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, 2018

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐	Small 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 30, 2018) was $48,716,169. The number of shares of Registrant's Common Stock outstanding as of March 19, 2019 was 18,580,430.

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 2019 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 timing or 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 transform the way therapy is delivered, advance patient care and reduce healthcare costs. Our proprietary platform 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 novel, buffered 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 incorporating the sc2Wear Infusor developed in partnership with Sensile Medical AG, or Sensile, with the U.S. Food and Drug Administration, or FDA, 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 Complete Response Letter, or 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, including clarification on an additional dose validation study and proposed device modifications necessary to advance FUROSCIX using the existing delivery technology, we have decided to discontinue use of the sc2Wear Infusor and transition to our next generation device being developed in partnership with West Pharmaceuticals 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). Our future regulatory filings will be based on delivery of scFurosemide using this next generation SmartDose drug delivery system. In addition, future clinical trials that we sponsor or conduct will use the SmartDose drug delivery platform.

Heart failure affects 6.5 million adults in the United States and is expected to grow to greater than 8 million by 2030. Our proprietary formulation of furosemide, or scFurosemide, 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 in heart failure patients, such as congestion, fatigue and shortness of breath. FUROSCIX is designed to offer alternative outpatient intervention in 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 potentially without admission to 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.

Currently, 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. We are also leveraging our subcutaneous formulation expertise to develop a suite of 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. 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 there are 15 million outpatient days in the United States of ceftriaxone therapy to treat various types of infections, including pneumonia, urinary tract infections, and Lyme Disease. 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, including a planned study in 2020 to evaluate skin safety after subcutaneous administration. We expect to submit an NDA for subcutaneous ceftriaxone in 2021.

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 antibiotics and evaluate other 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 the oral diuretics become 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 multiday 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 administered subcutaneously via a single-use, disposable and wearable infusor with an automatic needle insertion and retraction mechanism for self-administration. The user inserts the pre-filled cartridge in the wearable device, applies it to the abdomen using a medical-grade adhesive, and the device administers scFurosemide subcutaneously using a biphasic delivery profile with 30 mg administered over the first hour, followed by 12.5 mg/hour for the subsequent 4 hours (total dose is 80 mg furosemide 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, thereby reducing the number of days a heart failure patient remains in the hospital. 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 the use of 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, 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 upon discharge, or 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 scFurosemide could potentially 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 improves patient outcomes and quality of life.

Clinical Development of FUROSCIX

Our Subcutaneous Formulation of Furosemide

To date, 127 subjects with heart failure have received scFurosemide via subcutaneous administration in our clinical studies, where 101 subjects received scFurosemide via our previous delivery device, the sc2Wear Infusor, and 26 subjects received scFurosemide delivered 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 care givers outside the hospital, in clinical and home environments. To date, no clinical studies have been conducted using the next generation SmartDose drug delivery system.

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 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 the outcome of our interactions with the FDA, including clarification on an additional dose validation study and proposed device modifications necessary to advance FUROSCIX using the existing delivery technology, we have decided to discontinue use of the sc2Wear Infusor developed in partnership with Sensile, and transition to our next generation infusor being developed in 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 we also plan to support our application for marketing approval with existing data from our clinical studies evaluating our subcutaneous formulation of furosemide administered via the sc2Wear Infusor and the B. Braun Pump.

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, our subcutaneous formulation of furosemide was delivered 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 subcutaneous administration of our novel furosemide formulation 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, our novel formulation of furosemide was subcutaneously administered using the sc2Wear Infusor with a preset dosage of 30 mg furosemide over the first hour, then 12.5 mg per hour for the subsequent four hours.

Primary Endpoints

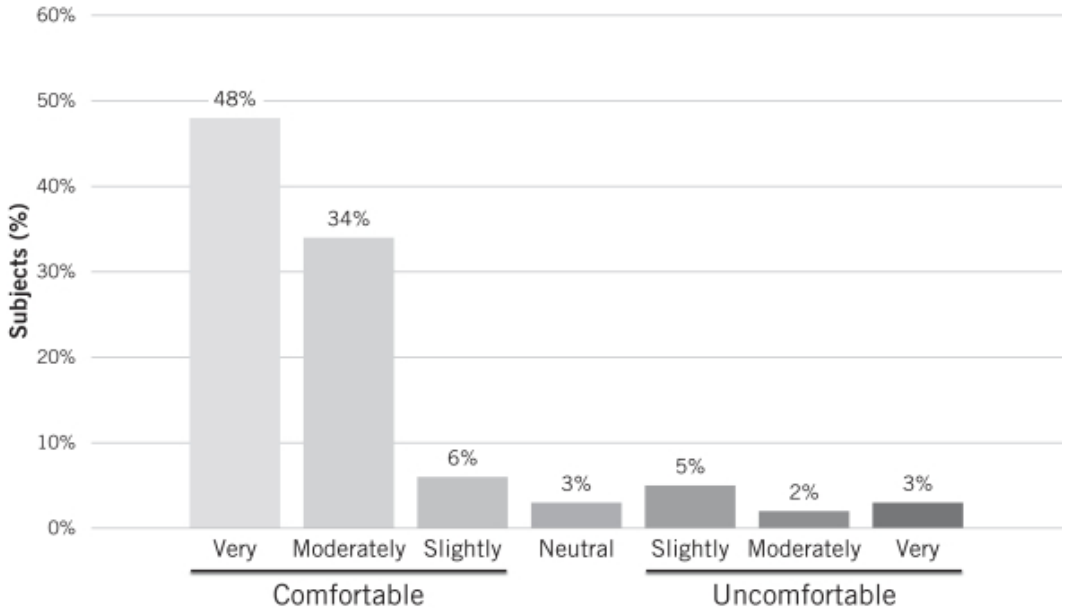
The primary objective of this study was to evaluate the on-body performance of FUROSCIX, defined as the absence of major product and major system related failures leading to inadequate delivery of drug product (performance criteria of 95% passage rate with 95% confidence) in the MITT population.

In the MITT population, 63 of 67 (94%) FUROSCIX infusions were free from major system-related failure, with a 95% confidence interval of 85% to 98%. As such, this study did not meet the FDA's prespecified performance criteria. All patients in the MITT population, however, achieved furosemide concentrations above the pre-defined target therapeutic threshold. In the four cases in which FUROSCIX administered dose fell below the predefined criteria of 80 mg (10 mL) ± 10%, only one 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. The three other dispensing failures were determined to be caused by an undetected, incomplete filling of the sc2Wear Infusor, likely due to user errors, as the three incomplete fillings observed in these devices were not able to be reproduced during bench testing. When the sc2Wear Infusor was filled adequately, 63 of 64 (98%) FUROSCIX infusions were within the prespecified performance criteria, with a 95% confidence interval of 92% to 100%.

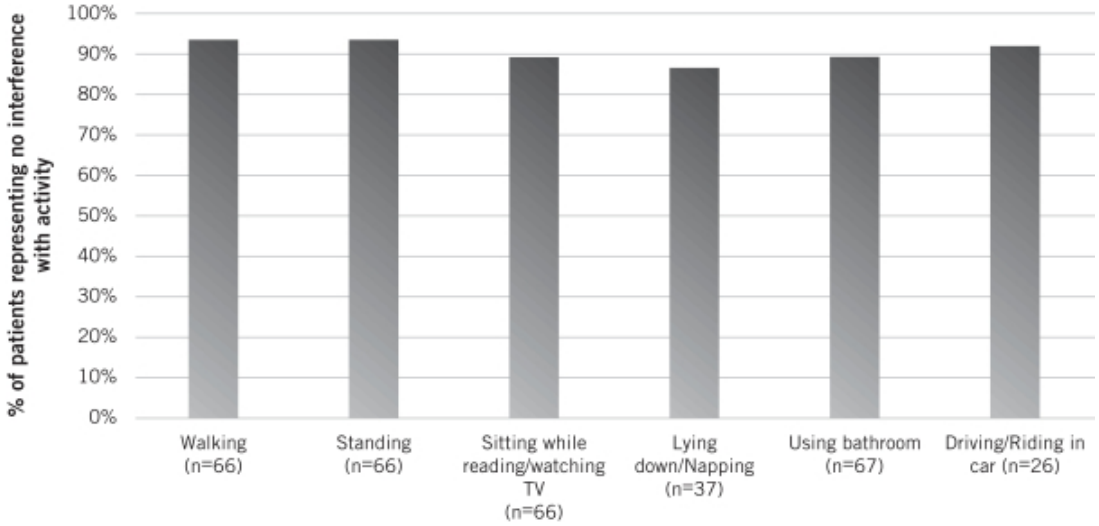
We discussed these data with the FDA at a pre-NDA meeting, held on June 1, 2017, and presented the results of a completed human factors study in which the frequency of undetected fill errors was 0%, as a result of our improvements to the quick reference guide and instructions for use. As part of our NDA submission, 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. Although the PDCV study did not meet the prespecified endpoint, during the meeting, the FDA requested that our NDA include an assessment of the data generated from all of our studies. In connection with the NDA that we submitted to the FDA in August 2017, we submitted the materials that we believe are responsive to the requests that the FDA made at our pre-NDA meeting. We reported to the FDA that we believe FUROSCIX will be used as designed by patients, caregivers and healthcare professionals in the clinic and in the home, even by first-time users, as supported by our observations that risk control measures such as our training videos, customer help line, and warning labels were sufficient in reducing the possibility of user errors to an acceptable level. In addition, we represented in our submission that the FDA may deem overall residual risks acceptable because i) furosemide is generally considered safe and effective due to its long history of use in the U.S., ii) FUROSCIX will not be indicated for emergency situations, iii) any under-dosing or error in treatment would be readily detectable due to the noticeable pharmacological response of furosemide, and iv) the sources of residual risk in administering FUROSCIX are limited to non-critical tasks that we believe do not pose a serious health hazard to users or the patient. We also submitted a safety assurance case that the design of FUROSCIX may be deemed safe for its intended use based on our belief that FUROSCIX is adequately defined, its design is adequately verified and validated, the risks associated with FUROSCIX and its system hazards have been identified and mitigated, and FUROSCIX is adequately reliable to ensure safety over its use life.

Secondary Analysis

The study also included secondary tolerability endpoints, including a comfort of wear questionnaire that was completed one hour after completion of FUROSCIX infusion. The graph below reflects the overall comfort reported by the patients in the MITT population:



In addition, administration of FUROSCIX was found to have only minimal impact on participants' daily living activities, which included walking, standing, sitting, lying down/napping, using the bathroom, or driving/riding in a car. Between 86% and 94% of participants who answered the questionnaire reported that FUROSCIX did not interfere with the activities reflected in the graph below:



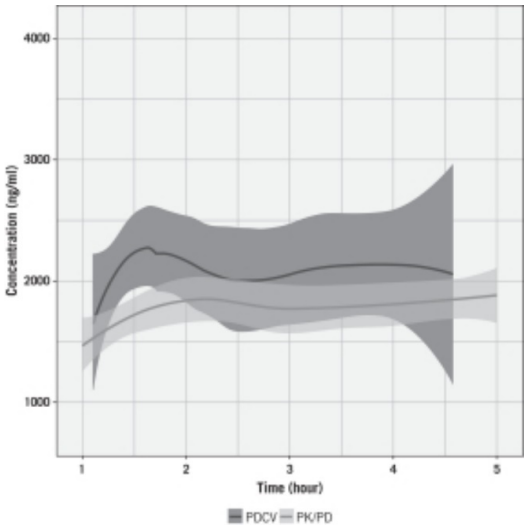
Safety Analysis

We observed no needle insertion failures, dislodgements or leaks. 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.

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. 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 our subcutaneous furosemide formulation is administered via the sc2Wear Infusor compared to the B. Braun Pump.

The same 80 mg dose and dosing regimen of 30 mg dosed over the first hour followed by 12.5 mg/hour for the subsequent four hours, was used in both studies. 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.

We plan to discuss with the FDA whether any additional clinical or bridging studies may be required to support approval of FUROSCIX incorporating the SmartDose drug delivery system.

Human Factors Summary

There were approximately 230 patients, caregivers and health care providers that participated in formative and summative usability testing from Fall 2015 to Fall 2018 using the sc2Wear Infusor, respectively.

West has conducted numerous formative and summative human factors with the SmartDose drug delivery system. We anticipate conducting additional formative and summative studies with the SmartDose drug delivery system in our intended user population.

Investigator Sponsored Study

In February 2016, an open label, randomized study of 40 patients was initiated to evaluate urine output and adverse events of our subcutaneous formulation of furosemide administered subcutaneously via B. Braun Pump compared to IV furosemide in patients with decompensated heart failure presenting to the John's Hopkins Heart Failure Bridge Clinic. In this study, subjects randomized to receive our subcutaneous formulation of furosemide were administered a single, 80 mg dose subcutaneously over five hours and patients randomized to IV furosemide received a single dose intravenously equivalent to their oral maintenance dose up to a maximum dose of 160 mg. The mean dose of IV furosemide that was administered was 123+47 mg and 58% received the maximum 160 mg dose. The primary endpoint of the study was to evaluate urine output after six hours. From the results of this study, the investigator concluded that treatment with our subcutaneous formulation of furosemide resulted in equivalent diuresis and weight loss and was well tolerated compared to IV furosemide in patients with decompensated heart failure presenting to an outpatient heart failure clinic. There was one adverse event, an episode of hypokalemia, which is a drop in a subject's potassium levels, observed in a subject who received our subcutaneous formulation of furosemide. In this subject, the serum potassium level at baseline was 4.1 milliequivalents per liter, or mEq/L and dropped to 3.3 mEq/L after subcutaneous infusion of furosemide, which is slightly below the normal range of 3.5 mEq/L to 5.0 mEq/L. There were no serious adverse events reported.

We intend to support additional investigator sponsored studies post approval and 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 establish collaborations with third-party intermediaries outside of the United States to distribute our products in foreign markets, if approved by the relevant foreign regulatory authorities.

We believe that we can effectively commercialize FUROSCIX, if approved, 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 350 hospitals and associated clinics 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 physicians and specialists in our key hospital targets. Our target call points within these hospitals 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, current medications are sufficient 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 would have prescribed our product candidate. We expect to supplement our sales force with representatives in the medical science, nursing, and reimbursement field personnel 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 American Heart Association, hospital networks, and individual hospitals to update treatment and discharge 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.

We expect to package FUROSCIX, if approved, as individual on-body infusor packs, reimbursed through Medicare Part D. Hospital outpatient departments, clinics, and physician’s offices would be able to train and initially place FUROSCIX for the patient and may be eligible for reimbursement for these training services under Medicare Part B, so long as certain criteria are met. Inpatients transitioning out of the hospital who require additional days of treatment may obtain FUROSCIX on-body infusor packs outside of the acute care setting. In April 2016, we held a meeting with 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, effective and convenient subcutaneous therapy may benefit patients, caregivers and payers.

- *scFurosemide*: Our lead product candidate, FUROSCIX, consists of our proprietary subcutaneous formulation of furosemide, previously delivered via the sc2Wear Infusor and now delivered via the SmartDose drug delivery system, for treatment of congestion in decompensated heart failure patients outside of the acute care setting. We have completed a pivotal pharmacokinetic study, a clinical design validation study, and 12 human factor studies for FUROSCIX incorporating our first generation sc2Wear Infusor. Our future regulatory filings will be based on delivery of scFurosemide using the SmartDose drug delivery system. In addition, future clinical trials that we sponsor or conduct will be conducted using the SmartDose drug delivery system.
- *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 and plan to conduct a skin safety study in 2020 to support an expected NDA filing in 2021.
- *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 eliminate the risks of complications from long term IV catheters. They also would provide a level of convenience and independence to patients and caregivers with a potential reduction in 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 conduct additional studies to evaluate optimal delivery for ceftriaxone and to evaluate the skin safety of ceftriaxone administered subcutaneously. If results from our clinical program for subcutaneous ceftriaxone are positive, we expect to be in a position to submit an NDA for this drug-device combination product candidate in 2021.

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 Infusor

Beginning in February 2019, our lead product candidate, FUROSCIX, incorporates the next generation SmartDose drug delivery system developed in partnership with West. Prior to that time, FUROSCIX incorporated the sc2Wear Infusor, developed in partnership with Sensile.

The next generation FUROSCIX infusor is completely disposable and incorporates a pre-filled cartridge filled with the FUROSCIX drug product. The pre-filled cartridge creates an easy-to-use system that does not require patient filling. The system also incorporates the safety features expected by regulatory agencies and incorporates updates to West's first-generation device.

The FUROSCIX cartridge is placed in the delivery system and then applied to the patient's abdomen. With the push of a button, the device is activated and an electromechanical drive pushes the medication through a fluid path and delivers the drug formulation into the patient's subcutaneous tissue. Our subcutaneous delivery system can be worn while patients perform typical daily life activities during that time, which we believe allows patients to receive treatment with minimal interference with their daily routine.

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. Following our transition to the second generation delivery device, scFurosemide will be packaged in a proprietary cartridge from West. We believe that our current third-party manufacturers, including West, 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.

scFurosemide formulation

As of March 14, 2019, 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, one pending U.S. patent application directed to liquid pharmaceutical formulations, one pending U.S. patent application directed to methods of treatment and pharmaceutical formulations, one granted patent in Japan, one pending patent application in each of Canada, China, Europe and Japan, and one granted patent and eight 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 No. 9,884,039 is scheduled to expire in April 2034.

Other furosemide formulations

As of March 14, 2019, we also own a U.S. provisional patent application 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. A provisional patent application is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of filing of the provisional patent application. If we continue to pursue patent protection and file a non-provisional patent application with respect to our provisional patent application, and if any patents issue based on the non-provisional 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 U.S. Registration No. 4851675 for the mark SCPHARMACEUTICALS for pharmaceutical preparations and substances for the treatment of cardiovascular and cardiopulmonary diseases and disorders and we own U.S. Registration No. 5287573 for the mark FUROSCIX for diuretics and pharmaceutical preparations for the treatment of edema, congestive heart failures, cirrhosis, and renal disease. We also own pending trademark applications and trade names for scPharmaceuticals and FUROSCIX in the United States and the EU for use in connection with our pharmaceutical research and development and potential products.

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

Sensile License Agreement

In June 2015, we entered into a license agreement with Sensile Medical AG and its former affiliates, Sensile Holding AG and Sensile Patent AG, which we refer to collectively as Sensile, through which we had been granted certain intellectual property rights owned or controlled by Sensile, to develop, commercialize and sell a drug-device combination product for subcutaneous administration in a defined field, which included generic loop diuretics, certain generic therapies for cardiovascular indications, and certain generic infectious disease therapies, including antibiotics. Sensile also granted us an exclusive worldwide manufacturing license to permit us, or an alternative supplier, to make the drug-device combination product described above, which we outsourced to third-party manufacturers. On January 29, 2019, we issued to Sensile a notice of termination for business reasons under the license agreement. The termination will become effective as of March 30, 2019.

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 device, 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;
- 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 significantly extended by FDA requests for additional information or clarification and may go through multiple review cycles.

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. 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. 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.

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.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 clinical trials to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

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. The applicant may rely upon published literature and/or the FDA's findings of safety and effectiveness for a previously approved drug. 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 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, or QS, regulations 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, 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 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 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, 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 their 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 typically may not market or promote such off-label uses.

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 QS 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, REMS 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 of 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 below, 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 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, 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 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;

- the federal Health Insurance Portability and Accountability Act of 1996, or 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, 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 receive 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 Affordable Care Act 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 a 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 Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act 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 Affordable Care Act 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 Affordable Care Act-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 Affordable Care Act, 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 Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act 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 Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act 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 Affordable Care Act will impact the Affordable Care Act.

Other legislative changes have been proposed and adopted since the Affordable Care Act 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, 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.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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, 2018, we had 23 employees, including five in research and development, 10 in clinical and medical affairs, regulatory affairs and quality assurance and eight in finance, general administrative and executive administration, of which 21 were full-time employees and two of which were part- time employees. On January 28, 2019, based on the feedback we received from the FDA in the CRL and on our Type A and Type C meetings with the FDA, we reduced our workforce to 13 employees, 11 of which are full-time employees and two of which are 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 $24.4 million, $23.8 million and $29.4 million for the years ended December 31, 2016, 2017 and 2018, respectively. In addition, our accumulated deficit as of December 31, 2018 was $96.5 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 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. Furthermore, the CRL will delay any potential commercialization of FUROSCIX, potentially indefinitely. There can be no guarantee that the FDA will accept our refiled 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:

- timely refile 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. Refiling 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 (including the net proceeds from our completed initial public offering) primarily for 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 (including the net proceeds from our completed initial public offering) 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 refile 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 decided to discontinue use of the sc2Wear Infusor and transition to the SmartDose drug delivery system. We plan to refile an NDA for FUROSCIX incorporating the SmartDose drug delivery system.

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 May 2017, we entered into a secured credit facility pursuant to a loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank, providing for term loans of up to an aggregate of $10.0 million. All obligations under our secured credit facility are secured by substantially all of our existing property and assets (excluding 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 have delivered a notice of termination of our partnership with Sensile and may discontinue collaborative relationships with 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 decided to discontinue use of the sc2Wear Infusor and transition to the SmartDose drug delivery system. We plan to refile an NDA for FUROSCIX incorporating the SmartDose drug delivery system.

