuant to Section 12(b) of the Securities and Exchange Act of 1934 and trades on the Nasdaq Global Select Market under the symbol SCPH. The summaries below do not purport to be complete statements of the relevant provisions of the certificate of incorporation, the bylaws or the DGCL.

General

Our authorized capital stock consists of 150,000,000 shares of common stock, par value $0.0001 per share, or the common stock, and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share, or the preferred stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. All outstanding shares of common stock are fully paid and nonassessable.

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "SCPH."

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Preferred Stock

We may issue shares of preferred stock in one or more series. Our board of directors will determine the rights, preferences and privileges of the shares of each wholly unissued series, and any qualifications, limitations or restrictions thereon, including dividend rights, conversion rights, preemptive rights, voting rights, terms of redemption or repurchase, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of any series. Convertible preferred stock will be convertible into our common stock or exchangeable for other securities. Conversion may be mandatory or at the holder's option and would be at prescribed conversion rates. 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 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.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least two-thirds of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our bylaws is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

SCPHARMACEUTICALS INC.

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of the 12th day of December 2019 (the "Effective Date"), between scPharmaceuticals Inc., a Delaware corporation (the "Company"), and Rachael Nokes (the "Executive").

WHEREAS, the Company and the Executive are parties to an offer letter, dated June 18, 2014 (the "Offer Letter"), and a Nondisclosure, Noncompetition, and Assignment of Intellectual Property Agreement, signed by the Executive on June 26, 2014 (the "NDA"); and

WHEREAS, the parties intend to and shall replace the Offer Letter with this Agreement, effective as of the Effective Date.

WHEREAS the NDA is unamended and unaffected by this Agreement and remains enforceable and in full effect in accordance with its terms.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The term of this Agreement shall commence on the Effective Date and continue until terminated in accordance with the provisions hereof (the "Term"). The Executive's employment with the Company will continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Executive shall serve as the Senior Vice President of Finance of the Company, and shall have supervision and control over and responsibility for the day-to-day business and affairs of the Company and shall have such other powers and duties as may from time to time be prescribed by the Board of Directors of the Company (the "Board"), the Chief Executive Officer of the Company (the "CEO") or other authorized executive. The Executive shall devote the Executive's full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on other boards of directors, provided the Executive obtains the advance written approval of the Board, or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not materially interfere with the Executive's performance of the Executive's duties to the Company as provided in this Agreement.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Executive's annual base salary shall be $309,000. The Executive's base salary shall be reviewed annually by the Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for executive officers.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee from time to time. The Executive's initial target annual incentive compensation shall be 30 percent of the Executive's Base Salary (the "Target Annual Incentive Compensation"). To earn any incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by the Executive during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its executive officers.

(d) Other Benefits. During the Term, the Executive shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(e) Vacations. During the Term, the Executive shall be eligible for paid vacation in accordance with the Company's policies and procedures. The Executive shall also be entitled to all paid holidays given by the Company to its executive officers.

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon the Executive's death.

(b) Disability. The Company may terminate the Executive's employment if the Executive is disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this

Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Executive constituting a material act of misconduct in connection with the performance of the Executive's duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Executive of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Executive that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries or affiliates if the Executive were retained in the Executive's position; (iii) continued non-performance by the Executive of the Executive's duties hereunder (other than by reason of the Executive's physical or mental illness, incapacity or disability) which has continued for more than 30 days following written notice of such non-performance from the CEO; (iv) a breach by the Executive of any of the provisions contained in Section 7 of this Agreement or the NDA; (v) a material violation by the Executive of the Company's written employment policies; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

(d) Termination Without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death of the Executive under Section 3(a) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate the Executive's employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the Good Reason Process following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location at which the Executive provides services to the Company; or (iv) the material breach of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" condition has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason condition within 60 days of the first occurrence of such condition; (iii) the Executive cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the condition; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Executive terminates the Executive's employment

within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(f) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by the Executive's death, the date of the Executive's death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company without Cause under Section 3(d), the date on which a Notice of Termination is given; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) without Good Reason, 30 days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) with Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

4. Compensation Upon Termination.

(a) Termination Generally. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to the Executive's authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement) and unused vacation that accrued through the Date of Termination on or before the time required by law but in no event more than 30 days after the Executive's Date of Termination; and (ii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

(b) Termination by the Company Without Cause or by the Executive with Good Reason. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates the Executive's employment for Good Reason as provided in Section 3(e), then the Company shall pay the Executive the Executive's Accrued Benefit. In addition, subject to the Executive signing a separation agreement containing, among other provisions, a general release of claims in favor of the Company and related persons and entities, confidentiality, return of property and non-disparagement, in a form and manner satisfactory to the Company (the "Separation Agreement and Release") and the Separation Agreement and Release becoming irrevocable and fully effective, all within the time required by the Separation Agreement and Release but in any event

no later than 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Executive an amount equal to nine (9) months of the Executive's Base Salary (the "Severance Amount"). Notwithstanding the foregoing, if the Executive breaches any of the provisions contained in Section 7 of this Agreement or the NDA, all payments of the Severance Amount shall immediately cease;

(ii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Executive a monthly cash payment for nine (9) months or the Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company; and

(iii) the amounts payable under Section 4(b)(i) and (ii) shall be paid out in substantially equal installments in accordance with the Company's payroll practice over nine (9) months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2).