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 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. Further, as a result of our transition from the sc2Wear Infusor to the next generation SmartDose drug delivery system, the FDA may require that we conduct additional studies to bridge FUROSCIX or any of our other product candidates incorporating the SmartDose drug delivery system to the earlier versions incorporating the sc2Wear Infusor, which could delay our clinical development plan or marketing approval for our product candidates. 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 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 refile an NDA for FUROSCIX to reflect our transition to the SmartDose drug delivery system. We cannot assure you that the FDA or other regulatory authorities will not require us to conduct analytical comparability analyses and/or clinical studies before approving our product candidates incorporating our next generation device. Moreover, we cannot assure you that any analytical comparability analyses or clinical trials that we are required to conduct will be sufficiently robust to support approval or our product candidates incorporating our next generation device. Failure to demonstrate such comparability, if required, or if we are required to conduct additional testing or additional clinical studies, would 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 our submissions 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 for the treatment of cardiovascular and infectious diseases, 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 home environment after limited training, we cannot control the successful use of the product by patients, caregivers and healthcare professionals. We make use of packaging, instructions for use, quick reference guide and training video components 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 pharmaceuticals 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.

We submitted our NDA for FUROSCIX incorporating the sc2Wear Infusor to the FDA in August 2017 for approval under 505(b)(2) of the FDCA. 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.

We submitted our NDA for FUROSCIX incorporating the sc2Wear Infusor to the FDA in August 2017 for approval under 505(b)(2) of the FDCA. 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 product for which we, or they, receive marketing approval for only their approved indications, 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 Affordable Care Act, 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 Affordable Care Act 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 Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act 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 Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. 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 Affordable Care Act-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 Affordable Care Act, 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 Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act 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 Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act of 2017, the remaining provisions of the Affordable Care Act 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 Affordable Care Act will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act 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 it will continue to seek new legislative and/or administrative measures to control drug costs. 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 whether the FDA regulations, guidance or interpretations will be changed, 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 Affordable Care Act, 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 in 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 receive 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 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 contract research organization 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 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. Although currently all of our patents and some of our patent applications are in-licensed, 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 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 a 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 right 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, methods of manufacturing compounds 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 products 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, 2018, we had 23 full-time or part-time employees. On January 28, 2019, based on the feedback we received from the FDA in the CRL and on our Type A and Type C meetings with the FDA, we reduced our workforce to 13 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. 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.

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, 2018, we had federal net operating loss carryforwards of $17.5 million, which expire at various dates through 2037, and $12.0 million, which may be carried forward indefinitely. At December 31, 2018, the Company had available state net operating loss carryforwards of $26.4 million, which expire at various dates through 2038, and $0.1 million, which may be carried forward indefinitely. If not utilized, the net operating loss carryforwards will expire. At December 31, 2018, we had federal and state research and development tax credit carryforwards of $1.5 million and $0.4 million, respectively. If not utilized, the research and development credits expire at various dates through 2038. 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, 2018, 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 69.0% 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 19, 2019, there were 32 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.

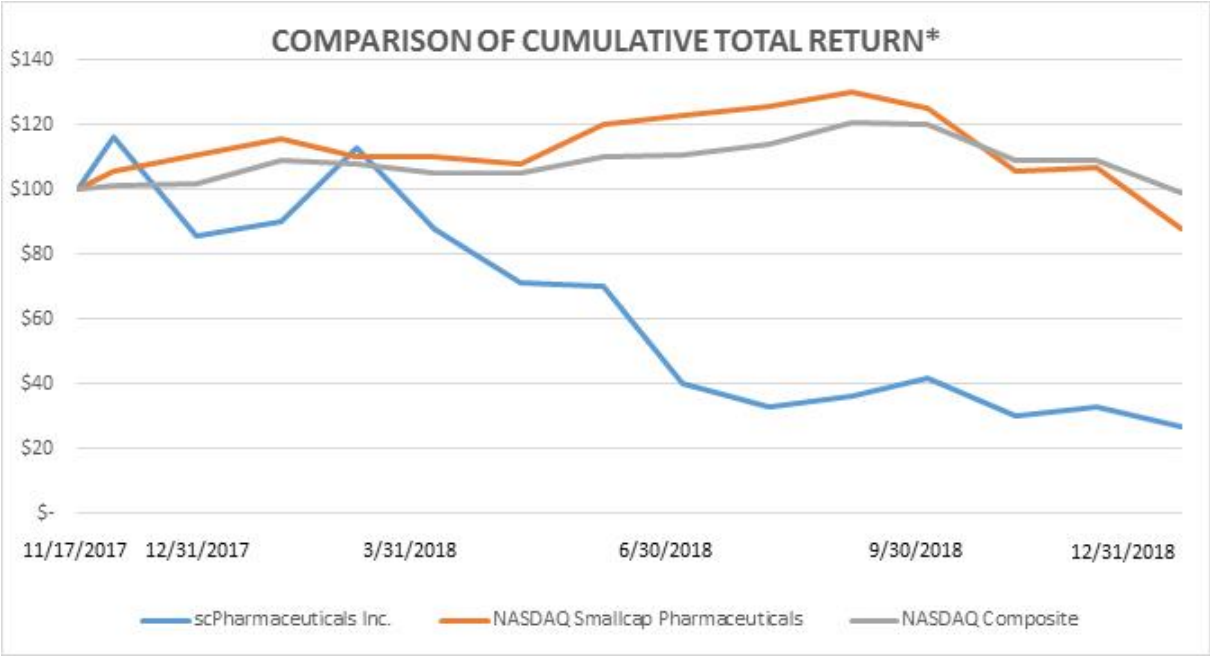
Issuer Purchases of Equity Securities

None.

Stock Performance Graph

The following graph shows a comparison from November 17, 2017, the date on which our common stock first began trading on the Nasdaq Global Select Market, of the cumulative total return on an assumed investment of $100.00 in cash on November 17, 2017, in our common stock as compared to the same investment in the Nasdaq Composite Index and the Nasdaq Smallcap Pharmaceuticals Index, all through December 31, 2018. These returns are based on historical results and are not intended to suggest future performance. Data assumes the reinvestment of dividends.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from the Nasdaq Stock Market LLC, a source believed to be reliable. The Nasdaq Stock Market LLC is not responsible for any errors or omissions in such information.



* $100 invested on November 17, 2017

Item 6. Selected Financial Data.

The selected statements of operations data for the years ended December 31, 2016, 2017 and 2018 and the balance sheet data as of December 31, 2017 and 2018 are derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected balance sheet data as of December 31, 2016 is derived from the audited consolidated financial statements that are not included in this Annual Report. 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)	2016	2017	2018
Consolidated Statements of Operations Data:			
Operating expenses:			
Research and development	$ 11,856	$ 14,331	$ 15,948
General and administrative	6,054	9,105	13,719
Total operating expenses	17,910	23,436	29,667
Loss from operations	(17,910)	(23,436)	(29,667)
Interest (expense) income, net	(6,505)	(456)	280
Other income (expense), net	38	75	(56)
Net loss and comprehensive loss	$ (24,377)	$ (23,817)	$ (29,443)
Net loss per share, basic and diluted (1)	$ (25.01)	$ (8.04)	$ (1.59)
Weighted-average common shares outstanding, basic and diluted (1)	974,660	2,962,859	18,556,126

(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)	2016	2017	2018
Consolidated Balance Sheet Data:			
Cash, cash equivalents and restricted cash (1)	$ 39,282	$ 118,480	$ 89,660
Working capital (2)	35,952	114,672	85,220
Total assets	40,091	122,048	93,755
Term loan	—	9,419	9,637
Convertible preferred stock	73,103	—	—
Accumulated deficit	(43,199)	(67,016)	(96,459)
Total stockholders' (deficit) equity	(37,074)	105,997	78,744

(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 transform the way therapy is delivered, advance patient care and reduce healthcare costs. Our proprietary platform 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 novel, buffered 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. The FDA notified us in October 2017 that it had accepted our NDA. On June 11, 2018 we received a Complete Response Letter, or CRL, from the FDA, which indicated that, among other things, certain device modifications to our 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, including clarification on an additional dose validation study and proposed device modifications necessary to advance FUROSCIX using the existing delivery technology, we have decided to discontinue use of the sc2Wear Infusor being developed in partnership with Sensile, and transition to our next generation device developed in partnership with West with their proprietary, wearable, SmartDose drug delivery system.

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. Prior to November 2017, we have funded our operations primarily with proceeds from the sale of preferred stock and borrowings under convertible notes and a term loan. As of December 31, 2018, we had received net cash proceeds of $56.7 million from sales of our preferred stock, net cash proceeds of $13.5 million from sales of convertible notes and net proceeds of $9.2 million from borrowings under our term loan. In November 2017, we closed our initial public offering with aggregate proceeds of $95.0 million, net of underwriters' discounts and commissions, before deduction of offering expenses of approximately $2.3 million.

For the years ended December 31, 2016, 2017 and 2018, our net loss was $24.4 million, $23.8 million and $29.4 million, respectively. We have not been profitable since inception, and as of December 31, 2018, our accumulated deficit was $96.5 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, continue research and development efforts, scale-up manufacturing, and seek regulatory approval for new product candidates and product enhancements. We will need additional funding to pay expenses relating 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;
- 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, 2017 and 2018

The following table summarizes our results of operations for the years ended December 31, 2017 and 2018:

(in thousands)	YEAR ENDED DECEMBER 31, 2017	2018	INCREASE (DECREASE)
Operating expenses:			
Research and development	$ 14,331	$ 15,948	$ 1,617
General and administrative	9,105	13,719	4,614
Total operating expenses	23,436	29,667	6,231
Loss from operations	(23,436)	(29,667)	6,231
Other income (expense)	75	(56)	(131)
Interest income	341	1,712	1,371
Interest expense	(797)	(1,432)	635
Net loss	$ (23,817)	$ (29,443)	$ 5,626

Research and development expenses. R&D expenses increased $1.6 million to $15.9 million during the year ended December 31, 2018, compared to $14.3 million during the year ended December 31, 2017. This increase was primarily attributable to a $1.0 million increase in employee-related costs due to growth within our clinical and medical affairs teams, a $1.1 million increase in clinical and medical affairs program activity, a $0.7 million increase in pharmaceutical development costs associated with batch manufacturing and testing, and a $0.2 million increase in facility costs during the year ended December 31, 2018. This increase was partially offset by a $0.7 million decrease in device development costs and a $0.7 million decrease in regulatory and quality assurance consulting.

General and administrative expenses. G&A expenses increased $4.6 million to $13.7 million during the year ended December 31, 2018, compared to $9.1 million during the year ended December 31, 2017. This increase was primarily attributable to a $1.1 million increase in employee-related expenses associated with the commercial organization growth in the first half of 2018 and stock-based compensation, a $1.2 million increase in consulting and professional services associated with preparation for the commercialization of FUROSCIX, if approved, and $2.2 million related to costs incurred as a public company, including expenses related to audit, legal, investor relations, board fees and director and officer insurance premiums, during the year ended December 31, 2018.

Other income (expense). Other income decreased $131,000 to $56,000 in other expense during the year ended December 31, 2018, compared to income of $75,000 during the year ended December 31, 2017. This decrease was primarily attributable to foreign exchange losses due to foreign currency fluctuations.

Interest income. Interest income increased $1.4 million to $1.7 million during the year ended December 31, 2018, compared to $341,000 during the year ended December 31, 2017. This increase was primarily attributable to higher cash balances during the year ended December 31, 2018 following our initial public offering in November 2017.

Interest expense. Interest expense increased $0.6 million from the year ended December 31, 2017 to $1.4 million during the year ended December 31, 2018. This increase was due to the $10.0 million loan entered into in May 2017 with Solar Capital Ltd. and Silicon Valley Bank which was outstanding for the full year in 2018.

Comparison of the Years Ended December 31, 2016 and 2017

The following table summarizes our results of operations for the years ended December 31, 2016 and 2017:

(in thousands)	YEAR ENDED DECEMBER 31, 2016	2017	INCREASE (DECREASE)
Operating expenses:			
Research and development	$ 11,856	$ 14,331	$ 2,475
General and administrative	6,054	9,105	3,051
Total operating expenses	17,910	23,436	5,526
Loss from operations	(17,910)	(23,436)	5,526
Other income	38	75	37
Interest income	7	341	334
Interest expense	(6,512)	(797)	(5,715)
Net loss	$ (24,377)	$ (23,817)	$ (560)

Research and development expenses. R&D expenses increased $2.5 million to $14.3 million during the year ended December 31, 2017, compared to $11.9 million during the year ended December 31, 2016. This increase was primarily attributable to a $0.4 million increase related to contract services for device engineering, a $1.1 million increase in regulatory consulting costs, a $0.3 million increase in supplies, storage and packaging costs related to clinical trials and development and a $1.7 million increase in employee-related expenses associated with additional headcount during the year ended December 31, 2017. This increase was partially offset by a $1.0 million decrease in outsourced clinical and medical affairs activity.

General and administrative expenses. G&A expenses increased $3.1 million to $9.1 million during the year ended December 31, 2017, compared to $6.1 million during the year ended December 31, 2016. This increase was primarily attributable to a $2.4 million increase in employee-related expenses associated with additional headcount and recruiting, a $0.7 million increase in consulting and professional services to support the expansion of our commercial organization, a $0.2 million increase in strategic and information technology consulting and $0.4 million related to costs incurred as a public company during the year ended December 31, 2017. This increase was partially offset by a $0.6 million decrease in market research and tradeshows.

Other income. Other income increased $37,000 to $75,000 during the year ended December 31, 2017, compared to $38,000 during the year ended December 31, 2016. This increase was primarily attributable to foreign exchange gains due to increased activity denominated in foreign currency combined with foreign currency fluctuations.

Interest income. Interest income increased $334,000 to $341,000 during the year ended December 31, 2017, compared to $7,000 during the year ended December 31, 2016. This increase was primarily attributable to higher cash balances during the year ended December 31, 2017 following our initial public offering in November 2017.

Interest expense. Interest expense decreased $5.7 million from the year ended December 31, 2016 to $0.8 million during the year ended December 31, 2017. This decrease was primarily attributable to the conversion of convertible notes issued in January 2016 into Series A preferred stock in August 2016.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through December 31, 2018 primarily through the sale of shares of our common stock in our initial public offering and, prior to that, through the private placement of our preferred stock and the incurrence of debt. As of December 31, 2018, we had received net cash proceeds of $92.7 million from our initial public offering, $56.7 million from sales of our preferred stock, and $13.5 million in net proceeds from convertible notes payable. Additionally, in May 2017 we incurred $10.0 million of debt under a loan and security agreement with Solar Capital Ltd. and Silicon Valley Bank. As of December 31, 2018, we had cash, cash equivalents and restricted cash of $89.7 million.

We expect to incur substantial additional expenditures in the next twelve 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 2020. 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 refile an 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. In November 2018 and December 2018, we entered into the First Amendment to the Loan and Security Agreement and the Second Amendment to the Loan and Security Agreement, respectively, collectively the “Amendments”. Upon execution of the First Amendment to the Loan and Security Agreement, we paid the lenders an Amendment Fee of $35,000. Additional fees incurred by the lenders for the Amendments, totaling $27,000, were paid subsequent to the execution of such Amendments.

The interest rate under the 2017 Loan Agreement is 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, which currently runs through May 2019. If and when certain conditions are met, the interest-only period may be extended to August or 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.

As of December 31, 2018, unpaid borrowings under the 2017 Loan Agreement totaled $10.0 million. For the year ended December 31, 2018, we recorded $280,000 related to the amortization of debt discount associated with the 2017 Loan Agreement.

The 2017 Loan Agreement allows us 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 of the 2017 Loan Agreement, prepayment of such borrowings or the acceleration of payment due to an event of default. The final payment fee was increased to $325,000 in the First Amendment to the Loan and Security Agreement. For the year ended December 31, 2018, we recorded $94,000 related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

In an event of default under the 2017 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 in connection with the 2017 Loan Agreement which provides for a payment to the lenders upon the occurrence of an exit event, as defined in the agreement, including an initial public offering, equal to 4% of the loan commitment, or $400,000. We paid this fee in November 2017 concurrent with our initial public offering.

The 2017 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.

CASH FLOWS

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

	YEAR ENDED DECEMBER 31,		
(in thousands)	**2016**	**2017**	**2018**
Net cash (used in) provided by:			
Operating activities	$ (15,455)	$ (22,682)	$ (28,812)
Investing activities	(9)	(194)	—
Financing activities	53,173	102,074	(8)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 37,709	$ 79,198	$ (28,820)

Net Cash Used in Operating Activities

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 decrease in working capital. 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.

During the year ended December 31, 2017, net cash used in operating activities was $22.7 million, consisting primarily of a net loss of $23.8 million and $0.2 million decrease in working capital. This was offset by non-cash charges of $1.3 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.

During the year ended December 31, 2016, net cash used in operating activities was $15.5 million, consisting primarily of a net loss of $24.4 million, offset by a decrease in net operating assets of $1.4 million and non-cash charges of $7.5 million. The decrease in net operating assets primarily consisted of increased accruals for pharmaceutical development and accounts payable for clinical trials, device engineering costs, the expansion of our commercial organization, and legal costs associated with our Series B preferred stock financing. 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 convertible notes payable.

Net Cash Used in Investing Activities

During the years ended December 31, 2016 and 2017, net cash used in investing activities consisted of purchases of property and equipment.

Net Cash Provided by (Used in) Financing Activities

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.

During the year ended December 31, 2017, net cash provided by financing activities was $102.1 million, consisting primarily of net proceeds of $92.7 million from our initial public offering, $9.3 million in borrowings under the 2017 Loan Agreement, and $0.1 million in proceeds from stock option exercises.

During the year ended December 31, 2016, net cash provided by financing activities was $53.2 million, consisting primarily of net proceeds of $40.6 million from the issuance of Series B convertible preferred stock and net proceeds of $12.5 million from convertible notes payable.

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, 2018 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	LESS THAN 1 YEAR	1-3 YEARS	3-5 YEARS	MORE THAN 5 YEARS
Operating lease obligations (1)	$ 2,074	$ 513	$ 1,065	$ 496	$ —
Total	$ 2,074	$ 513	$ 1,065	$ 496	$ —

(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 $10.0 million from our 2017 Loan Agreement, as of December 31, 2018. Our contractual commitments under the 2017 Loan Agreement as of December 31, 2018 consist of an aggregate of $11.9 million in repayment obligations, inclusive of related interest amounts and a $325,000 final fee. See "—Loan and Security Agreement" for additional information regarding the 2017 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.

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. 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 awards 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 are required to 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.
- *Fair value of common stock.* Prior to the IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be a date later than the most recent third-party valuation date, including:
    - the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
    - the progress of our research and development programs, including the status of preclinical studies and planned clinical trials for our product candidates;
    - our stage of development and commercialization and our business strategy;
    - external market conditions affecting the pharmaceutical and biotechnology industries, and trends within the biotechnology industry;
    - our financial position, including cash on hand, and our historical and forecasted performance and operating results;
    - the lack of an active public market for our common stock and our preferred stock;
    - the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or a sale of our company in light of prevailing market conditions; and
    - the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

Consequently, after the IPO, the fair value of the shares of common stock underlying the stock options is the closing price on the option grant date.

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, 2018, our aggregate outstanding indebtedness was $10.0 million, which bears interest at the rate equal to LIBOR plus 8.45%. 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. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' (deficit) equity and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle
As discussed in Note 2 to the financial statements, the Company elected to change its method of accounting for leasing transactions due to the adoption of Financial Accounting Standard Board's Accounting Standards Update 2016-02, *Leases*. This change has been retrospectively applied as of January 1, 2016.

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 21, 2019

SCPHARMACEUTICALS INC.

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

	DECEMBER 31, 2017 (as adjusted)	DECEMBER 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 118,298	$ 89,478
Prepaid expenses	823	1,757
VAT receivable	655	479
Other current assets	107	179
Total current assets	119,883	91,893
Restricted cash	182	182
Property and equipment, net	203	164
Right-of-use lease assets - operating (Type B), net	1,773	1,506
Deposits and other assets	7	10
Total assets	$ 122,048	$ 93,755
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,591	$ 587
Accrued expenses	3,063	2,922
Term loan, short term	314	2,811
Current portion of lease obligation - operating (Type B)	242	353
Other current liabilities	1	—
Total current liabilities	5,211	6,673
Term loan, long term	9,105	6,826
Long term lease obligation - operating (Type B)	1,683	1,353
Other liabilities	52	159
Total liabilities	16,051	15,011
Commitments and contingencies (Note 13)		
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, 2018; 18,534,240 and 18,569,289 shares issued and outstanding at December 31, 2017 and December 31, 2018, respectively	2	2
Additional paid-in capital	173,011	175,201
Accumulated deficit	(67,016)	(96,459)
Total stockholders' equity	105,997	78,744
Total liabilities and stockholders' equity	$ 122,048	$ 93,755

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,		
	2016	2017	2018
Operating expenses:			
Research and development	$ 11,856	$ 14,331	$ 15,948
General and administrative	6,054	9,105	13,719
Total operating expenses	17,910	23,436	29,667
Loss from operations	(17,910)	(23,436)	(29,667)
Other income (expense)	38	75	(56)
Interest income	7	341	1,712
Interest expense	(6,512)	(797)	(1,432)
Net loss and comprehensive loss	$ (24,377)	$ (23,817)	$ (29,443)
Net loss per share, basic and diluted	$ (25.01)	$ (8.04)	$ (1.59)
Weighted—average common shares outstanding, basic and diluted	974,660	2,962,859	18,556,126

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

SCPHARMACEUTICALS INC.

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

	CONVERTIBLE PREFERRED STOCK				STOCKHOLDERS' (DEFICIT) EQUITY				
	SERIES A		SERIES B		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' (DEFICIT) EQUITY
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT			
At December 31, 2015	17,565,679	$ 18,073	—	$ —	825,577	$ —	$ 582	$ (18,822)	$ (18,240)
Net loss	—	—	—	—	—	—	—	(24,377)	(24,377)
Beneficial conversion features on convertible notes payable	—	—	—	—	—	—	4,653	—	4,653
Conversion of convertible notes payable to Series A convertible preferred stock	8,183,792	8,429	—	—	—	—	—	—	—
Conversion of convertible notes payable to Series B convertible preferred stock	—	—	5,962,784	5,963	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of costs of $362	—	—	41,000,000	40,638	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	8,900	—	1	—	1
Vesting of restricted stock	—	—	—	—	235,610	—	13		13
Stock-based compensation	—	—	—	—	—	—	876	—	876
At December 31, 2016	25,749,471	26,502	46,962,784	46,601	1,070,087	—	6,125	(43,199)	(37,074)
Net loss	—	—	—	—	—	—	—	(23,817)	(23,817)
Issuance of common stock upon initial public offering, net of $7.1 million in underwriting discounts and commissions and $2.3 million in offering costs	—	—	—	—	7,294,968	1	92,709	—	92,710
Automatic conversion of preferred stock	(25,749,471)	(26,502)	(46,962,784)	(46,601)	10,126,771	1	73,124	—	73,125
Issuance of common stock upon exercise of stock options	—	—	—	—	39,636	—	101	—	101
Vesting of restricted stock	—	—	—	—	2,778	—	5		5
Stock-based compensation	—	—	—	—	—	—	947	—	947
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

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,		
	2016 (as adjusted)	2017 (as adjusted)	2018
Cash flows from operating activities			
Net loss	$ (24,377)	$ (23,817)	$ (29,443)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation expense	5	17	38
Amortization expense - right-of-use leased assets - operating (Type B)	91	150	294
Stock-based compensation	876	947	2,135
Non-cash interest expense	6,512	198	374
Changes in operating assets and liabilities			
Prepaid expenses and other assets	(214)	(1,128)	(833)
Accounts payable, accrued expenses and other liabilities	1,652	951	(1,377)
Net cash flows used in operating activities	(15,455)	(22,682)	(28,812)
Cash flows from investing activities			
Purchases of property and equipment	(9)	(194)	—
Net cash flows used in investing activities	(9)	(194)	—
Cash flows from financing activities			
Proceeds from common stock offering, net of underwriter discounts and offering costs	—	92,710	(4)
Proceeds from term loan, net of costs	—	9,273	(62)
Proceeds from issuance of Series B convertible preferred stock	41,000	—	—
Costs related to issuance of Series B convertible preferred stock	(362)	(8)	—
Proceeds from issuance of convertible notes	12,600	—	—
Costs related to issuance of convertible notes	(66)	—	—
Proceeds from the early exercise of stock options	—	1	—
Proceeds from the exercise of vested stock options	1	101	58
Purchase of restricted stock	—	(3)	—
Net cash flows provided by (used in) financing activities	53,173	102,074	(8)
Net increase (decrease) in cash	37,709	79,198	(28,820)
Cash, cash equivalents and restricted cash, beginning of year	1,573	39,282	118,480
Cash, cash equivalents and restricted cash, end of year	$ 39,282	$ 118,480	$ 89,660
Supplemental cash flow information			
Interest paid	$ —	$ 599	$ 1,059
Taxes paid	—	14	298
Supplemental disclosure of non-cash activities			
Conversion of convertible preferred stock into common stock	$ —	$ 73,102	$ —
Conversion of convertible notes into convertible preferred stock, including accrued interest	14,392	—	—
Beneficial conversion feature of convertible notes	4,653	—	—
Vesting of restricted stock	(13)	(5)	(1)
Acquisition of right-of-use leased assets - operating (Type B), net of disposal	—	1,603	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 transform the way therapy is delivered, advance patient care and reduce healthcare costs. The Company’s proprietary platform is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or 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, 2018, the Company had cash, cash equivalents and restricted cash of $89.7 million and working capital of $85.2 million. During the year ended December 31, 2018, the Company incurred a net loss totaling $29.4 million and used cash in operating activities totaling $28.8 million. The Company expects to continue to incur losses and use cash in operating activities in 2019.

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 $89.5 million as of December 31, 2018 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, valuation of stock options used for the calculation of stock-based compensation prior to the Company’s IPO, valuation of common and preferred stock used in the determination of the beneficial conversion feature of convertible notes and preferred stock, 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, 2018, 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 13). Cash, cash equivalents and restricted cash consists of the following:

	December 31, 2017	December 31, 2018
Cash and cash equivalents	$ 118,298	$ 89,478
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 118,480	$ 89,660

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, the Company had no such accruals.

Stock-Based Compensation

Stock-based compensation expense is recognized based on the grant-date fair value using the Black-Scholes valuation model. 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.

The Company accounts for stock-based awards issued to non-employees by recognizing compensation expense based on the fair value of such awards when the services are completed over the vesting period of the award.

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.

Change in Accounting Principle

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases that extend more than twelve months from the balance sheet date. This accounting update also requires additional disclosures surrounding the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. Early adoption is permitted. The Company elected to early adopt ASU 2016-02 as of January 1, 2018 with retrospective application to January 1, 2016, the beginning of the earliest period to be presented in the Annual Report on Form 10-K for the year ended December 31, 2018. The Company has elected the package of practical expedients permitted in ASC Topic 842. Accordingly, the Company accounted for its existing operating leases as operating leases under the new guidance, without reassessing (a) whether the contracts contain a lease under ASC Topic 842, (b) whether classification of the operating leases would be different in accordance with ASC Topic 842, or (c) whether the unamortized initial direct costs before transition adjustments (as of December 31, 2015) would have met the definition of initial direct costs in ASC Topic 842 at lease commencement. The Company does not allocate the consideration between lease and non-lease components. As a result of the adoption of the new lease accounting guidance, the Company recognized on January 1, 2016 (a) a lease liability of approximately $409,000, which represents the present value of the remaining lease payments, as of the date of adoption, of approximately $540,000, discounted using the Company's incremental borrowing rate of 9.63%, and (b) a right-of-use asset of approximately $396,000 which represents the lease liability of $409,000 adjusted for accrued rent of approximately $13,000. Adoption of the standard requires the Company to restate certain previously reported results, including the recognition of additional ROU assets and lease obligations for operating leases. This standard did not have a material impact on the Company's consolidated balance sheets or cash flows from operations and had no impact on the Company's operating results. The most significant impact was the recognition of ROU assets and lease obligations for operating leases.

Recently Issued Accounting Standards

In May 2014, the FASB and the International Accounting Standards Board jointly issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606) ("ASC 606"), which supersedes the revenue recognition requirements in ASC 605 and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services. The update also requires additional disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASC 606 is effective for public entities for annual and interim periods within those annual periods beginning after December 15, 2017. The Company has adopted ASC 606 as of January 1, 2018 and there was no impact to the Company's financial statements. The future impact of ASC 606 will be dependent on the nature of the Company's future revenue contracts and arrangements, if any.

In July 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10"). ASU 2018-10 is intended to address questions on the application of ASU No. 2016-02 and to clarify its guidance. ASU 2018-10 is effective for financial statements issued for annual and interim periods beginning after December 15, 2018 for public business entities. For entities who have early adopted ASU No. 2016-02, the guidance is effective upon the issuance of ASU 2018-10. The Company adopted ASU 2018-10 in July 2018 and there was no impact to the Company's financial statements.

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 convertible preferred stock, 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, 2016	DECEMBER 31, 2017	DECEMBER 31, 2018
Net loss and comprehensive loss	$ (24,377)	$ (23,817)	$ (29,443)
Weighted—average common shares outstanding, basic and diluted	974,660	2,962,859	18,556,126
Net loss per share, basic and diluted	$ (25.01)	$ (8.04)	$ (1.59)

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, 2016	DECEMBER 31, 2017	DECEMBER 31, 2018
Convertible preferred stock, on an as-converted basis	10,126,771	—	—
Stock options to purchase common stock	444,410	1,195,495	1,588,306
Unvested restricted stock	5,053	488	—
	10,576,234	1,195,983	1,588,306

4. Property and Equipment

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

	ESTIMATED USEFUL LIFE	2017	2018
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		(26)	(65)
Property and equipment, net		$ 203	$ 164

Depreciation expense for the years ended December 31, 2016, 2017 and 2018 was $5,000, $17,000 and $38,000, respectively.

Leased property and equipment consist of the following as of December 31, (dollars in thousands):

	ESTIMATED USEFUL LIFE	2017	2018
Right-of-use lease assets - operating (Type B)	Lease term	$ 2,014	$ 2,041
Less: Accumulated amortization		(241)	(535)
Right-of-use lease assets - operating (Type B), net		$ 1,773	$ 1,506

Amortization expense for the years ended December 31, 2016, 2017 and 2018 was $91,000, $150,000, and $294,000, respectively.

5. Accrued Expenses

Accrued expenses at December 31 consist of (in thousands):

	2017	2018
Contract research and development	$ 1,610	$ 1,492
Employee compensation and related costs	871	860
Consulting and professional service fees	287	356
State taxes	192	165
Financing related costs	90	—
Other	13	49
Total accrued expenses	$ 3,063	$ 2,922

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 statements 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, 2017 and 2018. Components of the net deferred tax asset at December 31, 2017 and 2018 are as follows (in thousands):

	2017	2018
Federal net operating loss carryforwards	$ 3,672	$ 6,189
State net operating loss carryforwards	1,000	1,670
Research and development tax credits	1,087	1,824
Accrued liabilities	278	257
Stock-based compensation	—	510
Depreciation and amortization	10	10
Capitalized research and development costs	10,452	14,227
Other	153	20
	16,652	24,707
Valuation allowance	(16,652)	(24,707)
Net deferred tax asset	$ —	$ —

At December 31, 2018, the Company had available federal net operating loss carryforwards of $17.5 million, which expire at various dates through 2037, and $12.0 million, which may be carried forward indefinitely. At December 31, 2018, the Company had available state net operating loss carryforwards of $26.4 million, which expire at various dates through 2038, 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, 2017 and 2018 since it is more likely than not that these future tax benefits will not be realized. During 2018, the valuation allowance increased by $8.1 million.

At December 31, 2018, the Company had federal and state research and development credit carryforwards of $1.5 million and $0.4 million, respectively. The net credit carryforwards may be used to offset future income taxes and expire at various dates through 2038. 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%. In the fourth quarter of 2017, the Company recognized a provisional charge of $6.9 million for the revaluation of the Company's deferred tax assets at the lower enacted corporate tax rate. This charge was offset by a corresponding reduction in the valuation allowance. U.S. GAAP requires companies to recognize the effect of tax law changes in the period of enactment. The Company's assessment of the remeasurement of deferred tax assets at the lower enacted corporate tax rate is now complete.

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, 2016, 2017 and 2018 are as follows:

	2016	2017	2018
Federal income tax at statutory rate	34.00%	34.00%	21.00%
State income tax, net of federal benefit	3.46%	4.85%	5.45%
Research and development credits	1.46%	2.07%	2.35%
Book compensation related to stock options	(0.93)%	(0.16)%	(0.61)%
Change in income tax rate	(0.18)%	—	(0.38)%
Effect on Tax Cuts & Job Acts rate reduction	—	(29.15)%	—
Non-cash interest	(9.08)%	—	—
Other	(0.40)%	(0.51)%	(0.45)%
Increase in valuation allowance	(28.33)%	(11.10)%	(27.36)%
Effective tax rate	—%	—%	—%

The Company files tax returns in the United States, Massachusetts and other states. The tax years 2015 through 2018 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):

	2016	2017	2018
Beginning uncertain tax benefits	$ 104	$ 178	$ 284
Prior year - increases	—	—	46
Current year - decreases	—	(19)	—
Current year - increases	74	125	146
Ending uncertain tax benefits	$ 178	$ 284	$ 476

7. Stock-Based Compensation

Stock Options

The Company's 2014 Stock Incentive Plan (the "2014 Stock Plan") terminated in November 2017 effective upon the completion of the Company's initial public offering. No additional options will be granted under the 2014 Stock Plan. At December 31, 2018, there were 946,609 options outstanding under the 2014 Stock Plan.

In October 2017, the board of directors approved the 2017 Stock Option and Incentive Plan (or the "2017 Stock Plan") which became effective in November 2017, upon the closing of the initial public offering. 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 and other stock-based awards. 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 will automatically increase 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 and January 1, 2019, the number of shares issuable under the 2017 Stock Plan increased by 741,389 and 742,772 shares, respectively.

Total stock-based compensation expense, including the effect of forfeitures, recorded in research and development and general and administrative expenses, respectively, for employees, directors and non-employees during the years ended December 31, 2016, 2017 and 2018 is as follows (in thousands):

	2016	2017	2018
Research and development	$ 175	$ 159	$ 567
General and administrative	701	788	1,568
Total	$ 876	$ 947	$ 2,135

At December 31, 2018, there were 1,686,893 options available for issuance and 641,697 options outstanding under the 2017 Stock Plan. Options granted under the 2017 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:

	2016	2017	2018
Risk-free interest rate	1.08%—1.58%	1.89%—2.24%	2.42%—2.86%
Expected dividend yield	0%	0%	0%
Expected life	6.0—6.4 years	5.0—7.0 years	5.5—7.0 years
Expected volatility	86%—93%	78%—88%	76%—86%
Weighted-average grant date fair value	$ 6.51	$ 3.62	$ 7.57

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 2017 and 2018 (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, 2016	444,410	$ 6.99		
Granted	888,497	4.82		
Exercised	(39,722)	2.57		
Forfeited	(97,690)	8.88		
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	8.44	$ 86
Vested and exercisable, December 31, 2018	572,376	$ 5.23	7.71	$ 86
Vested and expected to vest, December 31, 2018	1,391,103	$ 6.71	8.37	$ 86

During 2016, 2017 and 2018, the Company received $1,000, $102,000 and $58,000, respectively, upon exercise of stock options. The intrinsic value of the options exercised in 2016, 2017 and 2018 was $64,000, $330,000 and $270,000, respectively. Among those options exercised, 86 were exercised prior to vesting in 2017 pursuant to the 2014 Stock Plan. Options exercised prior to vesting are held under restricted stock agreements and will vest according to the provisions under the original stock option agreements. The cash received upon early exercise of options, $1,000 in 2017, was recorded as a deposit liability on the Company's consolidated balance sheet and was recorded as common stock and additional paid in capital as the shares vested in 2018. The Company repurchased 1,871 unvested restricted stock shares in 2017 for $3,000. The deposit liability as of December 31, 2017 was $1,000.

Unrecognized compensation expense related to unvested awards as of December 31, 2018 was $3.5 million, net of forfeitures, 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 2.62 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.

Restricted Stock

At the time of the Company's conversion from a Limited Liability Company to a Delaware Corporation in 2014, the Company imposed restrictions on 821,512 shares of common stock owned by a founder ("2014 Restricted Stock Awards"). The terms of the restrictions allowed for 50% of the shares to vest immediately, with the remainder of the shares vesting over 3 years. The initial vesting of the shares was deemed to be non-substantive for accounting purposes, as there was no service required for the lapse of the restrictions. The fair value of the common stock at the time of the restrictions was $1.66.

In May 2016, the Company terminated its right to repurchase the remaining unvested shares of the 2014 Restricted Stock Awards, thereby causing all unvested shares to become vested and any unrecognized compensation to be accelerated. During the year ended December 31, 2016, $0.4 million was recognized as compensation expense for the vesting of the 2014 Restricted Stock Awards.

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 Company does not have any recurring fair value measurements as of December 31, 2018. The carrying values of the Company's cash, cash equivalents and restricted cash, prepaid expenses, 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 Company's cash equivalents are classified within Level 1 of the fair value hierarchy. The following table summarizes the Company's money market funds as of December 31, 2018 (in thousands):

	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents:				
Cash equivalents	$ 75,306	$ 75,306	$ —	$ —
Total cash equivalents	$ 75,306	$ 75,306	$ —	$ —

9. Term Loan

In May 2017, the Company entered into a loan and security agreement, or 2017 Loan Agreement, with Solar Capital Ltd. and Silicon Valley Bank for $10.0 million. The 2017 Loan Agreement has a maturity date of May 1, 2021.

In connection with the 2017 Loan Agreement, the Company entered into an exit fee agreement which provides for an aggregate payment of 4% of the loan commitment, or $400,000, to the lenders upon the occurrence of an exit event, including an initial public offering. 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 payment obligation of $392,000 as a derivative liability in the Company's consolidated balance sheet. The Company paid the fee in November 2017 in conjunction with the Company's IPO.

Debt issuance costs for the 2017 Loan Agreement amounting to $727,000, including the exit payment obligation, were recorded as a debt discount in 2017. In November 2018 and December 2018, the Company entered into the First Amendment to the Loan and Security Agreement and the Second Amendment to the Loan and Security Agreement, respectively, collectively the “Amendments”. In connection with the Amendments, the Company incurred additional debt issuance costs of $62,000. The debt issuance costs will 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 is 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, which currently runs through May 2019. If and when certain conditions are met, the interest-only period may be extended to August or November 2019. The rate at December 31, 2018 was 10.82888%. 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.

As of December 31, 2018, unpaid borrowings under the 2017 Loan Agreement totaled $10.0 million. For the years ended December 31, 2017 and 2018, the Company recorded $146,000 and $280,000, respectively, related to the amortization of debt discount associated with the 2017 Loan Agreement.

The 2017 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 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 Loan and Security Agreement. For the years ended December 31, 2017 and 2018, the Company recorded $52,000 and $94,000, respectively, related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

In an event of default under the 2017 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 2017 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, 2017	DECEMBER 31, 2018
Face value	$ 10,000	$ 10,000
Less: discount	(581)	(363)
Total	$ 9,419	$ 9,637
Less: current portion	(314)	(2,811)
Long-term portion	$ 9,105	$ 6,826

As of December 31, 2018, future principal payments due under the 2017 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2019	$ 2,917
December 31, 2020	5,000
December 31, 2021	2,083
Total minimum principal payments	$ 10,000

10. Convertible Notes

On January 21, 2016, the Company executed a Convertible Note Purchase Agreement ("the January 2016 Convertible Note Purchase Agreement") under which the Company was authorized to issue $7.5 million in convertible promissory notes in an initial closing, subsequent closing and a second closing tied to the achievement of development milestones. The initial closing occurred on January 21, 2016 whereby the Company issued $3.0 million of convertible notes pursuant to the January 2016 Convertible Note Purchase Agreement.

In January and February 2016, the Company issued $0.7 million of additional convertible notes as part of the subsequent closing to the January 2016 Convertible Note Purchase Agreement.

The Company achieved the development milestones in May 2016 and, as such, was able to draw on the second closing of the January 2016 Convertible Note Purchase Agreement.

In May and June 2016, the Company issued $3.7 million of additional convertible notes as part of the second closing to the January 2016 Convertible Note Purchase Agreement.

On July 1, 2016, the Company executed the First Amendment to Note Purchase Agreement which replaced the principal amount of notes to which Company could issue with $8.2 million. On July 7, 2016, the Company issued $0.6 million of additional convertible notes under the First Amendment to Note Purchase Agreement.

Principal and interest on all note issuances under the January 2016 Convertible Note Purchase Agreement, which accrued at a rate of 8% per annum, was due and payable upon the earlier of written demand by holders of the requisite noteholders any time on or after January 21, 2017, unless earlier converted upon automatic conversion at (i) a "Qualified Equity Financing" where such transaction results in the Company having raised gross proceeds of at least $15.0 million or (ii) a "Qualified IPO" where the Company sells shares of common stock to investors at a price per share equal to at least $21.55 and gross proceeds to the Company of at least $35.0 million, or upon optional conversion at (i) a "Non-Qualified Equity Financing" or (ii) a "Non-Qualified IPO" or upon the sale of the Company.

Certain of the conversion features of the notes under the January 2016 Convertible Note Purchase Agreement allowed holders to convert principal and interest on each issuance into shares of the Company at a discount. The conversion price was equal to eighty percent (80%) of the per share price at which shares of equity financing securities or common stock are to be sold.