5. Change in Control Payment. The provisions of this Section 5 set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to the Executive's assigned duties and the Executive's objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 4(b) regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 12 months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect beginning 12 months after the occurrence of a Change in Control.

(a) Change in Control. During the Term, if within 12 months after a Change in Control, the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates the Executive's employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming irrevocable and fully effective, all within 60 days after the Date of Termination (or such shorter time period provided in the Separation Agreement and Release):

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to the sum of (A) the Executive's current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) the Executive's Average Incentive Compensation (For purposes of this Agreement, "Average Incentive Compensation" shall mean the average of the Target Annual Incentive Compensation received by the Executive for the three immediately preceding fiscal years. In no event shall "Average Incentive Compensation" include any sign-on bonus, retention bonus or any other special bonus.);

(ii) notwithstanding anything to the contrary in any applicable option agreement or stock-based award agreement, all time-based stock options and other time-based stock-based awards held by the Executive shall immediately accelerate and become fully exercisable or nonforfeitable as of the Date of Termination;

(iii) if the Executive was participating in the Company's group health plan immediately prior to the Date of Termination and elects COBRA health continuation, then the Company shall pay to the Executive a monthly cash payment for 12 months or the Executive's COBRA health continuation period, whichever ends earlier, in an amount equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company; and

(iv) The amounts payable under Section 5(a)(i) and (iii) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Internal Revenue Code of 1986, as amended (the "Code") and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-

based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 5(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 5(b)(i) shall be made by a nationally recognized accounting firm selected by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(c) Definitions. For purposes of this Section 5, the following terms shall have the following meanings:

"Change in Control" shall mean any of the following:

(i) any "person," as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended (the "Act") (other than the Company, any of its subsidiaries, or any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any of its subsidiaries), together with all "affiliates" and "associates" (as such terms are defined in Rule 12b-2 under the Act) of such person, shall become the "beneficial owner" (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, of securities of the Company representing 50 percent or more of the combined voting power of the Company's then outstanding securities having the right to vote in an election of the Board ("Voting Securities") (in such case other than as a result of an acquisition of securities directly from the Company); or

(ii) the date a majority of the members of the Board is replaced during any 12-month period by directors whose appointment or election is not endorsed by a majority of the members of the Board before the date of the appointment or election; or

(iii) the consummation of (A) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation

or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Act), directly or indirectly, shares representing in the aggregate more than 50 percent of the voting shares of the Company issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any), or (B) any sale or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company.

Notwithstanding the foregoing, a "Change in Control" shall not be deemed to have occurred for purposes of the foregoing clause (i) solely as the result of an acquisition of securities by the Company which, by reducing the number of shares of Voting Securities outstanding, increases the proportionate number of Voting Securities beneficially owned by any person to 50 percent or more of the combined voting power of all of the then outstanding Voting Securities; provided, however, that if any person referred to in this sentence shall thereafter become the beneficial owner of any additional shares of Voting Securities (other than pursuant to a stock split, stock dividend, or similar transaction or as a result of an acquisition of securities directly from the Company) and immediately thereafter beneficially owns 50 percent or more of the combined voting power of all of the then outstanding Voting Securities, then a "Change in Control" shall be deemed to have occurred for purposes of the foregoing clause (i).

6. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

7. Certain Covenants of the Executive.

(a) NDA. The Parties agree that the NDA is attached hereto strictly for reference, is unaltered and unamended by this Agreement, and remains enforceable and in full effect in accordance with its terms as originally entered into by the Parties.

(b) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such

claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 7(f).

(d) Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the promises set forth in this Section 7, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, subject to Section 8 of this Agreement, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of this Agreement, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company. In addition, in the event the Executive breaches this Section 7 during a period when the Executive is receiving severance payments pursuant to Section 4 or Section 5 hereof, the Company shall have the right to suspend or terminate such severance payments. Such suspension or termination shall not limit the Company's other options with respect to relief for such breach and shall not relieve the Executive of the Executive's duties under this Agreement.