Based on the terms of the notes under the January 2016 Convertible Note Purchase Agreement and the Company's assessment that conversion of the notes prior to maturity in a "Qualified Equity Financing" was the predominant feature, the Company determined that the notes were share-settled debt, and as such accreted the notes over their term, to the value of the preferred stock into which the notes would be converted, $9.9 million, recognizing accretion to the redemption value through the date the convertible notes were converted as interest expense.

Upon maturity, the noteholders had the option to convert any outstanding principal and accrued but unpaid interest into shares of Series A convertible preferred stock at a purchase price equal to $1.00. This embedded conversion feature met the definition of a beneficial conversion feature and was recognized by allocating a portion of the proceeds equal to the intrinsic value of the beneficial conversion feature measured at the commitment date, or $4.7 million, to additional paid in capital. The accretion of the beneficial conversion feature was recognized through the date the convertible notes were converted as interest expense.

The Company allocated $38,000 in transaction costs as a discount to the notes.

On August 22, 2016, the Company executed the Second Amendment to Note Purchase Agreement and Election to Convert. This amendment added a conversion option to convert the outstanding principal and accrued but unpaid interest into Series A convertible preferred stock at a purchase price equal to $1.00. At that time, the convertible notes, plus accrued interest, converted into 8,183,792 shares of Series A convertible preferred stock pursuant to the new redemption feature (Note 11).

The amendment was treated as an extinguishment of debt which required the carrying value of the debt to be derecognized and the fair value of the debt to be recognized as new debt. At the amendment date, the carrying value of the debt included principal of $8.0 million, and accrued interest, accretion to the redemption value, and accretion of the beneficial conversion feature of $0.2 million, $0.9 million, and $2.1 million, respectively. Additionally, the unamortized beneficial conversion feature of $2.6 million was allocated to the carrying value of the debt and the fair value of the new debt was established at $8.4 million. The intrinsic value of the beneficial conversion feature was measured at the amendment date, $0.3 million, and recorded as a reduction in additional paid in capital. The loss on extinguishment of $1.8 million was recorded as interest expense.

On August 22, 2016, the Company executed a Note Purchase Agreement (“the August 2016 Note Purchase Agreement”) under which the Company was authorized to issue $10.0 million in convertible promissory notes in an initial closing, second closing, third closing, and subsequent closings. The second closing was subject to the second closing development milestone. The third closing was subject to the third closing development milestone. The subsequent closings had to occur on or before the occurrence of the third closing.

The initial closing occurred on August 22, 2016 whereby the Company issued $4.0 million of convertible notes pursuant to the August 2016 Note Purchase Agreement.

In September 2016, the Company issued $0.7 million of additional convertible notes as part of the subsequent closing to the August 2016 Note Purchase Agreement.

Principal and interest on all note issuances under the August 2016 Note Purchase Agreement, which accrued at a rate of 8% per annum, was due and payable upon the earlier of written demand by holders of the requisite noteholders any time on or after August 22, 2017, unless sooner accelerated upon automatic conversion at (i) a “Qualified Equity Financing” where such transaction results in the Company having raised gross proceeds of at least $25.0 million or (ii) a “Qualified IPO” where the Company sells shares of common stock to investors at a price per share equal to at least $21.55 and gross proceeds to the Company of at least $40.0 million, or upon optional conversion at (i) a “Non-Qualified Equity Financing” or (ii) a “Non-Qualified IPO” or upon the sale of the Company.

Certain of the conversion features of the notes under the August 2016 Note Purchase Agreement allowed holders to convert principal and interest on each issuance into shares of the Company at a discount. For the Qualified Equity Financing, the conversion price was equal to ninety percent (90%), if converted before the 60th day following the initial closing, or eighty percent (80%), thereafter, of the per share price at which shares of equity financing securities or common stock are to be sold. For all other applicable conversion features, the conversion price was equal to eighty percent (80%) of the per share price.

Based on the terms of the notes under the August 2016 Convertible Note Purchase Agreement and the Company’s assessment that conversion of the notes prior to maturity in a “Qualified Equity Financing” was the predominant feature, the Company determined that the notes were share-settled debt, and as such accreted the notes over their term, to the value of the preferred stock into which the notes would be converted, $5.8 million, recognizing accretion to the redemption value through the date the convertible notes were converted as interest expense.

Upon maturity, the noteholders have the option to convert any outstanding principal and accrued but unpaid interest into shares of Series A convertible preferred stock at a purchase price equal to $1.00. This embedded conversion feature meets the definition of a beneficial conversion feature and was recognized by allocating a portion of the proceeds equal to the intrinsic value of the beneficial conversion feature measured at the commitment date, or $0.2 million, to additional paid in capital. The accretion of the beneficial conversion feature was recognized through the date the convertible notes were converted as interest expense.

The Company allocated $28,000 in transaction costs as a discount to the notes.

On December 22, 2016, pursuant to the August 2016 Note Purchase Agreement and in connection with the issuance of Series B convertible preferred stock (Note 11), the convertible notes and accrued interest converted into 5,962,784 shares of Series B convertible preferred stock.

The redemption was treated as an extinguishment of debt which required the carrying value of the debt to be derecognized and the fair value of the debt to be recognized as new debt. At the redemption date, the carrying value of the debt included principal of $4.7 million, and accrued interest, accretion to the redemption value, and accretion of the beneficial conversion feature of $120,000, $356,000, and $60,000, respectively. Additionally, the unamortized portion of the beneficial conversion feature of $126,000 was allocated to the carrying value of the debt and the fair value of the new debt was established at $6.0 million. The beneficial conversion feature at the conversion date was determined to be out of the money and, as such, was derecognized. The loss on extinguishment of $1.0 million was recorded as interest expense.

11. Convertible Preferred Stock

On March 24, 2014, the Company entered into a Series A Preferred Stock Purchase Agreement ("Series A Preferred SPA"). Per the Series A Preferred SPA, the Company agreed to sell to the Purchasers, for cash, an aggregate of up to 16,000,000 shares of Series A convertible preferred stock, par value $0.0001 per share, for the purchase price of $1.00 per share over two closings, an Initial Closing and a Milestone Closing. In addition, pursuant to the convertible note agreements, the Convertible Notes converted into 1,315,679 shares of Series A convertible preferred stock at the Initial Closing. The Initial Closing occurred on the date of the Series A Preferred SPA and the Milestone Closing was to occur on the 15th business day following delivery of the Milestone Closing Notice. This Milestone Closing was subject to the Company achieving several milestones related to its pharmaceutical and device development programs.

In conjunction with the execution of the Series A Preferred SPA, the Company received $8.0 million from the sale of 8,000,000 shares of Series A convertible preferred stock, par value $0.0001, at a price of $1.00 per share at the Initial Closing. Costs associated with the financing were $0.2 million resulting in net cash received of $7.8 million.

In October 2014, the Series A Preferred SPA was amended to include an additional investment of $250,000. The Company received $250,000 from the sale of 250,000 shares of Series A convertible preferred stock, par value $0.0001, at a price of $1.00 per share on October 14, 2014.

On April 8, 2015, the Company received $8.0 million from the sale of 8,000,000 shares of Series A convertible preferred stock, par value $0.0001, at a price of $1.00 per share at the Milestone Closing of the Series A Preferred SPA. Costs associated with the financing were $7,000 resulting in net cash received of $7,993,000.

On August 22, 2016, pursuant to the January 2016 Convertible Note Purchase Agreement, the Company issued 8,183,792 shares of Series A convertible preferred stock upon conversion of the underlying convertible notes (Note 10).

On December 22, 2016, the Company entered into a Series B Preferred Stock Purchase Agreement ("Series B Preferred SPA"). Per the Series B Preferred SPA, the Company agreed to sell to the Purchasers, for cash, an aggregate of up to 46,962,784 shares of Series B convertible preferred stock, par value $0.0001 per share, for the purchase price of $1.00 per share. As part of the Series B Preferred SPA, pursuant to the August 2016 Note Purchase Agreement, the underlying convertible notes converted into 5,962,784 shares of Series B convertible preferred stock (Note 10).

In conjunction with the execution of the Series B Preferred SPA, the Company received $41.0 million from the sale of 41,000,000 shares of Series B convertible preferred stock, par value $0.0001, at a price of $1.00 per share. Costs associated with the financing were $0.4 million resulting in net cash received of $40.6 million.

On November 16, 2017, immediately prior to the closing of the IPO, the Company's Series A convertible preferred stock and the Series B convertible preferred stock, collectively "Convertible Preferred Stock", converted into 10,126,771 shares of common stock.

Prior to their conversion into shares of common stock, the Convertible Preferred stock had the following characteristics:

Dividends

Holders of each share of Series A convertible preferred stock were entitled to receive non-cumulative cash dividends, prior and in preference to any declaration or payment of any dividend on shares of common stock at the rate of six percent of the Series A original issue price, payable only when, as and if declared by the Board of Directors.

Through December 31, 2017, holders of each share of Series B convertible preferred stock were entitled to receive non-cumulative cash dividends, prior and in preference to any declaration or payment of any dividend on shares of common stock at the rate of six percent of the Series B original issue price, payable only when, as and if declared by the Board of Directors.

From and after January 1, 2018, dividends at the rate per annum of six percent were to accrue on each share of Series B Preferred Stock and would become payable at the election of the Board of Directors in cash. In no event should the value of the Series B Preferred Stock dividend exceed twenty percent of the Series B original issue price on a cumulative basis.

Voting Rights

Holders of each share of Convertible Preferred Stock were entitled to that number of votes equal to the number of whole shares of common stock into which a holder's shares of Convertible Preferred Stock could be converted as of the record date of any vote.

Conversion Rights

Shares of Convertible Preferred Stock were convertible, at the option of the holder, into shares of the Company's common stock at a conversion value determined by dividing the Series A original issue price or the Series B original issue price, as the case may be, by the applicable conversion price. The Series A conversion price of $7.180193 (which reflects the stock split described in Note 12) and the Series B conversion price of $7.180193 (which reflects the stock split described in Note 12) are collectively referred to as the "Conversion Price". All outstanding shares of Convertible Preferred Stock automatically converted into common stock upon the closing of the Company's IPO.

Liquidation Preference

In the event of any liquidation, dissolution or winding-up of the Company, which would include the sale of the Company, the Series B convertible preferred stockholders were entitled to be paid, before any distribution or payment could be made upon the holders of Series A convertible preferred stock or common stock, an amount per share equal to the Series B original issue price, plus any Series B original dividend declared but unpaid thereon, plus any unpaid Series B accruing dividends accrued thereon, beginning in January 2018, plus any other dividends declared but unpaid thereon. Any assets remaining following the preferential distribution to the holders of Series B convertible preferred stock would have been available for distribution to the holders of Series A convertible preferred stock in an amount per share equal to the Series A original issue price, plus any dividends declared but unpaid thereon. In the event that assets remained after all the preferential amounts required to be paid to the holders of shares of preferred stock are paid, the remaining assets would have been distributed among the holders of the shares of preferred stock and common stock, ratably among all holders of preferred stock and common stock pro-rata based on the number of shares held by each holder, treating the preferred stock as if they had been converted to common stock prior to such liquidation, dissolution, or winding-up.

The maximum amount distributed to holders of Series B convertible preferred stock would have been the greater of three times the Series B original issue price or the amount the holders would have received if all shares of Series B convertible preferred stock had been converted into common stock immediately prior to such liquidation, dissolution or winding-up of the Company. The maximum amount distributed to holders of Series A convertible preferred stock would have been the greater of three times the Series A original issue price or the amount the holders would have received if all shares of Series A convertible preferred stock had been converted into common stock immediately prior to such liquidation, dissolution or winding-up of the Company.

Because a majority of voting power of the outstanding common stock could be obtained without the Company's approval, redemption of the Convertible Preferred Stock could have been triggered. This required the Company to record the Convertible Preferred Stock in temporary equity between liabilities and equity in the balance sheet. Convertible Preferred Stock was recorded net of issuance costs.

Registration Rights

The holders of shares of Convertible Preferred Stock were entitled to certain demand registration rights with respect to these securities, as set forth in the investors' rights agreement between the Company and the holders of these securities. These registration rights would require the Company to use its commercially reasonable efforts to register the shares of the Company's common stock underlying the Convertible Preferred Stock under the Securities Act of 1933, subject to certain conditions and limitations. The cost of registration would be incurred by the Company.

12. Stockholders' Equity

Stock Split

On November 6, 2017, the Company effectuated a 1-for-7.180193 reverse stock split of its outstanding common stock, which was approved by the Company's board of directors on October 27, 2017 and by the Company's stockholders on November 6, 2017. The reverse stock split resulted in an adjustment to the preferred stock conversion prices to reflect a proportional decrease in the number of shares of common stock to be issued upon conversion. The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the reverse stock split for all periods presented. The shares of common stock retained a par value of $0.0001 per share. Accordingly, the stockholders' (deficit) equity reflects the reverse stock split by reclassifying from common stock to additional paid-in capital in an amount equal to the par value of the decreased shares resulting from the reverse stock split.

Common Stock

The Company issued 39,722 and 34,561 additional shares in 2017 and 2018, respectively, as a result of restricted stock issuances and stock option exercises. In addition, the Company repurchased 1,871 shares of unvested restricted stock in 2017. There were 18,534,240 and 18,569,289 shares outstanding at December 31, 2017 and 2018, 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 1,588,306 shares of common stock for the exercise of outstanding options to purchase common stock.

13. 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 $0.2 million, $0.3 million and $0.5 million for the years ended December 31, 2016, 2017 and 2018, 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, 2018 (in thousands):

Year ended:	
December 31, 2019	$ 513
December 31, 2020	528
December 31, 2021	537
December 31, 2022	496
Total minimum lease payments	2,074
Less imputed interest	(368)
Total	$ 1,706

	2017	2018
Lease cost:		
Operating lease cost	$ 290	$ 483
Short-term lease cost	3	8
Sublease income	—	(39)
Total lease cost	$ 293	$ 452
Other information		
Cash paid for amounts included in the measurement of liabilities	$ 92	$ 429
Operating cash flows from operating leases	$ 141	$ 49
Weighted-average remaining lease term - operating leases	4.9 years	3.9 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.

14. 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, 2016, 2017 and 2018, the Company has recognized compensation expense of $122,000, $165,000 and $225,000, respectively, for the employer match contribution.

15. 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.

On January 9, 2019, the Company held a Type C meeting with the FDA to discuss the dose delivery validation protocol. At the January 2019 Type C meeting, the FDA informed the Company that the FDA did not agree that the Company's proposed dose validation study was adequate, and an agreement was not reached during the January 2019 meeting.

In January 2019, the Company entered into a Development Agreement (the "Development Agreement") with West Pharmaceutical Services, Inc. ("West"). Under the terms of the Development Agreement, the Company paid to West a one-time upfront payment of approximately $1.7 million upon signing of the agreement. In addition, the Company has committed to pay West for development and validation milestones, as well as exclusivity fees for treating congestion with loop diuretics.

In January 2019, the Company implemented a restructuring plan to reduce its workforce by approximately 43%, to 13 employees. The Company currently estimates that it will record a charge in 2019 of approximately $1.4 million, consisting of severance, benefits and outplacement services.

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, 2018, our principal executive officer and principal financial 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 a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act are recorded, processed, summarized and reported within the time periods specified in the SEC'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 Exchange Act is accumulated and communicated to our management, including our principal executive and financial officer and principal accounting officer, 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) (COSO). Based on its assessment, management believes that, as of December 31, 2018, 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, 2018, 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 (1)
3.2	Amended and Restated By-laws of the Registrant (1)
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 22, 2016 (2)
10.1#	2014 Stock Incentive Plan, as amended, and forms of award agreements thereunder (2)
10.2#	2017 Stock Option and Incentive Plan and forms of award agreements thereunder (1)
10.3#	Senior Executive Cash Incentive Bonus Plan (1)
10.4#	2017 Employee Stock Purchase Plan (1)
10.5#	Form of Indemnification Agreement (1)
10.6	Office Lease Agreement, dated as of June 2, 2017, by and between the Registrant and NEEP Investors Holdings LLC (2)
10.7†	License Agreement, dated as of June 29, 2015, by and among the Registrant, Sensile Medical AG, Sensile Holdings AG, and Sensile Patent AG, as amended by (i) First Amendment to License Agreement, dated as of June 29, 2016, (ii) Amendment No. 2 to License Agreement, dated as of August 5, 2016, (iii) Third Amendment to License Agreement, dated as of November 22, 2016 and (iv) Fourth Amendment to License Agreement, dated as of February 25, 2017 (2)
10.8*	Loan and Security Agreement, dated as of May 23, 2017, 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, as amended by (i) First Amendment to Loan and Security Agreement, dated November 21, 2018, by and among the Registrant, Solar Capital Ltd. and Silicon Valley Bank, and (ii) Consent and Second Amendment to Loan and Security Agreement, dated December 12, 2018, by and among the Registrant, Solar Capital Ltd. and Silicon Valley Bank

10.9#	Amended and Restated Employment Agreement, by and between the Registrant and John H. Tucker (1)
10.10#	Amended and Restated Employment Agreement, by and between the Registrant and Troy Ignelzi (1)
10.11#	Separation Agreement, by and between the Registrant and Abraham Ceesay, dated October 18, 2018 (filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K on October 22, 2018, and incorporated by reference herein)
21.1	Subsidiaries of the Registrant (2)
23.1*	Consent of RSM US LLP, Independent Registered Public Accounting Firm
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	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.
(1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) filed with the Securities and Exchange Commission on November 7, 2017.
(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) filed with the Securities and Exchange Commission on October 23, 2017.

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 21, 2019

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 21, 2019
/s/ Rachael Nokes **Rachael Nokes**	Principal Accounting Officer	March 21, 2019
/s/ Mette Kirstine Agger **Mette Kirstine Agger**	Director	March 21, 2019
/s/ Dorothy Coleman **Dorothy Coleman**	Director	March 21, 2019
/s/ Minnie V. Baylor-Henry **Minnie V. Baylor-Henry**	Director	March 21, 2019
/s/ Jack A. Khattar **Jack A. Khattar**	Director	March 21, 2019
/s/ Mason Freeman, M.D. **Mason Freeman**	Director	March 21, 2019
/s/ Leonard D. Schaeffer **Leonard D. Schaeffer**	Director	March 21, 2019
/s/ Klaus Veitinger, M.D., Ph.D. **Klaus Veitinger, M.D., Ph.D.**	Director	March 21, 2019
/s/ Frederick Hudson **Frederick Hudson**	Director	March 21, 2019

Exhibit 10.8

Execution Version

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may be amended, restated, modified, or supplemented from time to time, this "**Agreement**") dated as of May 23, 2017 (the "**Effective Date**") among Solar Capital Ltd. ("**Solar**"), as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Solar in its capacity as a Lender and Silicon Valley Bank ("**Bank**") as a Lender each a "**Lender**" and collectively, the "**Lenders**"), and scPharmaceuticals Inc., a Delaware corporation with offices located at 131 Hartwell Avenue, Suite 215, Lexington, MA 02421 ("**Borrower**"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

1. DEFINITIONS AND OTHER TERMS

1.1 **Terms**. Capitalized terms used herein shall have the meanings set forth in Section 1.3 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules.

1.2 **Section** References. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

1.3 **Definitions**. The following terms are defined in the Sections or subsections referenced opposite such terms:

"**Agreement**"	Preamble
"**Borrower**"	Preamble
"**Claims**"	Section 12.2
"**Closing Fee**"	Section 2.4(a)
"**Collateral Agent**"	Preamble
"**Collateral Agent Report**"	Exhibit B, Section 5
"**Communications**"	Section 10
"**Default Rate**"	Section 2.3(b)
"**Effective Date**"	Preamble
"**Event of Default**"	Section 8
"**Indemnified Person**"	Section 12.2
"**Lender**" and "**Lenders**"	Preamble
"**Lender Transfer**"	Section 12.1
"**Non-Funding Lender**"	Exhibit B, Section 10(c)(ii)
"**Other Lender**"	Exhibit B, Section 10(c)(ii)
"**Perfection Certificate**"	Section 5.1
"**Solar**"	Preamble
"**Termination Date**"	Exhibit B, Section 8
"**Term Loan**"	Section 2.2(a)
"**Transfer**"	Section 7.1

In addition to the terms defined elsewhere in this Agreement, the following terms have the following meanings:

"**Account**" is any "account" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

"**Account Debtor**" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**ACH Letter**" is ACH debit authorization in the form of Exhibit F hereto.

"**Affiliate**" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.

"**Amortization Date**" is December 1, 2018.

"**Anti-Terrorism Laws**" are any laws, rules, regulations or orders relating to terrorism or money laundering, including without limitation Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

"**Approved Fund**" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

"**Blocked Person**" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti- Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"**Borrower's Books**" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which commercial banks in New York, New York are required or authorized to be closed.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent, and (d) any money market or similar funds that exclusively hold any of the foregoing.

"**Code**" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

"**Collateral Agent**" is Solar, not in its individual capacity, but solely in its capacity as collateral agent on behalf of and for the ratable benefit of the Secured Parties.

"**Commitment Percentage**" is set forth in Schedule 1.1, as amended from time to time.

"**Commodity Account**" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Compliance Certificate**" is that certain certificate in substantially the form attached hereto as Exhibit D.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith in accordance with GAAP; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower or such Subsidiary, as applicable, and Collateral Agent pursuant to which Collateral Agent, for the ratable benefit of the Secured Parties, obtains "control" (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Deposit Account**" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Designated Deposit Account**" is Borrower's deposit account, account number 3301140431, maintained at Bank.
"**Dollars**," "**dollars**" and "**$**" each mean lawful money of the United States.
"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made under the Code, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"**Exigent Circumstance**" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

"**Exit Fee Agreement**" is that certain Exit Fee Agreement dated as of the Effective Date, between Borrowers, Solar and Bank.
"**FDA**" means the U.S. Food and Drug Administration or any successor thereto or any other comparable Governmental Authority.
"**Final Fee**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest or any other fee

payable hereunder) (a) due on the earliest to occur of (i) the Maturity Date, (ii) the acceleration of any Term Loan pursuant to Section 9.1, and (iii) the prepayment of a Term Loan by Borrower pursuant to Section 2.2(c) or (d), and (b) equal to $250,000. The Final Fee shall be fully earned on the date so paid, non-refundable for any reason and payable to the Lenders in accordance with their respective Pro Rata Shares.

"**Foreign Currency**" means lawful money of a country other than the United States.

"**Foreign Subsidiary**" is a Subsidiary that is not an entity organized under the laws of the United States or any state or territory thereof. "**Funding Date**" is any date on which a Term Loan is made to or on account of Borrower which shall be a Business Day.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body (including, without limitation, the FDA), court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Guarantor**" is any Person providing a Guaranty of the Obligations in favor of Collateral Agent for the benefit of the Secured Parties. "**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, (d) non-contingent obligations of such Person to reimburse any bank or other Person in respect of amounts paid under a letter of credit, banker's acceptance or similar instrument, (e) equity securities of such Person subject to repurchase or redemption other than at the sole option of such Person, (f) obligations secured by a Lien on any asset of such Person, whether or not such obligation is otherwise an obligation of such Person, (g) "earnouts", purchase price adjustments, profit sharing arrangements, deferred purchase money amounts and similar payment obligations or continuing obligations of any nature of such Person arising out of purchase and sale contracts, (h) all Indebtedness of others guaranteed by such Person, (i) off-balance sheet liabilities and/or pension plan or multiemployer plan liabilities of such Person, (j) obligations arising under non- compete agreements, (k) obligations arising under bonus, deferred compensation, incentive compensation or similar arrangements, other than those arising in the ordinary course of business and (l) Contingent Obligations.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"**Intellectual Property**" means all of Borrower's or any of its Subsidiaries' right, title and interest in and to the following:

(a) its Copyrights, Trademarks and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to Borrower;

(e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**IPO**" means the initial public offering and sale of Borrower's common stock.

"**Key Person**" is each of Borrower's (i) President and Chief Executive Officer, who is John Tucker as of the Effective Date and (ii) Chief Financial Officer, who is Troy Ignelzi as of the Effective Date.

"**Knowledge**" means to the "best of Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

"**Lender**" is any one of the Lenders.

"**Lenders**" are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"**Lenders' Expenses**" are (a) all audit fees and expenses, costs, and expenses (including reasonable documented attorneys' fees and expenses (whether generated in house or by outside counsel), as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating and administering the Loan Documents, and (b) all fees and expenses (including reasonable documented attorneys' fees and expenses , as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents. Borrower agrees that the sufficiency of documentation of any attorney fees hereunder shall be in Agent's and Lender's sole discretion, and Agent and Lenders have no obligation to provide detailed invoices of attorney's fees to Borrower.

"**LIBOR Rate**" means the rate per annum rate published by the Intercontinental Exchange Benchmark Administration Ltd. (the "**Service**") (or on any successor or substitute page of such Service, or any successor to or substitute for such Service) for a term of one month, which determination by Collateral Agent shall be conclusive in the absence of manifest error.

"**Lien**" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement, each Control Agreement, the Perfection Certificates, each Compliance Certificate, the ACH Letter, each Loan Payment Request Form, any Guarantees, the Exit Fee Agreement, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, any agreements creating or perfecting rights in the Collateral (including all insurance certificates and endorsements, landlord consents and bailee consents) and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent, as applicable, in connection with this Agreement; all as amended, restated, or otherwise modified.

"**Loan Payment Request Form**" is that certain form attached hereto as Exhibit C.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or

(c) a material impairment of the prospect of repayment of any portion of the Obligations when due.

"**Material Agreement**" is (a) any license, agreement or other contractual arrangement (other than purchase orders in the ordinary course of business) whereby Borrower or any of its Subsidiaries is reasonably likely to be required to transfer, either in-kind or in cash, in any period of twelve consecutive months prior to the Maturity Date, assets or property valued (book or market) at more than Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate and (b) each Sensile Agreement.

"**Maturity Date**" is May 1, 2021.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Premium, the Final Fee, and any other amounts Borrower owes the Collateral Agent or the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, including without limitation, all obligations relating to letters of credit, cash management services and foreign exchange contracts, if any, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent in connection with this Agreement and the other Loan Documents, and the performance of Borrower's duties under the Loan Documents.

"**OFAC**" is the U.S. Department of Treasury Office of Foreign Assets Control.

"**OFAC Lists**" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Patents**" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, re-examination certificates, utility models, extensions and continuations-in-part of the same.

"**Payment Date**" is the first (1st) calendar day of each calendar month, commencing on July 1, 2017. "**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate;

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors and in connection with credit cards incurred in the ordinary course of business not to exceed $100,000 in the aggregate outstanding at any time;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made);

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

(g) Subordinated Debt; and

(h) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (g) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

"**Permitted Investments**" are:

(a) Investments disclosed on the Perfection Certificate and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of Deposit Accounts in which Collateral Agent has a perfected Lien (subject to the terms of this Agreement) for the ratable benefit of the Secured Parties;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's board of directors; not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary; and

(i) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non- exclusive licensing of technology, the development of technology or the providing of technical support.

"**Permitted Licenses**" are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, and (C) exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in this clause (C), the license (i) constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property, (ii) is limited in territory with respect to a specific geographic country or region (i.e., Japan, Germany, northern China) outside of the United States, and (iii) Borrower has obtained the consent and acknowledgement of the counterparty to such license for the collateral assignment of such license to the Collateral Agent for the benefit of the Lenders.

"**Permitted** Liens" are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificate or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clause (e) of the definition of "Permitted Indebtedness," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed Two Hundred Fifty Thousand Dollars ($250,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;

(g) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(h) Liens arising by reason of zoning restrictions, easements, licenses, reservations, restrictions, covenants, rights-of-way, encroachments, minor defects or irregularities in title (including leasehold title) and other similar encumbrances on the use of real property that do not materially (i) impair the value or marketability of such real property or (ii) interfere with the ordinary conduct of the business conducted and proposed to be conducted at such real property;

(i) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(a) hereof;

(j) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7; and

(k) Permitted Licenses.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Prepayment Premium**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Effective Date through and including the first anniversary of the Effective Date, three percent (3.00%) of the principal amount of such Term Loan prepaid; and

(ii) for a prepayment made after the date which is after the first anniversary of the Effective Date and prior to the Maturity Date, one percent (1.00%) of the principal amount of the Term Loans prepaid.

Notwithstanding the foregoing, Collateral Agent and Lender agree to waive the Prepayment Premium if Collateral Agent and Lender (in its sole and absolute discretion) agree in writing to refinance the Term Loans prior to the Maturity Date.

"**Property**" means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

"**Registered Organization**" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Registration**" means any registration, authorization, approval, license, permit, clearance, certificate, and exemption issued or allowed by the FDA or state pharmacy licensing authorities (including, without limitation, new drug applications, abbreviated new drug applications, biologics license applications, investigational new drug applications, over-the-counter drug monograph, device pre-market approval applications, device pre- market notifications, investigational device exemptions, product recertifications, manufacturing approvals, registrations and authorizations, CE Marks, pricing and reimbursement approvals, labeling approvals or their foreign equivalent, controlled substance registrations, and wholesale distributor permits).

"**Regulatory Action**" means an administrative, regulatory, or judicial enforcement action, proceeding, investigation or inspection, FDA Form 483 notice of inspectional observation, warning letter, untitled letter, other notice of violation letter, recall, seizure, Section 305 notice or other similar written communication, injunction or consent decree, issued by the FDA or a federal or state court.

"**Related Persons**" means, with respect to any Person, each Affiliate of such Person and each director, officer, employee, agent, trustee, representative, attorney, accountant and each insurance, environmental, legal, financial and other advisor and other consultants and agents of or to such Person or any of its Affiliates.

"**Required Lenders**" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "**Original Lender**") have not assigned or transferred any of their interests in their Term Loan other than to an Affiliate of such Lender, Lenders holding one hundred percent (100%) of the aggregate

outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

"**Requirement of Law**" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officer**" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.
"**Secured Parties**" means the Collateral Agent and the Lenders.
"**Securities Account**" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made under the Code.

"**Sensile Agreements**" are each of the agreements listed in Exhibit H hereto and each other agreement among Borrower and Sensile Holding AG or its Affiliates, in each case as may be amended, amended and restated, supplemented or otherwise modified from time to time.

"**Solvent**" means, with respect to any Person, that (a) the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities, (b) such Person is not left with unreasonably small capital giving effect to the transactions contemplated by this Agreement and the other Loan Documents, and (c) such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Required Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Required Lenders in their sole discretion.

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1. "**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower and each of its Subsidiaries connected with and symbolized by such trademarks.

"**Unqualified Opinion**" means an opinion on financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion which opinion shall not include any qualifications or any going concern limitations.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower on the Effective Date in an aggregate principal amount of Ten Million Dollars ($10,000,000.00) according to each Lender's Term Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term Loan**", and collectively as the "**Term Loans**"). After repayment, no Term Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date after such Funding Date. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall (i) make monthly payments of interest, directly to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon the effective rate of interest applicable to the Term Loan, as determined in Section 2.3(a) plus (ii) make consecutive equal monthly payments of principal directly to each Lender in accordance with its Pro Rata Share, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (A) the respective principal amounts of such Lender's Term Loans outstanding, and (B) a repayment schedule equal to thirty (30) months. All unpaid principal and accrued and unpaid interest with respect to each such Term Loan is due and payable in full on the Maturity Date. The Term Loans may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated pursuant to Section 9.1 following the occurrence and during the continuance of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Fee, (iii) the Prepayment Premium, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Fee had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to each Lender in accordance with its respective Pro Rata Share, the Final Fee in respect of the Term Loans.

(d) Permitted Prepayment of Term Loans. Borrower shall have the option to prepay all, but not less than all of the outstanding principal balance of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least five (5) Business Days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Fee, (C) the Prepayment Premium, plus (D) all other Obligations that are due and payable on such prepayment date, including any Lenders' Expenses and interest at the Default Rate (if any) with

respect to any past due amounts.

2.3 Payment of Interest on the Term Loans.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the LIBOR Rate in effect from time to time *plus* 8.45%, which aggregate interest rate shall be determined by Collateral Agent on the third Business Day prior to the Funding Date of the applicable Term Loan and on the date occurring on the first Business Day of the month prior to each Payment Date occurring thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Except as set forth in Section 2.2(b), such interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full (or any payment is made hereunder).

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, all Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year for the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Person's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 pm Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds. Collateral Agent may at its discretion and with prior notice of at least one (1) Business Day, initiate debit entries to the Borrower's account as authorized on the ACH Letter (i) on each payment date of all Obligations then due and owing, (ii) at any time any payment due and owing with respect to Lender Expenses, and (iii) upon an Event of Default, any other Obligations outstanding.

2.4 Fees. Borrower shall pay to Collateral Agent and/or Lenders (as applicable) the following fees, which shall be deemed fully earned and non-refundable upon payment:

(a) Closing Fee. To Solar, a fully-earned, non-refundable closing fee in the amount of $80,000 (the "**Closing Fee**"), which shall be due on the Effective Date;

(b) Final Fee. The Final Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Share;

(c) Prepayment Premium. The Prepayment Premium, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) Lenders' Expenses. All Lenders' Expenses (including reasonable documented attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

2.5 Withholding. Payments received by the Collateral Agent or the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction (and including any such withholdings and deductions applicable to additional sums payable under this Section), each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.5 shall survive the termination of this Agreement.

2.6 Secured Promissory Notes. If requested by a Lender, the Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit G hereto (each a "**Secured Promissory Note**"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be, absent manifest error, prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit (with customary indemnification) of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Initial Term Loan. Each Lender's obligation to make a Term Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may have reasonably requested, including, without limitation:

(a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;

(b) a completed Perfection Certificate for Borrower and its Subsidiaries;

(c) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries;

(d) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

(e) a certificate of Borrower in substantially the form of Exhibit E hereto executed by the Secretary of Borrower with appropriate insertions and attachments, including with respect to (i) the Operating Documents of Borrower (which Certificate of Incorporation of Borrower shall be certified by the Secretary of State of the State of Delaware) and (ii) the resolutions adopted by Borrower's board of directors for the purpose of approving the transactions contemplated by the Loan Documents;

(f) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Term Loan, will be terminated or released;

(g) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;

(h) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect; and

(i) payment of the Closing Fee and Lenders' Expenses then due as specified in Section 2.4 hereof.

3.2 Conditions Precedent **to all Term Loans**. The obligation of each Lender to extend each Term Loan, including the initial Term Loan, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Loan Payment Request Form in the form of Exhibit C attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the Funding Date of each Term Loan; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the funding of such Term Loan;

(c) in such Lender's reasonable discretion, there has not been any Material Adverse Change;

(d) No Event of Default or an event that with the passage of time could result in an Event of Default, shall exist; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.4 hereof.

3.3 Post-Closing Condition. Borrower shall deliver to Collateral Agent within thirty (30) days after the Effective Date, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Secured Parties.

3.4 Covenant to Deliver. Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Term Loan. Borrower expressly agrees that a Term Loan made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Term Loan in the absence of a required item shall be made in each Lender's sole discretion.

3.5 Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan (other than the Term Loan funded on the Effective Date), Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 2:00 pm New York City time three (3) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to Collateral Agent by electronic mail or facsimile a completed Loan Payment Request Form executed by a Responsible Officer or his or her designee. The Collateral Agent may rely on any telephone notice given by a person whom Collateral Agent reasonably believes is a Responsible Officer or designee.

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Borrower hereby grants Collateral Agent, for the ratable benefit of the Secured Parties, to secure the payment and performance in full of all of the Obligations, a continuing first priority security interest in, and pledges to Collateral Agent, for the ratable benefit of the Secured Parties, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products and supporting obligations (as defined in the Code) in respect thereof. If Borrower shall acquire any commercial tort claim (as defined in the Code), Borrower shall grant to Collateral Agent, for the ratable benefit of the Secured Parties, a first priority security interest therein and in the proceeds and products and supporting obligations (as defined in the Code) thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to extend Term Loans has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, terminate and release its Liens in the Collateral and all rights therein shall revert to Borrower.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral (held for the ratable benefit of the Secured Parties), without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents.

5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

5.1 **Due Organization**, **Authorization: Power and Authority**. Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be so qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and its Subsidiaries have delivered to Collateral Agent a completed perfection certificate and any updates or supplements thereto on, before or after the Effective Date (the "**Perfection Certificate**"). Borrower represents and warrants that all the information set forth on the Perfection Certificate (as may be updated pursuant to specific provisions herein) pertaining to Borrower and its Subsidiaries is accurate and complete.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is, or they are, a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower, any of its Subsidiaries or any of their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

5.2 **Collateral**.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificate delivered to Collateral Agent in connection herewith in respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein as required under this Agreement. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to involuntary Permitted Liens that, under applicable law, have priority over Collateral Agent's Lien.

(c) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral (other than mobile equipment such as laptop computers in the possession of Borrower's employees in the ordinary course of business) is not in the possession of any third party bailee, and (ii) no such third party bailee possesses components of the Collateral in excess of Two Hundred Fifty Thousand Dollars ($250,000.00).

(d) All Inventory and Equipment is in all material respects of good and marketable quality, free from material defects.

(e) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificate (which, upon the consummation of a transaction not prohibited by this Agreement, may be updated to reflect such transaction), neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other Material Agreement.

5.3 **Litigation**. Except as disclosed on the Perfection Certificate or with respect to which Borrower has provided notice as required hereunder, there are no actions, suits, investigations, or proceedings pending or, to the Knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars ($250,000.00).

5.4 **No Material Adverse Change; Financial Statements**. All consolidated financial statements for Borrower and its consolidated Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, and in all material respects the consolidated financial condition of Borrower and its consolidated Subsidiaries, and the consolidated results of operations of Borrower and its consolidated Subsidiaries, as of the date thereof, except that unaudited financial statements may be subject to normal adjustments and need not contain adjustments for items such as stock compensation or depreciation, or footnotes. Since December 31, 2016, there has not been a Material Adverse Change.

5.5 **Solvency**. Borrower is Solvent. Borrower and each of its Subsidiaries, when taken as a whole, is Solvent.

5.6 **Regulatory Compliance**. Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's Knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all material consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the Knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

5.7 **Investments**. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for

Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries in an amount greater than Ten Thousand Dollars ($10,000), in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the next sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted; (b) notifies Collateral Agent of the commencement of, and any material development in, the proceeding; and (c) adequate reserves or other appropriate provisions are maintained on the books of such Borrower or Subsidiary, as applicable, in accordance with GAAP and which do not involve, in the reasonable judgment of the Collateral Agent, any risk of the sale, forfeiture or loss of any material portion of the Collateral. Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries', prior tax years which could result in additional taxes in an amount greater than Ten Thousand Dollars ($10,000) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Term Loans, as working capital and to fund its general business requirements, and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement, when taken as a whole, given to Collateral Agent or any Lender in connection with the Loan Documents or the transactions contemplated thereby, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in light of the circumstances under which they were made (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.11 Intellectual Property. Borrower and each of its Subsidiaries have sufficient title and ownership of or licenses to all patents, trademarks, service marks, trade names, domain names, copyrights, trade secrets, information, proprietary rights and processes necessary for the business of Borrower and each of its Subsidiaries as now conducted and presently proposed to be conducted without any known violation or infringement of the rights of others, and has no reason to believe that any Patents included in such Intellectual Property is not or, once issued will not be, valid and enforceable in any material manner. To Borrower's knowledge, there is no material prior art that would likely render the claims in any such Patents unpatentable, invalid, or unenforceable in whole or in part, or would preclude the issuance of claims covering Borrower's products and product candidates. To Borrower's knowledge, no third party is infringing or misappropriating any of the Intellectual Property or has challenged the ownership, scope, duration, validity, enforceability, priority or right to use any of the Intellectual Property (including, by way of example, through the institution of or written threat of institution of inter partes review, interference, reexamination, protest, opposition, nullity or similar invalidity proceeding before the United States Patent and Trademark Office or any analogous foreign entity) that is material to the business of Borrower and each of its Subsidiaries as now conducted and presently proposed to be conducted. Except for the Sensile Agreements, to Borrower's knowledge there are no options, licenses, agreements, understandings, instruments, contracts, proposed transactions, judgments, orders, writs, decrees, claims, encumbrances or shared ownership of interests of any kind relating to anything referred to above in this Section 5.11 that is to any extent owned by or exclusively licensed to Borrower or any of its Subsidiaries or that may involve any material license of any patent, copyright, trade secret or other proprietary right to or from Borrower or any of its Subsidiaries, in all cases that is material to the business of Borrower and each of its Subsidiaries as now conducted and proposed to be conducted. Except with respect to the Intellectual Property licensed under the Sensile Agreements, neither Borrower nor any of its Subsidiaries is bound by or a party to any options, licenses, agreements, understandings, instruments, or contracts of any kind with respect to the patents, trademarks, service marks, trade names, domain names, copyrights, trade secrets, licenses, information, proprietary rights and/or processes of any other person or entity, except, in either case, for standard end-user, object code, internal-use software license and support/maintenance agreements or customary research or commercial contracts in the ordinary course of the Borrower's business. Neither Borrower nor any of its Subsidiaries has received any written communications alleging, and Borrower is not aware of any facts that could give rise to any allegation, that Borrower or any of its Subsidiaries has infringed, misappropriated, or violated or would infringe, misappropriate, or violate, or offering to grant rights with respect to, any of the patents, trademarks, service marks, domain names, trade names, copyrights or trade secrets or other proprietary rights of any other person or entity. Borrower is not aware that any employees of Borrower or any of its Subsidiaries is obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with the use of his or her reasonable efforts to promote the interests of Borrower and its Subsidiaries or that would conflict with the business of Borrower or its Subsidiaries. Neither the execution nor delivery of this Agreement, nor the carrying on of the business of Borrower or its Subsidiaries by the employees of Borrower or its Subsidiaries, will, to Borrower's knowledge, conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, any contract, covenant or instrument under which any of such employees is now obligated. Borrower does not presently believe it is or will be necessary to utilize any inventions of any of the employees of Borrower or its Subsidiaries made prior to or outside the scope of their employment by Borrower or its Subsidiaries.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance.