(e) Protected Disclosures. The Executive understands that nothing contained in this Agreement limits the Executive's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company. The Executive also understands that nothing in this Agreement limits the Executive's ability to share compensation information concerning the Executive or others, except that this does not permit the Executive to disclose compensation information concerning others that the Executive obtains because the Executive's job responsibilities require or allow access to such information.

(f) Defend Trade Secrets Act of 2016. The Executive understands that pursuant to the federal Defend Trade Secrets Act of 2016, the Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (a) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

8. Arbitration of Disputes. Any controversy or claim arising out of or relating to this Agreement or the breach thereof or otherwise arising out of the Executive's employment or the termination of that employment (including, without limitation, any claims of unlawful employment discrimination whether based on age or otherwise) shall, to the fullest extent permitted by law, be settled by arbitration in any forum and form agreed upon by the parties or, in the absence of such an agreement, under the auspices of the American Arbitration Association ("AAA") in Boston, Massachusetts in accordance with the Employment Dispute Resolution

Rules of the AAA, including, but not limited to, the rules and procedures applicable to the selection of arbitrators. In the event that any person or entity other than the Executive or the Company may be a party with regard to any such controversy or claim, such controversy or claim shall be submitted to arbitration subject to such other person or entity's agreement. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. This Section 8 shall be specifically enforceable. Notwithstanding the foregoing, this Section 8 shall not preclude either party from pursuing a court action for the sole purpose of obtaining a temporary restraining order or a preliminary injunction in circumstances in which such relief is appropriate, provided that any other relief shall be pursued through an arbitration proceeding pursuant to this Section 8.

9. Consent to Jurisdiction. To the extent that any court action is permitted consistent with or to enforce Section 8 of this Agreement, the parties hereby consent to the jurisdiction of the Superior Court of the Commonwealth of Massachusetts and the United States District Court for the District of Massachusetts. Accordingly, with respect to any such court action, the Executive (a) submits to the personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

10. Integration. This Agreement and (separately) the NDA constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements between the parties concerning such subject matter, including without limitation the Offer Letter and any agreement, representation, promise or communication, whether oral or written (and whether from the Company, the Chief Executive Officer or any other agent of the Company), regarding severance benefits.

11. Withholding. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law.

12. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

13. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

14. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

15. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

16. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

17. Governing Law. This is a Massachusetts contract and shall be construed under and be governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of laws principles thereof.

18. Assignment. Neither the Executive nor the Company may make any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, that the Company may assign its rights and obligations under this Agreement without the Executive's consent to any affiliate or to any person or entity with whom the Company shall hereafter effect a reorganization, consolidate with, or merge into or to whom it transfers all or substantially all of its properties or assets; provided further that if the purchaser in any transaction involving the transfer of all or substantially all of the Company's assets assumes this Agreement and the Executive accepts a position with the purchaser that is equivalent or better to the Executive's position immediately preceding such transaction, then the Executive shall not be entitled to any Severance Amount or other benefits pursuant to Section 4(b) or any compensation or benefits pursuant to Section 5(a). This Agreement shall inure to the benefit of and be binding upon the Executive and the Company, and each of the Executive's and the Company's respective successors, executors, administrators, heirs and permitted assigns.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

20. Recitals. This Agreement's WHEREAS clauses are incorporated by reference herein as material, operative terms of this Agreement.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

SCPHARMACEUTICALS INC.

By: /s/ John H. Tucker
Name: John H. Tucker
Its: President and Chief Executive Officer

EXECUTIVE

/s/ Rachael Nokes
Rachael Nokes

Exhibit A: NDA

Exhibit 21.1

SUBSIDIARIES

Subsidiary	Jurisdiction of Incorporation
scPharmaceuticals Securities Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Nos. 333-221677, 333-227071 and 333-229122) on Forms S-8 and the Registration Statement (No. 333-229120) on Form S-3 of scPharmaceuticals Inc. of our report dated March 24, 2020, relating to the consolidated financial statements of scPharmaceuticals Inc., appearing in this Annual Report on Form 10-K of scPharmaceuticals Inc. for the year ended December 31, 2019.

/s/ RSM US LLP

Boston, Massachusetts

March 24, 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 H. Tucker, certify that:

1. I have reviewed this Annual Report on Form 10-K of scPharmaceuticals Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: March 24, 2020

By: /s/ John H. Tucker

John H. Tucker
President, Chief Executive Officer, Principal Executive Officer and Principal Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of scPharmaceuticals 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 results of operations of the Company.

Date: March 24, 2020

By: /s/ John H. Tucker
John H. Tucker
President, Chief Executive Officer, Principal Executive Officer and Principal Financial Officer

* This certification shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.