(a) Other than specifically permitted hereunder, maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Secured Parties, in all of the Collateral.

6.2 Financial Statements, Reports, Certificates; Notices.

(a) Deliver to each Lender:

(i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and, if prepared by Borrower or if reasonably requested by the Lenders, consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its consolidated Subsidiaries for such month certified by a Responsible Officer and in a form

reasonably acceptable to the Collateral Agent;

(ii) as soon as available, but no later than one hundred eighty (180) days after the last day of Borrower's fiscal year or within five (5) days of filing of the same with the SEC, audited consolidated financial statements covering the consolidated operations of Borrower and its consolidated Subsidiaries for such fiscal year, prepared under GAAP, consistently applied, together with an Unqualified Opinion on the financial statements;

(iii) as soon as available after approval thereof by Borrower's board of directors, but no later than the earlier of (x) ten (10) days' after such approval and (y) February 28 of such year, Borrower's annual budget and financial projections for the entire current fiscal year as approved by Borrower's board of directors; provided that, any material revisions to such projections approved by Borrower's board of directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such approval);

(iv) within five (5) days of delivery, copies of all non-ministerial statements, reports and notices made available to Borrower's security holders generally or holders of Subordinated Debt (other than materials provided to members of the Borrower's board of directors solely in their capacities as security holder or holders of Subordinated Debt);

(v) in the event that Borrower becomes subject to the reporting requirements under the Securities Exchange Act of 1934, as amended, within five (5) days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission;

(vi) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s);

(vii) prompt delivery of (and in any event within five (5) days after the same are sent or received) copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or that otherwise could reasonably be expected to have a Material Adverse Change;

(viii) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the value of the Intellectual Property or (B) could reasonably be expected to result in a Material Adverse Change;

(ix) written notice delivered at least (30) days' prior to Borrower's (A) adding any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Two Hundred Fifty Thousand Dollars ($250,000.00) in assets or property of Borrower or any of its Subsidiaries), (B) changing its respective jurisdiction of organization, (C) changing its organizational structure or type, (D) changing its respective legal name, or (E) changing any organizational number(s) (if any) assigned by its respective jurisdiction of organization;

(x) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, and Borrower's proposal regarding how to cure such Event of Default or event;

(xi) immediate notice if Borrower or such Subsidiary has Knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering;

(xii) notice of any commercial tort claim (as defined in the Code) or letter of credit rights (as defined in the Code) held by Borrower or any Guarantor, in each case in an amount greater than One Hundred Thousand Dollars ($100,000.00) and of the general details thereof;

(xiii) if Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, written notice of such occurrence and information regarding such Person's organizational identification number within seven (7) Business Days of receiving such organizational identification number; and

(xiv) other information as reasonably requested by Collateral Agent or any Lender.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender:

(i) a duly completed Compliance Certificate signed by a Responsible Officer;

(ii) an updated Perfection Certificate to reflect any amendments, modifications and updates, if any, to certain information in the Perfection Certificate after the Effective Date to the extent such amendments, modifications and updates are permitted by one or more specific provisions in this agreement;

(iii) copies of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries;

(iv) written notice of the commencement of, and any material development in, the proceedings contemplated by Section 5.8 hereof;

(v) prompt written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars ($250,000.00); and

(vi) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00) individually or in the aggregate in any calendar year.

(c) Keep proper, complete and true books of record and account in accordance with GAAP in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

6.3 **Inventory; Returns**. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, as applicable, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist as of the Effective Date. Borrower must promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00) individually or in the aggregate in any calendar year.

6.4 **Taxes; Pensions**. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 5.8 hereof, and shall deliver to the Lenders, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

6.5 **Insurance**. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and shall waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent (for the ratable benefit of the Secured Parties), as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver to the Collateral Agent certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Secured Parties, on account of the then-outstanding Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy within one hundred eighty (180) days of receipt thereof up to Two Hundred Fifty Thousand Dollars ($250,000), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest (subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 **Operating Accounts**.

(a) All of the Borrower's and its Subsidiaries' Collateral Accounts must be maintained in Collateral Accounts with Bank or its Affiliates, each of which are subject to a Control Agreement in favor of Collateral Agent for the ratable benefit of the Secured Parties.

(b) Borrower shall provide Collateral Agent ten (10) days' prior written notice before Borrower or any Guarantor establishes any Collateral Account. In addition, for each Collateral Account that Borrower or any Guarantor, at any time maintains, Borrower or such Guarantor shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account (held for the ratable benefit of the Secured Parties) in accordance with the terms hereunder prior to the establishment of such Collateral Account. The provisions of the previous sentence shall not apply to Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificate, provided that the amount deposited therein shall not exceed the amount reasonably expected to be due and payable for the next succeeding pay period.

(c) Neither Borrower nor any Guarantor shall maintain any Collateral Accounts except Collateral Accounts maintained in accordance with this Section 6.6.

6.7 **Protection of Intellectual Property Rights**. Borrower and each of its Subsidiaries shall: (a) protect, defend and maintain the validity and enforceability of its respective Intellectual Property that is material to its business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its respective Intellectual Property material to its business; and (c) not allow any of its respective Intellectual Property material to its respective business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

6.8 **Litigation Cooperation**. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders and upon reasonable prior notice, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably request to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.9 **Landlord Waivers; Bailee Waivers**. In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then, in the event that the Collateral at any new location is valued (based on book value) in excess of Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate, at Collateral Agent's election, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

6.10 **Further Assurances**. Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 **Dispositions**. Convey, sell, lease, transfer, assign, dispose of, license (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out, obsolete or surplus Equipment; (c) in connection with Permitted Liens, Permitted Investments or Permitted Licenses; (d) sale or issuance of any stock permitted under Section 7.2; (e) pursuant to the Sensile Agreements (as may be amended in accordance with Section 7.13); or (f) cash or Cash Equivalents pursuant to transactions not prohibited by this Agreement.

7.2 **Changes in Business**, **Management**, **Ownership**, **or Business Locations**. (a) Engage in or permit any of its Subsidiaries to engage in any

business other than the businesses engaged in by Borrower or such Subsidiary, as applicable, as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) permit any Key Person to cease being actively engaged in the management of Borrower unless written notice thereof is provided to each Lender within ten (10) days of such cessation, or (ii) enter into any transaction or series of related transactions in which (A) the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than 40% of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital or private equity investors so long as Borrower identifies to Collateral Agent the investors prior to the closing of the transaction) and (B) except as permitted by Section 7.3, Borrower ceases to own, directly or indirectly, 100% of the ownership interests in each Subsidiary of Borrower. Borrower shall not, and shall not permit any of its Subsidiaries to, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than Two Hundred Fifty Thousand Dollars ($250,000.00) in assets or property of Borrower or any of its Subsidiaries, as applicable); (B) change its respective jurisdiction of organization, (C) except as permitted by Section 7.3, change its respective organizational structure or type, (D) change its respective legal name, or (E) change any organizational number(s) (if any) assigned by its respective jurisdiction of organization.

7.3 **Mergers or Acquisitions**. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person. A Subsidiary may merge or consolidate into another Subsidiary (provided if one of the Subsidiaries is a "co-Borrower" or guarantor hereunder, such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom.

7.4 **Indebtedness**. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

7.5 **Encumbrance**. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Secured Parties) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens".

7.6 **Maintenance of Collateral Accounts**. With respect to Borrower any Guarantors, maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

7.7 **Restricted Payments**. (a) Declare or pay any dividends (other than dividends payable solely in capital stock) or make any other distribution or payment in respect of or redeem, retire or purchase any capital stock (other than (i) the declaration or payment of dividends to Borrower, (ii) so long as no Event of Default or event that with the passage of time would result in an Event of Default exists or would result therefrom, the declaration or payment of any dividends solely in the form of equity securities, and (iii) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed Two Hundred Fifty Thousand Dollars ($250,000.00) in the aggregate per fiscal year), (b) other than the Obligations in accordance with the terms hereof, purchase, redeem, defease or prepay any principal of, premium, if any, interest or other amount payable in respect of any Indebtedness prior to its scheduled maturity unless being replaced with Indebtedness of at least the same principal amount and such new Indebtedness is Permitted Indebtedness, or (c) be a party to or bound by an agreement that restricts a Subsidiary from paying dividends or otherwise distributing property to Borrower.

7.8 **Investments**. Directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so other than Permitted Investments.

7.9 **Transactions with Affiliates**. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non- affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries and (c) transactions permitted pursuant to the terms of Section 7.2.

7.10 **Subordinated Debt**. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

7.11 **Compliance**. (a) Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Term Loan for that purpose; (b) fail to meet the minimum funding requirements of ERISA; (c) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; (d) fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; or (e) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7.12 **Compliance with Anti-Terrorism Laws**. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (a) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (b) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (c) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

7.13 **Sensile Agreements**. Neither Borrower nor any of its Subsidiaries shall, without the consent of Collateral Agent, (a) enter into a Sensile Agreement, (b) materially amend a Sensile Agreement or (c) terminate any Sensile Agreement.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 **Payment Default**. Borrower fails to (a) make any payment of principal or interest on any Term Loan on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1 (a) hereof);

8.2 Covenant Default.

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Landlord Waivers; Bailee Waivers) or Borrower violates any provision in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document to which such person is a party, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower or such Subsidiary, as applicable, be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Term Loans shall be made during such cure period).

8.3 Material Adverse Change. A Material Adverse Change has occurred;

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) of this clause (a) are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Term Loans shall be extended while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Other Agreements. There is a default in (a) any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of One Hundred Thousand Dollars ($100,000.00) or that could reasonably be expected to have a Material Adverse Change or (b) there is any default under a Material Agreement that permits the counterparty thereto to accelerate the payments owed thereunder;

8.7 Judgments. One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least One Hundred Thousand Dollars ($100,000.00) (not covered by independent third-party insurance as to which (a) Borrower reasonably believes such insurance carrier will accept liability, (b) Borrower or the applicable Subsidiary has submitted such claim to such insurance carrier and
(c) liability has not been rejected by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or the Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made;

8.9 Subordinated Debt. A default or breach occurs under any subordination agreement, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

8.10 Guaranty. (a) Any Guaranty terminates or ceases for any reason to be in full force and effect other than pursuant to the terms of such Guaranty; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Section 8 occurs with respect to any Guarantor.

8.11 Governmental Approvals; FDA Action. (a) Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or (b) (i) the FDA, DOJ or other Governmental Authority initiates a Regulatory Action or any other enforcement action against Borrower or any of its Subsidiaries or any supplier of Borrower or any of its Subsidiaries that causes Borrower or any of its Subsidiaries to recall, withdraw, remove or discontinue manufacturing, distributing, and/or marketing any of its products, even if such action is based on previously disclosed conduct; (ii) the FDA issues a warning letter to Borrower or any of its Subsidiaries with respect to any of its activities or products which could reasonably be expected to result in a Material Adverse Change; (iii) Borrower or any of its Subsidiaries conducts a mandatory or voluntary recall which could reasonably be expected to result in liability and expense to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars ($250,000.00) or more; (iv) Borrower or any of its Subsidiaries enters into a settlement agreement with the FDA, DOJ or other Governmental Authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions, of Two Hundred Fifty Thousand Dollars ($250,000.00) or more, or that could reasonably be expected to result in a Material Adverse Change, even if such settlement agreement is based on previously disclosed conduct; or (v) the FDA revokes any authorization or permission granted under any Registration, or Borrower or any of its Subsidiaries withdraws any Registration, that could reasonably be expected to result in a Material Adverse Change.

8.12 Lien Priority. Except as the result of the action or inaction of the Collateral Agent or the Lenders, any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens arising as a matter of applicable law.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be

immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right and at the written direction of Required Lenders shall, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) make a demand for payment upon any Guarantor pursuant to the Guaranty delivered by such Guarantor;

(iii) apply to the Obligations then due any (A) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, (B) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower, or (C) amounts received from any Guarantors in accordance with the respective Guaranty delivered by such Guarantor; and/or (iv) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its Liens in the Collateral (held for the ratable benefit of the Secured Parties). Borrower shall assemble the Collateral if Collateral Agent requests and make it available at such location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge by Borrower, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, any of the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any

similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any Collateral Account maintained with Collateral Agent or any Lender or otherwise in respect of which a Control Agreement has been delivered in favor of Collateral Agent (for the ratable benefit of the Secured Parties) and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and (vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts of Borrower directly with the applicable Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make extend Term Loans hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Term Loans terminates.

9.3 Protective Payments. If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice

of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

9.4 Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses (in proportion to such costs and expenses theretofore incurred by each); second, to the Lenders ratably, in an amount up to the sum of all accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the Lenders ratably, in an amount up to the outstanding principal amount of the Obligations outstanding; and fourth, the Collateral Agent and Lenders ratably (in proportion to all remaining Obligations owing to each), in an amount of up to the sum of all other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to the Lenders' Pro Rata Shares unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's Pro Rata Share of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its Pro Rata Share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other the Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its Pro Rata Share, then the portion of such payment or distribution in excess of such Lender's Pro Rata Share shall be received and held by such Lender in trust for and shall be promptly paid over to the other Lenders (in accordance with their respective Pro Rata Shares) for application to the payments of amounts due on such other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for the Secured Parties for purposes of perfecting Collateral Agent's security interest therein (held for the ratable benefit of the Secured Parties).

9.5 Liability for Collateral. So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or by Borrower or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.7 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

Other than as specifically provided herein, all notices, consents, requests, approvals, demands, or other communication (collectively, "**Communications**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: SCPHARMACEUTICALS INC.
131 Hartwell Avenue, Suite 215
Lexington, MA 02421 Attn: Troy Ignelzi
Email: tignelzi@scpharma.com

with a copy (which shall not constitute notice) to: GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
Attn: Mark D. Smith
Fax: (617) 801-8825
Email: marksmith@goodwinlaw.com

If to Collateral Agent: SOLAR CAPITAL LTD.

500 Park Avenue, 3rd Floor New
York, NY 10022 Attention: Anthony
Storino Fax: (212) 993-1698
Email: storino@Solarltd.com

with a copy (which shall not constitute notice) to: GOODWIN PROCTER LLP
505 Montgomery Street, Suite 2000
San Francisco, CA 94111
Attention: Haim Zaltzman
Facsimile: (415) 395-8095
Email: haim.zaltzman@lw.com

with a copy (which shall not constitute notice) to: LATHAM & WATKINS LLP
100 Northern Avenue
Boston, MA 02210
Attn: Mark D. Smith
Fax: (617) 801-8825
Email: marksmith@goodwinlaw.com

with a copy to: SILICON VALLEY BANK, as lender
275 Grove Street, Suite 2-200
Newton, Massachusetts 02466 Attn:
Kate Walsh
Fax: (617) 527-0177
Email: KWalsh@svb.com

11. NOTICES

12. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

12.1 Waiver of Jury Trial. EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONGBORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

12.2 Governing Law and Jurisdiction. THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAW OTHER THAN THE LAW OF SUCH STATE), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN NEW YORK SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

12.3 Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the State of New York located in the City of New York, Borough of Manhattan, or of the United States of America for the Southern District of New York and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of *forum non conveniens,* that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

12.4 Service of Process. Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

12.5 Non-exclusive Jurisdiction. Nothing contained in this Article 11 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

13. GENERAL PROVISIONS

13.1 **Successors and Assigns**. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents. Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such assignee as Collateral Agent reasonably shall require.

13.2 **Indemnification**. Borrower agrees to indemnify, defend and hold each Secured Party and their respective directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing such Secured Party (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses and Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents (including reasonable attorneys' fees and expenses), except, in each case, for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further agrees to indemnify, defend and hold each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

13.3 **Severability of Provisions**. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

13.4 **Correction of Loan Documents**. Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.

13.5 **Amendments in Writing; Integration**. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its Guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.9. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(b) Other than as expressly provided for in Section 12.5(a)(i)-(iii), Collateral Agent may, at its discretion, or if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

13.6 **Counterparts**. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

13.7 **Survival**. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the withholding provision in Section 2.5 hereof and the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

13.8 **Confidentiality**. In handling any confidential information of Borrower, each of the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loans (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, rule, regulation, regulatory or self-regulatory authority, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and/or Collateral Agent, as applicable, with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent through no breach of this provision by the Lenders or the Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

13.9 **Right of Set Off**. Borrower hereby grants to Collateral Agent and to each Lender, a Lien, security interest and right of set off as security for all Obligations to Secured Parties hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of any Secured Party or any entity under the control of such Security Party (including a Collateral Agent Affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, any Secured Party may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

13.10 **Cooperation of Borrower**. If necessary, Borrower agrees to (i) execute any documents reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment (or portion thereof) or Term Loan (or portion thereof) to an assignee in accordance with Section 12.1, (ii) make Borrower's management personnel available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments, the Term Loans or portions thereof (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent and the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment (or portions thereof) or Term Loan (or portions thereof) reasonably may request. Subject to the provisions of Section 12.8, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment (or portions thereof), any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

13.11 **Public Announcement**. Borrower hereby agrees that Collateral Agent and each Lender may make a public announcement of the transactions contemplated by this Agreement, and may publicize the same in marketing materials, newspapers and other publications, and otherwise, and in connection therewith may use Borrower's name, tradenames and logos. Collateral Agent and the Lenders may also make disclosures to the Securities and Exchange Commission or other governmental agency and any other public disclosure with investors, other governmental agencies or other related persons.

13.12 **Collateral Agent and Lender Agreement**. Collateral Agent and the Lenders hereby agree to the terms and conditions set forth on Exhibit B attached hereto. Borrower acknowledges and agrees to the terms and conditions set forth on Exhibit B attached hereto.

13.13 **Time of Essence**. Time is of the essence for the performance of Obligations under this Agreement.

13.14 **Termination Prior to Maturity Date; Survival**. All covenants, representations and warranties made in this Agreement continue in full force until this Agreement has terminated pursuant to its terms and all Obligations have been satisfied. So long as Borrower has satisfied the Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement and for which no claim has been made) in accordance with the terms of this Agreement, this Agreement may be terminated prior to the Maturity Date by Borrower, effective five (5) Business Days after written notice of termination is given to the Collateral Agent and the Lenders.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

SCPHARMACEUTICALS INC.

By /s/ John Tucker
Name: John Tucker
Title: President and Chief Executive Officer

COLLATERAL AGENT AND LENDER:

SOLAR CAPITAL LTD.

By	/s/ Anthony J. Storino
Name:	Anthony J. Storino
Title:	Authorized Signatory

LENDER:

SILICON VALLEY BANK

By	/s/ Kate Walsh
Name:	Kate Walsh
Title:	Director

SCHEDULE 1.1

Lenders and Commitments

Lender	Term Loan Commitment	Commitment Percentage
Solar Capital Ltd.	5,000,000	50.00%
Silicon Valley Bank	5,000,000	50.00%
TOTAL	**$10,000,000**	**100.00%**

EXHIBIT A
Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property.

EXHIBIT B

Collateral Agent and Lender Terms

1. Appointment of Collateral Agent.

(a) Each Lender hereby appoints Solar (together with any successor Collateral Agent pursuant to Section 1.7 of this Exhibit B) as Collateral Agent under the Loan Documents and authorizes Collateral Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from Borrower, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Collateral Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) Without limiting the generality of clause (a) above, Collateral Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Lender is hereby authorized to make such payment to Collateral Agent except to the extent the Loan Documents specifically require a payment to be made directly to a Lender, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of Collateral Agent and Lenders with respect to any Obligation in any bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Lender), (iii) act as collateral agent for Collateral Agent and each Lender for purposes of the perfection of all Liens created by the Loan Documents and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, and subject to clause (d) below, exercise all remedies given to Collateral Agent and the other Lenders with respect to the Borrower and/or the Collateral, whether under the Loan Documents, applicable Requirements of Law or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver all of the foregoing actions to be taken in Collateral Agent's reasonable business discretion; provided, however, that Collateral Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Collateral Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any Deposit Account maintained by Borrower with, and cash and Cash Equivalents held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Collateral Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed. Collateral Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Lender).

(c) Under the Loan Documents, Collateral Agent (i) is acting solely on behalf of the Lenders, with duties that are entirely administrative in nature, notwithstanding the use of the defined term "Collateral Agent", the terms "agent", "Collateral Agent" and "collateral agent" and similar terms in any Loan Document to refer to Collateral Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Person and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document, and each Lender, by accepting the benefits of the Loan Documents, hereby waives and agrees not to assert any claim against Collateral Agent based on the roles, duties and legal relationships expressly disclaimed in clauses (i) through (iii) above. Except as expressly set forth in the Loan Documents, Collateral Agent shall not have any duty to disclose, and shall not be liable for failure to disclose, any information relating to Borrower or any of its Subsidiaries that is communicated to or obtained by Solar or any of its Affiliates in any capacity.

(d) Upon the occurrence of an Event of Default, Collateral Agent, at the request of Lenders, shall take such actions and only such actions as Lenders mutually agree to take to enforce Collateral Agent's and their rights and remedies under the Loan Agreement, provided, that, notwithstanding anything to the contrary contained in the foregoing or anything else in this Agreement, unless Collateral Agent shall have received an objection or contrary instructions from the other Lender, Collateral Agent may take such actions (not to include acceleration of the Loan Agreement, the institution of foreclosure proceedings or secured creditors' sales or the giving of notice to any account debtors) as Collateral Agent shall deem reasonably necessary to preserve and protect the rights of Collateral Agent and Lenders under the Loan Agreement and the other Loan Documents and with respect to the Collateral, including without limitation satisfaction of other security interests, liens or encumbrances on the Collateral not permitted under the Loan Documents, payment of taxes on behalf of Borrower, payments to landlords, warehouseman, bailees and other persons in possession of the Collateral and other actions to protect and safeguard the Collateral, and actions with respect to insurance claims for casualty events affecting Borrower and/or the Collateral. If, after consultation, Lenders cannot mutually agree on what action to take or direct Collateral Agent to take, then the other Lender shall have the right upon prior written notice to the other to cause the acceleration of the Loan Agreement on behalf of both Lenders. Upon such acceleration, the Lenders shall mutually agree as to what Enforcement Action to take; provided, however, that if after consultation, Lenders cannot mutually agree on what action to take, then the Lender wishing to take the stronger Enforcement Action (the "Enforcing Lender") shall have the right to determine and shall control the timing, order and type of Enforcement Actions which will be taken and all other matters in connection with any such Enforcement Actions. To facilitate these rights to control Enforcement Actions, upon either Lender becoming the Enforcing Lender, if the Enforcing Lender is not already the Collateral Agent, then automatically and without the necessity of any further action being taken by any party, (x) the original Collateral Agent shall be deemed to have resigned as Collateral Agent and (y) the Lenders shall be deemed to have unanimously appointed the Enforcing Lender as successor Collateral Agent under this Agreement and the Loan Documents (and the Enforcing Lender shall be deemed to have accepted such appointment) in accordance with Section 7 of this Agreement, provided, that, once the Enforcing Lender shall have been appointed as the Collateral Agent under the provisions of this sentence, the Enforcing Lender as such successor Collateral Agent shall no longer be bound by the restrictions of the first sentence of this paragraph, but instead shall have the right to determine and control all Enforcement Actions as provided for in the immediately preceding sentence (subject to the provisions of the following sentence). In taking such Enforcement Actions pursuant to the previous sentence, the Enforcing Lender as such successor Collateral Agent shall act reasonably and in good faith and shall consult with and keep the other Lender informed thereof at reasonable intervals; provided, however, that notwithstanding any such consultations and provision of information to the other Lender, the Enforcing Lender as such successor Collateral Agent shall retain the right to make all determinations in the event of disagreements between the Enforcing Lender and the other Lender. In all cases with respect to Enforcement Actions, the Enforcing Lender shall have the right to act both on its own behalf and as agent for the other Lender with respect thereto. In addition, the other Lender shall take such actions and execute such documents and instruments as the Enforcing Lender may reasonably request in connection with and to facilitate any such Enforcement Actions. As used herein, "Enforcement Action" means, with respect to any Lender and with respect to any Claim of such Lender or any item of Collateral in which such Lender has or claims a security interest, lien or right of offset, any action, whether judicial or nonjudicial, to repossess, collect, accelerate, offset, recoup, give notification to third parties with respect to, sell, dispose of, foreclose upon, give notice of sale, disposition, or foreclosure with respect to, or obtain equitable or injunctive relief with respect to, such Claim or Collateral. The filing by any Lender of, or the joining in the filing by any Lender of, an involuntary bankruptcy or insolvency proceeding against Borrower also is an Enforcement Action. Notwithstanding anything herein to the contrary, this clause (d) only applies and only grants rights to Bank and Solar.

2. Binding Effect; Use of Discretion; E-Systems.

(a) Each Lender, by accepting the benefits of the Loan Documents, agrees that (i) any action taken by Collateral Agent or Required

Lenders (or, if expressly required in any Loan Document, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Collateral Agent in reliance upon the instructions of Required Lenders (or, where so required, such greater proportion) and (iii) the exercise by Collateral Agent or Required Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of Lenders.

(b) If Collateral Agent shall request instructions from Required Lenders or all affected Lenders with respect to any act or action (including failure to act) in connection with any Loan Document, then Collateral Agent shall be entitled to refrain from such act or taking such action unless and until Collateral Agent shall have received instructions from Required Lenders or all affected Lenders, as the case may be, and Collateral Agent shall not incur liability to any Person by reason of so refraining. Collateral Agent shall be fully justified in failing or refusing to take any action under any Loan Document (i) if such action would, in the opinion of Collateral Agent, be contrary to any Requirement of Law or any Loan Document, (ii) if such action would, in the opinion of Collateral Agent, expose Collateral Agent to any potential liability under any Requirement of Law or (iii) if Collateral Agent shall not first be indemnified to its satisfaction against any and all liability and expense which may be incurred by it by reason of taking or continuing to take any such action. Without limiting the foregoing, no Lender shall have any right of action whatsoever against Collateral Agent as a result of Collateral Agent acting or refraining from acting under any Loan Document in accordance with the instructions of Required Lenders or all affected Lenders, as applicable.

(c) Collateral Agent is hereby authorized by Borrower and each Lender to establish procedures (and to amend such procedures from time to time) to facilitate administration and servicing of the Term Loans and other matters incidental thereto. Without limiting the generality of the foregoing, Collateral Agent is hereby authorized to establish procedures to make available or deliver, or to accept, notices, documents (including, without limitation, borrowing base certificates) and similar items on, by posting to or submitting and/or completion, on E-Systems. Borrower and each Lender acknowledges and agrees that the use of transmissions via an E-System or electronic mail is not necessarily secure and that there are risks associated with such use, including risks of interception, disclosure and abuse, and Borrower and each Lender assumes and accepts such risks by hereby authorizing the transmission via E-Systems or electronic mail. Each "e-signature" on any such posting shall be deemed sufficient to satisfy any requirement for a "signature", and each such posting shall be deemed sufficient to satisfy any requirement for a "writing", in each case including pursuant to any Loan Document, any applicable provision of any Code, the federal Uniform Electronic Transactions Act, the Electronic Signatures in Global and National Commerce Act and any substantive or procedural Requirement of Law governing such subject matter. All uses of an E-System shall be governed by and subject to, in addition to this Section, the separate terms, conditions and privacy policy posted or referenced in such E-System (or such terms, conditions and privacy policy as may be updated from time to time, including on such E-System) and related contractual obligations executed by Collateral Agent, Borrower and/or Lenders in connection with the use of such E-System. ALL E-SYSTEMS AND ELECTRONIC TRANSMISSIONS SHALL BE PROVIDED "AS IS" AND "AS AVAILABLE". NO REPRESENTATION OR WARRANTY OF ANY KIND IS MADE BY AGENT, ANY LENDER OR ANY OF THEIR RELATED PERSONS IN CONNECTION WITH ANY E-SYSTEMS.

3. Collateral Agent's Reliance, Etc. Collateral Agent may, without incurring any liability hereunder, (a) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, Borrower) and (b) rely and act upon any document and information (including those transmitted by electronic transmission) and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties. None of Collateral Agent and its Related Persons shall be liable for any action taken or omitted to be taken by any of them in connection with the duties of Collateral Agent under or in connection with any Loan Document, and each Lender and Borrower hereby waives and shall not assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment of a court of competent jurisdiction) in connection with the duties of Collateral Agent expressly set forth herein. Without limiting the foregoing, Collateral Agent: (i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Required Lenders or for the actions or omissions of any of its Related Persons, except to the extent that a court of competent jurisdiction determines in a final non-appealable judgment that Collateral Agent acted with gross negligence or willful misconduct in the selection of such Related Person; (ii) shall not be responsible to any Lender or other Person for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of, or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document; (iii) makes no warranty or representation, and shall not be responsible, to any Lender or other Person for any statement, document, information, representation or warranty made or furnished by or on behalf of Borrower or any Related Person of Borrower in connection with any Loan Document or any transaction contemplated therein or any other document or information with respect to Borrower, whether or not transmitted or (except for documents expressly required under any Loan Document to be transmitted to the Lenders) omitted to be transmitted by Collateral Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Collateral Agent in connection with the Loan Documents; and (iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of Borrower or as to the existence or continuation or possible occurrence or continuation of any Event of Default, and shall not be deemed to have notice or Knowledge of such occurrence or continuation unless it has received a notice from Borrower or any Lender describing such Event of Default that is clearly labeled "notice of default" (in which case Collateral Agent shall promptly give notice of such receipt to all Lenders, provided that Collateral Agent shall not be liable to any Lender for any failure to do so, except to the extent that such failure is attributable to Collateral Agent's gross negligence or willful misconduct as determined by a final non-appealable judgment of a court of competent jurisdiction); and, for each of the items set forth in clauses (i) through (iv) above, each Lender and Borrower hereby waives and agrees not to assert (and Borrower shall cause its Subsidiaries to waive and agree not to assert) any right, claim or cause of action it might have against Collateral Agent based thereon.

4. Collateral Agent Individually. Collateral Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, engage in any kind of business with, Borrower or any Affiliate of Borrower as though it were not acting as Collateral Agent and may receive separate fees and other payments therefor. To the extent Collateral Agent or any of its Affiliates makes any Term Loans or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Required Lender" and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Collateral Agent or such Affiliate, as the case may be, in its individual capacity as Lender, or as one of the Required Lenders.

5. Lender Credit Decision; Collateral Agent Report. Each Lender acknowledges that it shall, independently and without reliance upon Collateral Agent, any Lender or any of their Related Persons or upon any document solely or in part because such document was transmitted by Collateral Agent or any of its Related Persons, conduct its own independent investigation of the financial condition and affairs of Borrower and make and continue to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate. Except for documents expressly required by any Loan Document to be transmitted by Collateral Agent to the Lenders, Collateral Agent shall not have any duty or responsibility to provide any Lender with any credit or other information concerning the business, prospects, operations, Property, financial and other condition or creditworthiness of Borrower or any Affiliate of Borrower that may come in to the possession of Collateral Agent or any of its Related Persons. Each Lender agrees that is shall not rely on any field examination, audit or other report provided by Collateral Agent or its Related Persons (a "**Collateral Agent Report**"). Each Lender further acknowledges that any Collateral Agent Report (a) is provided to the Lenders solely as a courtesy, without consideration, and based upon the understanding that such Lender will not rely on such Collateral Agent Report, (b) was prepared by Collateral Agent or its Related Persons based upon

information provided by Borrower solely for Collateral Agent's own internal use, and (c) may not be complete and may not reflect all information and findings obtained by Collateral Agent or its Related Persons regarding the operations and condition of Borrower. Neither Collateral Agent nor any of its Related Persons makes any representations or warranties of any kind with respect to (i) any existing or proposed financing, (ii) the accuracy or completeness of the information contained in any Collateral Agent Report or in any related documentation, (iii) the scope or adequacy of Collateral Agent's and its Related Persons' due diligence, or the presence or absence of any errors or omissions contained in any Collateral Agent Report or in any related documentation, and (iv) any work performed by Collateral Agent or Collateral Agent's Related Persons in connection with or using any Collateral Agent Report or any related documentation. Neither Collateral Agent nor any of its Related Persons shall have any duties or obligations in connection with or as a result of any Lender receiving a copy of any Collateral Agent Report. Without limiting the generality of the foregoing, neither Collateral Agent nor any of its Related Persons shall have any responsibility for the accuracy or completeness of any Collateral Agent Report, or the appropriateness of any Collateral Agent Report for any Lender's purposes, and shall have no duty or responsibility to correct or update any Collateral Agent Report or disclose to any Lender any other information not embodied in any Collateral Agent Report, including any supplemental information obtained after the date of any Collateral Agent Report. Each Lender releases, and agrees that it will not assert, any claim against Collateral Agent or its Related Persons that in any way relates to any Collateral Agent Report or arises out of any Lender having access to any Collateral Agent Report or any discussion of its contents, and agrees to indemnify and hold harmless Collateral Agent and its Related Persons from all claims, liabilities and expenses relating to a breach by any Lender arising out of such Lender's access to any Collateral Agent Report or any discussion of its contents.

6. **Indemnification**. Each Lender agrees to reimburse Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents) promptly upon demand for its Pro Rata Share of any reasonable out-of-pocket costs and expenses (including, without limitation, reasonable fees, charges and disbursements of financial, legal and other advisors and any taxes or insurance paid in the name of, or on behalf of, Borrower) incurred by Collateral Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, amendment, consent, waiver or enforcement of, or the taking of any other action (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding (including, without limitation, preparation for and/or response to any subpoena or request for document production relating thereto) or otherwise) in respect of, or legal advice with respect to, its rights or responsibilities under, any Loan Document. Each Lender further agrees to indemnify Collateral Agent and each of its Related Persons (to the extent not reimbursed by Borrower as required under the Loan Documents), ratably according to its Pro Rata Share, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever (including, to the extent not indemnified by the applicable Lender, taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to or for the account of any Lender) that may be imposed on, incurred by, or asserted against Collateral Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Collateral Agent or any of its Related Persons under or with respect to the foregoing; provided that no Lender shall be liable to Collateral Agent or any of its Related Persons under this Section 6 of this Exhibit B to the extent such liability has resulted from the gross negligence or willful misconduct of Collateral Agent or, as the case may be, such Related Person, as determined by a final non-appealable judgment of a court of competent jurisdiction. To the extent required by any applicable Requirement of Law, Collateral Agent and Lenders may withhold from any payment to any Lender under a Loan Document an amount equal to any applicable withholding tax. If the Internal Revenue Service or any other Governmental Authority asserts a claim that Collateral Agent did not properly withhold tax from amounts paid to or for the account of any Lender for any reason, or if Collateral Agent reasonably determines that it was required to withhold taxes from a prior payment to or for the account of any Lender but failed to do so, such Lender shall promptly indemnify Collateral Agent fully for all amounts paid, directly or indirectly, by Collateral Agent as tax or otherwise, including penalties and interest, and together with all expenses incurred by Collateral Agent. Collateral Agent may offset against any payment to any Lender under a Loan Document, any applicable withholding tax that was required to be withheld from any prior payment to such Lender but which was not so withheld, as well as any other amounts for which Collateral Agent is entitled to indemnification from such Lender under the immediately preceding sentence of this Section 6 of this Exhibit B.

7. **Successor Collateral Agent**. Collateral Agent may resign at any time by delivering notice of such resignation to the Lenders and Borrower, effective on the date set forth in such notice or, if no such date is set forth therein, upon the date such notice shall be effective, in accordance with the terms of this Section 7 of this Exhibit B. If Collateral Agent delivers any such notice, the Required Lenders shall have the right to appoint a successor Collateral Agent. If, after 30 days after the date of the retiring Collateral Agent's notice of resignation, no successor Collateral Agent has been appointed by the Required Lenders that has accepted such appointment, then the retiring Collateral Agent may, on behalf of the Lenders, appoint a successor Collateral Agent from among the Lenders. Effective immediately upon its resignation, (a) the retiring Collateral Agent shall be discharged from its duties and obligations under the Loan Documents, (b) the Lenders shall assume and perform all of the duties of Collateral Agent until a successor Collateral Agent shall have accepted a valid appointment hereunder, (c) the retiring Collateral Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to any actions taken or omitted to be taken while such retiring Collateral Agent was, or because such Collateral Agent had been, validly acting as Collateral Agent under the Loan Documents, and (iv) subject to its rights under Section 2(b) of this Exhibit B, the retiring Collateral Agent shall take such action as may be reasonably necessary to assign to the successor Collateral Agent its rights as Collateral Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Collateral Agent, a successor Collateral Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the retiring Collateral Agent under the Loan Documents.

8. **Release of Collateral**. Each Lender hereby consents to the release and hereby directs Collateral Agent to release (or in the case of clause (b)(ii) below, release or subordinate) the following:

(a) any Guarantor if all of the stock of such Subsidiary owned by Borrower is sold or transferred in a transaction permitted under the Loan Documents (including pursuant to a valid waiver or consent), to the extent that, after giving effect to such transaction, such Subsidiary would not be required to guaranty any Obligations pursuant to any Loan Document; and

(b) any Lien held by Collateral Agent for the benefit of itself and the Lenders against (i) any Collateral that is sold or otherwise disposed of by Borrower in a transaction permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any Collateral subject to a Lien that is expressly permitted under clause (c) of the definition of the term "Permitted Lien" and (iii) all of the Collateral and Borrower, upon (A) termination of all of the Commitments, (B) payment in full in cash of all of the Obligations (other than inchoate indemnity Obligations) that Collateral Agent has theretofore been notified in writing by the holder of such Obligation are then due and payable, and (C) to the extent requested by Collateral Agent, receipt by Collateral Agent and Lenders of liability releases from Borrower in form and substance acceptable to Collateral Agent (the satisfaction of the conditions in this clause (iii), the "**Termination Date**").

9. **Setoff and Sharing of Payments**. In addition to any rights now or hereafter granted under any applicable requirement of law and not by way of limitation of any such rights, upon the occurrence and during the continuance of any Event of Default and subject to Section 10(d) of this Exhibit B, each Lender is hereby authorized at any time or from time to time upon the direction of Collateral Agent, without notice to Borrower or any other Person, any such notice being hereby expressly waived, to setoff and to appropriate and to apply any and all balances held by it at any of its offices for the account of Borrower (regardless of whether such balances are then due to Borrower) and any other properties or assets at any time held or owing by that Lender or that holder to or for the credit or for the account of Borrower against and on account of any of the Obligations that are not paid when due. Any Lender exercising a right of setoff or otherwise receiving any payment on account of the Obligations in excess of its Pro Rata Share thereof shall purchase for cash (and the other Lenders

or holders shall sell) such participations in each such other Lender's or holder's Pro Rata Share of the Obligations as would be necessary to cause such Lender to share the amount so offset or otherwise received with each other Lender or holder in accordance with their respective Pro Rata Shares of the Obligations. Borrower agrees, to the fullest extent permitted by law, that (a) any Lender may exercise its right to offset with respect to amounts in excess of its Pro Rata Share of the Obligations and may purchase participations in accordance with the preceding sentence and (b) any Lender so purchasing a participation in the Term Loans made or other Obligations held by other Lenders or holders may exercise all rights of offset, bankers' lien, counterclaim or similar rights with respect to such participation as fully as if such Lender or holder were a direct holder of the Term Loans and the other Obligations in the amount of such participation. Notwithstanding the foregoing, if all or any portion of the offset amount or payment otherwise received is thereafter recovered from the Lender that has exercised the right of offset, the purchase of participations by that Lender shall be rescinded and the purchase price restored without interest.

10. Advances; Payments; Non-Funding Lenders; Actions in Concert.

(a) Advances; Payments. If Collateral Agent receives any payment with respect to a Term Loan for the account of Lenders on or prior to 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on such Business Day. If Collateral Agent receives any payment with respect to a Term Loan for the account of Lenders after 2:00 p.m. (New York time) on any Business Day, Collateral Agent shall pay to each applicable Lender such Lender's Pro Rata Share of such payment on the next Business Day.

(b) Return of Payments.

(i) If Collateral Agent pays an amount to a Lender under this Agreement in the belief or expectation that a related payment has been or will be received by Collateral Agent from Borrower and such related payment is not received by Collateral Agent, then Collateral Agent will be entitled to recover such amount (including interest accruing on such amount at the rate otherwise applicable to such Obligation) from such Lender on demand without setoff, counterclaim or deduction of any kind.

(ii) If Collateral Agent determines at any time that any amount received by Collateral Agent under any Loan Document must be returned to Borrower or paid to any other Person pursuant to any insolvency law or otherwise, then, notwithstanding any other term or condition of any Loan Document, Collateral Agent will not be required to distribute any portion thereof to any Lender. In addition, each Lender will repay to Collateral Agent on demand any portion of such amount that Collateral Agent has distributed to such Lender, together with interest at such rate, if any, as Collateral Agent is required to pay to Borrower or such other Person, without setoff, counterclaim or deduction of any kind and Collateral Agent will be entitled to set off against future distributions to such Lender any such amounts (with interest) that are not repaid on demand.

(c) Non-Funding Lenders.

(i) Unless Collateral Agent shall have received notice from a Lender prior to the date of any Term Loan that such Lender will not make available to Collateral Agent such Lender's Pro Rata Share of such Term Loan, Collateral Agent may assume that such Lender will make such amount available to it on the date of such Term Loan in accordance with Section 2(b) of this Exhibit B, and Collateral Agent may (but shall not be obligated to), in reliance upon such assumption, make available a corresponding amount for the account of Borrower on such date. If and to the extent that such Lender shall not have made such amount available to Collateral Agent, such Lender and Borrower severally agree to repay to Collateral Agent forthwith on demand such corresponding amount together with interest thereon, for each day from the day such amount is made available to Borrower until the day such amount is repaid to Collateral Agent, at a rate per annum equal to the interest rate applicable to the Obligation that would have been created when Collateral Agent made available such amount to Borrower had such Lender made a corresponding payment available. If such Lender shall repay such corresponding amount to Collateral Agent, the amount so repaid shall constitute such Lender's portion of such Term Loan for purposes of this Agreement.

(ii) To the extent that any Lender has failed to fund any Term Loan or any other payments required to be made by it under the Loan Documents after any such Term Loan is required to be made or such payment is due (a "**Non-Funding Lender**"), Collateral Agent shall be entitled to set off the funding short-fall against that Non-Funding Lender's Pro Rata Share of all payments received from Borrower. The failure of any Non-Funding Lender to make any Term Loan or any payment required by it hereunder shall not relieve any other Lender (each such other Lender, an "**Other Lender**") of its obligations to make such Term Loan, but neither any Other Lender nor Collateral Agent shall be responsible for the failure of any Non-Funding Lender to make such Term Loan or make any other payment required hereunder. Notwithstanding anything set forth herein to the contrary, a Non-Funding Lender shall not have any voting or consent rights under or with respect to any Loan Document or constitute a "Lender" (or be included in the calculation of "Required Lender" hereunder) for any voting or consent rights under or with respect to any Loan Document. At Borrower's request, Collateral Agent or a Person reasonably acceptable to Collateral Agent shall have the right with Collateral Agent's consent and in Collateral Agent's sole discretion (but Collateral Agent or any such Person shall have no obligation) to purchase from any Non-Funding Lender, and each Lender agrees that if it becomes a Non-Funding Lender it shall, at Collateral Agent's request, sell and assign to Collateral Agent or such Person, all of the Term Loan Commitment (if any), and all of the outstanding Term Loan of that Non-Funding Lender for an amount equal to the aggregate outstanding principal balance of the Term Loan held by such Non-Funding Lender and all accrued interest with respect thereto through the date of sale, such purchase and sale to be consummated pursuant to an executed assignment agreement in form and substance reasonably satisfactory to, and acknowledged by, Collateral Agent.

(d) Actions in Concert. Anything in this Agreement to the contrary notwithstanding, each Lender hereby agrees with each other Lender that no Lender shall take any action to protect or enforce its rights arising out of any Loan Document (including exercising any rights of setoff) without first obtaining the prior written consent of Collateral Agent or Required Lenders, it being the intent of Lenders that any such action to protect or enforce rights under any Loan Document shall be taken in concert and at the direction or with the consent of Collateral Agent or Required Lenders.

EXHIBITC

Loan Payment Request Form

Fax To:(212)993-1698 Date:

LOAN PAYMENT:

SCPHARMACEUTICALS INC.

From Account # (Deposit Account #) To Account # (Loan Account #)

Principal $ and/or Interest $

Authorized Signature: Phone Number:
Print Name/Title:

LOAN ADVANCE:
Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account # (Loan Account #) To Account # (Deposit Account #)

Amount of Advance $

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date:

Authorized Signature: Phone Number:
Print Name/Title:

OUTGOING WIRE REQUEST:

Complete only if all or a portion of funds from the loan advance above is to be wired.

Beneficiary Name: Amount of Wire: $
Beneficiary Bank: Account Number:
City and State:

Beneficiary Bank Transit (ABA) #: Beneficiary Bank Code (Swift, Sort, Chip, etc.): **(For International Wire Only)**

Intermediary Bank: Transit (ABA) #:
For Further Credit to:

Special Instruction:

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: 2nd Signature (if required):
Print Name/Title: Print Name/Title:
Telephone #: Telephone #:]

EXHIBITD

Compliance Certificate

TO: SOLAR CAPITAL LTD., as Collateral Agent and Lender SILICON VALLEY BANK, as Lender

FROM: SCPHARMACEUTICALS INC.

The undersigned authorized officer ("**Officer**") of SCPHARMACEUTICALS INC. ("**Borrower**"), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement dated as of May 23, 2017, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "**Loan Agreement**;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement), with all required

(a) Borrower is in complete compliance for the period ending covenants except as noted below;

(b) There are no defaults or Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	Complies
1)	Financial statements	Monthly within 30 days		Yes No N/A
2)	Annual (CPA Audited) statements	within 180 days after FYE		Yes No N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within earlier 30 days of approval or 60 days of FYE), and when revised		Yes No N/A
4)	A/R & A/P agings	If applicable		Yes No N/A
5)	8-K 10-K and 10-Q Filings	If applicable, within 5 days of filing		Yes No N/A
6)	Compliance Certificate	Monthly within 30 days		Yes No N/A
7)	IP Report	When required		Yes No N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		**$** _	Yes No N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		**$** _	Yes No N/A

Deposit and Securities Accounts

(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?	Account Control Agreement in place?
1)			Yes No	Yes No
2)			Yes No	Yes No
3)			Yes No	Yes No
4)			Yes No	Yes No

Other Matters

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00)?	Yes	No
4)	Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No
5)	Has Borrower or any Subsidiary entered into or amended any Material Agreement? If yes, please explain and provide a copy of the Material Agreement(s) and/or amendment(s).	Yes	No
6)	Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

SCPHARMACEUTICALS INC.

By: _____
Name: _____
Title: _____
Date: _____

COLLATERAL AGENT USE ONLY

Received by: Date:
Verified by: Date:

Compliance Status: Yes No

Exhibit E

CORPORATE BORROWING CERTIFICATE

BORROWER:	SCPHARMACEUTICALS INC.	**DATE**: [ ], 2017
LENDERS:	SOLAR CAPITAL LTD., as Collateral Agent and Lender SILICON VALLEY BANK, as Lender	

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

2. Borrower's exact legal name is set forth above. Borrower is a corporation existing under the laws of the State of Delaware.

3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.

4. The following resolutions were duly and validly adopted by Borrower's board of directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

[***Balance of Page Intentionally Left Blank***]

RESOLVED, that **any one** of the following officers or employees of Borrower, whose names, titles and signatures are below, may act on behalf of Borrower:

Name	Title	Signature	Authorized to Add or Remove Signatories
			☐
			☐
			☐
			☐

RESOLVED FURTHER, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

RESOLVED FURTHER, that such individuals may, on behalf of Borrower:

Borrow Money. Borrow money from the Lenders.
Execute Loan Documents. Execute any loan documents any Lender requires.
Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.
Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.
Pay Fees. Pay fees under the Loan Agreement or any other Loan Document.
Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

RESOLVED FURTHER, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

[***Balance of Page Intentionally Left Blank***]

5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

By: _____
Name: _____
Title: _____

**** If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.*

I, the of Borrower, hereby certify as to paragraphs 1 through 5 above, as of the date set forth above. [print title]

By: _____
Name: _____
Title: _____

[Signature Page to Corporate Borrowing Certificate]

EXHIBIT A

Certificate of Incorporation (including amendments)

[see attached]

EXHIBIT B

Bylaws

[see attached]

EXHIBIT F

ACH LETTER

SOLAR CAPITAL LTD.
500 Park Avenue, 3rd Floor
New York, NY 10022
Attention: Neil Bonanno
Fax: (212) 993-1698
Email: bonanno@solarcapltd.com

Re: Loan and Security Agreement dated as of May 23, 2017 (the "Agreement") by and among SCPHARMACEUTICALS INC. ("Borrower"), Solar Capital Ltd. ("Solar"), as collateral agent (in such capacity, "Collateral Agent") and the Lenders listed on Schedule 1.1 thereof or otherwise a party thereto from time to time, including Solar in its capacity as a Lender and Silicon Valley Bank (each a "Lender" and collectively, the "Lenders"). Capitalized terms used but not otherwise defined herein shall have the meanings given them under the Agreement.

In connection with the above referenced Agreement, the Borrower hereby authorizes the Collateral Agent to, at its discretion and with prior notice of at least one (1) Business Day, initiate debit entries to the Borrower's account indicated below (i) on each payment date of all Obligations then due and owing, (ii) at any time any payment due and owing with respect to Lender Expenses, and (iii) upon an Event of Default, any other Obligations outstanding, in each case pursuant to Section 2.3(e) of the Agreement. The Borrower authorizes the depository institution named below to debit to such account.

DEPOSITORY NAME	BRANCH
CITY	STATE AND ZIPCODE
TRANSIT/ABA NUMBER	ACCOUNT NUMBER

This authority will remain in full force and effect so long as any amounts are due under the Agreement.

[*Signature page to follow*]

SCPHARMACEUTICALS INC.

By: _____
Title: _____
Date: _____

[Signature Page to ACH Letter]

Exhibit G
Form of Secured Promissory Note

SECURED PROMISSORY NOTE
(Term Loan)

$ Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, SCPHARMACEUTICALS INC., a Delaware corporation with offices located at [ ] ("**Borrower**") HEREBY PROMISES TO PAY to the order of [ ] ("**Lender**") the principal amount of [ ] DOLLARS ($) or such lesser amount as shall equal the outstanding principal balance of the Term Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated [ ], 2017 by and among Borrower, Lender, Solar Capital Ltd., as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**"). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term Loan, interest on the Term Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all Lenders' Expenses incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due subject to the terms of the Loan Agreement.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

[*Balance of Page Intentionally Left Blank*]

IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

SCPHARMACEUTICALS INC.

By _____

Name: _____

Title: _____

LOAN AND PAYMENTS OF PRINCIPAL

Date	Interest Rate	Principal Amount	Scheduled Payment Amount	Notation By

Exhibit H

Sensile Agreements

- Device Development Agreement between Borrower and Sensile Holding AG dated as of March 22, 2013, as amended as of July 29, 2013 and February 17, 2014
- Strategic Partnership Agreement between Borrower and Sensile Holding AG dated as of March 18, 2013, as amended as of January 31, 2014
- Development Option Agreement between Borrower and Sensile Holding AG dated as of June 24, 2013
- Notice of Exercise of Option to Develop and Commercialize between Borrower and Sensile Holding AG dated as of October 31, 2013
- Omnibus Amendment to Strategic Partnership Agreement, Device Development Agreement and Development Option Agreement by and among Borrower, Sensile Medical AG, Sensile Holding AG and Sensile Patent AG dated as of February 28, 2014, as amended as of September 5, 2014
- License Agreement between the Company and Sensile Medical AG, Sensile Holding AG and Sensile Patent AG dated as of June 29, 2015, as amended as of June 29, 2016, August 5, 2016, November 22, 2017 and February 25, 2017

Execution Version

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of November 21, 2018 (the "**Amendment Effective Date**"), is made among scPharmaceuticals Inc., a Delaware corporation ("**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender and Silicon Valley Bank ("**Bank**") as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

The Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of May 23, 2017 (as amended, restated or modified from time to time, the "**Loan and Security Agreement**"). The Borrower has requested that the Lenders agree to certain amendments to the Loan and Security Agreement. The Lenders have agreed to such request, subject to the terms and conditions hereof.

Accordingly, the parties hereto agree as follows:

SECTION1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION2 Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) New Definitions. The following definitions are added to Section 1.3 in their proper alphabetical order:

"**First Interest Only Extension Conditions**" shall mean satisfaction of each of the following: (a) no Event of Default shall have occurred and be continuing and (b) the Borrower shall have maintained compliance with Section 7.14 at all times, subject to verification by Collateral Agent and each Lender (including supporting documentation reasonably requested by Collateral Agent or any Lender).

"**Qualified Cash**" means the amount of Borrower's cash and Cash Equivalents held in accounts subject to a Control Agreement in favor of Collateral Agent.

"**Qualified Cash A/P Amount**" means the amount of Borrower's accounts payable that have not been paid within ninety (90) days from the invoice date of the relevant account payable (other than accounts that are subject to good faith disputes as permitted herein and for which Borrower maintains adequate reserves in accordance with GAAP).

"**Second Interest Only Extension Conditions**" shall mean satisfaction of each of the following: (a) no Event of Default shall have occurred and be continuing; (b) the Borrower shall have maintained compliance with Section 7.14 at all times, subject to verification by Collateral Agent and each Lender (including supporting documentation reasonably requested by Collateral Agent or any Lender);

(c) on or before May 15, 2019, Borrower has furnished Collateral Agent and each Lender with (i) FDA minutes of Borrower's Type C meetings with the FDA evidencing agreement regarding protocols for a dose delivery validation study, (ii) written response from the FDA evidencing agreement regarding protocols for the human factors studies (collectively, the "**Dose Delivery Validation and Human Factors Studies**") required for FUROSCIX® and (iii) evidence that the FDA does not require additional clinical trials prior to resubmission of the new drug application for FUROSCIX®, in each case, in form and substance satisfactory to Collateral Agent and each Lender; (d) as of May 31, 2019, Qualified Cash is at least Seventy-Two Million Dollars ($72,000,000.00) plus the Qualified Cash A/P Amount; and

(e) achievement of the First Interest Only Extension Conditions.

"**Third Interest Only Extension Conditions**" shall mean satisfaction of each of the following: (a) no Event of Default shall have occurred and be continuing; (b) the Borrower shall have maintained compliance with Section 7.14 at all times, subject to verification by Collateral Agent and each Lender (including supporting documentation reasonably requested by Collateral Agent or any Lender);

(c) on or before August 31, 2019, Borrower has furnished Collateral Agent and each Lender with evidence satisfactory to Collateral Agent and each Lender of completion of enrollment of the Dose Delivery Validation and Human Factors Studies; (d) as of August 31, 2019, Qualified Cash is at least Sixty-Three Million Dollars ($63,000,000.00) plus the Qualified Cash A/P Amount; and (e) achievement of the Second Interest Only Extension Conditions.

(ii) Amended Definition. The definition of "Final Fee" is hereby amended by replacing "$250,000" appearing therein with "$325,000" therein.

(iii) Amended and Restated Definition. The following definitions are hereby amended and restated as follows:

"**Amortization Date**" is December 1, 2018; *provided* that, (i) if the First Interest Only Extension Conditions are satisfied and the Borrower so elects, then June 1, 2019; (ii) if the Second Interest Only Extension Conditions are satisfied and the Borrower so elects, then September 1, 2019; and (iii) if the Third Interest Only Extension Conditions are satisfied and Borrower so elects, then December 1, 2019.

(iv) Section 2.2(b) is hereby amended by replacing "thirty (30) months" appearing therein with "the number of Payment Dates from the Amortization Date through the Maturity Date".

(v) Section 7 is hereby amended by inserting a new Section 7.14 at the end thereof as follows:

7.14 Minimum Liquidity Requirement. Permit, at any time, Qualified Cash to be less than Ten Million Dollars

($10,000,000.00) plus the Qualified Cash A/P Amount.

(vi) Exhibit D to the Loan and Security Agreement is hereby amended and restated in its entirety in the form attached hereto as Exhibit A.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 3 Conditions of Effectiveness. The effectiveness of Section 2 of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) **Fees and Expenses**. The Borrower shall have paid (i) an amendment fee of Thirty-Five Thousand Dollars ($35,000), which shall be deemed fully earned and non-refundable upon payment, (ii) all invoiced costs and expenses then due in accordance with Section 5(e), and (iii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This Amendment**. Collateral Agent shall have received this Amendment, executed by the Borrower.

(c) **Officer's Certificate**. Collateral Agent shall have received a certificate of an officer of the Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Agreement, in form acceptable to Collateral Agent and the Lenders.

(d) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 4 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 4 Representations and Warranties. To induce the Lenders to enter into this Amendment, the Borrower hereby confirms, as of the date hereof,

(a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Change; and (c) that the information included in the Perfection Certificate delivered to Collateral Agent on the Effective Date remains true and correct in all material respects. For the purposes of this Section 4, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete in all material respects as of such earlier date).

SECTION 5 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. The Borrower hereby reaffirms the grant of security under Section 4.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, including without limitation any Term Loans funded on or after the Amendment Effective Date, as of the date hereof.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 3, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **Release**. In consideration of the agreements of Collateral Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Collateral Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(d) **No Reliance**. The Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that the Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses**. The Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable documented out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable documented fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) Governing Law. **THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.**

(h) **Complete Agreement; Amendments; Exit Fee Agreement**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents. For the avoidance of doubt and notwithstanding anything to the contrary in this Amendment, Borrower (a) reaffirms its obligations under the Exit Fee Agreement, including without limitation its obligation to pay the Exit Fee (as defined in the Exit Fee Agreement) if and when due thereunder, and (b) agrees that the defined term "Loan Agreement" as defined in the Exit Fee Agreement shall on and after the Amendment Effective Date mean the Loan and Security Agreement as amended by this Amendment and as may be amended, restated or modified from time to time on or after the Amendment Effective Date.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

[*Balance of Page Intentionally Left Blank;*
Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:
SCPHARMACEUTICALS INC.,
as Borrower

By: /s/ John Tucker
Name: John Tucker
Title: President and Chief Executive Officer

COLLATERAL AGENT AND LENDER:
SOLAR CAPITAL LTD.,
as Collateral Agent and a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Authorized Signatory

LENDER:
SILICON VALLEY BANK,
as a Lender

By: /s/ Lauren Cole
Name: Lauren Cole
Title: Vice President

EXHIBIT A

EXHIBIT D

Compliance Certificate

TO: SOLAR CAPITAL LTD., as Collateral Agent and Lender
SILICON VALLEY BANK, as Lender
FROM: SCPHARMACEUTICALS INC.

The undersigned authorized officer ("**Officer**") of SCPHARMACEUTICALS INC. ("**Borrower**"), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement dated as of May 23, 2017, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "**Loan Agreement**;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending with all required covenants except as noted below;

(b) There are no defaults or Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	Complies
1)	Financial statements	Monthly within 30 days		Yes No N/A
2)	Annual (CPA Audited) statements	Within 180 days after FYE		Yes No N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within earlier 30 days of approval or 60 days of FYE), and when revised		Yes No N/A
4)	A/R & A/P agings	If applicable		Yes No N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing		Yes No N/A
6)	Compliance Certificate	Monthly within 30 days		Yes No N/A
7)	IP Report	When required		Yes No N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		**$**	Yes No N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		**$**	Yes No N/A

Deposit and Securities Accounts
(Please list all accounts; attach separate sheet if additional space needed)

Institution Name	Account Number	New Account?	Account Control Agreement in place?
1)		Yes No	Yes No
2)		Yes No	Yes No
3)		Yes No	Yes No
4)		Yes No	Yes No

Financial Covenants

Minimum Liquidity Requirement	(A) Qualified Cash	(B) A/P not paid within 90 days from invoice date	Complies with Minimum Liquidity Requirement (Is (B) plus $10,000,000 less than (A))?
			Yes No N/A

Other Matters

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00)?	Yes	No
4)	Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No
5)	Has Borrower or any Subsidiary entered into or amended any Material Agreement? If yes, please explain and provide a copy of the Material Agreement(s) and/or amendment(s).	Yes	No
6)	Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state “No exceptions.” Attach separate sheet if additional space needed.)

SCPHARMACEUTICALS INC.

By: _____

Name: _____

Title: _____

Date:

COLLATERAL AGENT USE ONLY

Received by:	_____	Date:	_____
Verified by:	_____	Date:	_____
Compliance Status:	Yes	No	

US-DOCS\104482907.4

CONSENT AND SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **CONSENT AND SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Amendment**"), dated as of December 12, 2018 (the "**Amendment Effective Date**"), is made among scPharmaceuticals Inc., a Delaware corporation ("**Borrower**"), Solar Capital Ltd., a Maryland corporation ("**Solar**"), in its capacity as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**") and the Lenders listed on Schedule 1.1 of the Loan and Security Agreement (as defined below) or otherwise a party hereto from time to time including Solar in its capacity as a Lender and Silicon Valley Bank ("**Bank**") as a Lender (each a "**Lender**" and collectively, the "**Lenders**").

The Borrower, the Lenders and Collateral Agent are parties to a Loan and Security Agreement dated as of May 23, 2017 (as amended by that certain First Amendment to Loan and Security Agreement dated as of November 21, 2018, and as further amended, restated or modified from time to time, the "**Loan and Security Agreement**").

The Borrower intends to form a wholly-owned subsidiary incorporated in the Commonwealth of Massachusetts named scPharmaceuticals Securities Corporation ("**Securities Corp**") for the purpose of making investments as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code (the "**MSC Subsidiary Formation**").

The Borrower has requested that the Lenders (a) provide their consent to the MSC Subsidiary Formation and (b) agree to certain amendments to the Loan and Security Agreement. Subject to the terms and conditions hereof, the Lenders have agreed to (a) provide such consent and (b) such amendments to the Loan and Security Agreement.

Accordingly, the parties hereto agree as follows:

SECTION 1 Definitions; Interpretation.

(a) **Terms Defined in Loan and Security Agreement**. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan and Security Agreement.

(b) **Interpretation**. The rules of interpretation set forth in Section 1.1 of the Loan and Security Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

SECTION 2 Limited Consent. Subject to the terms of Section 4 below, the Lenders hereby consent to the MSC Subsidiary Formation and to Borrower's ownership of the stock of Securities Corp, and agrees that (a) Borrower's ownership of the stock of Securities Corp shall be deemed "Permitted Investments" under the Loan and Security Agreement; and (b) the MSC Subsidiary Formation and Borrower's ownership of the stock of Securities Corp shall not be deemed a breach of the negative covenant regarding investments pursuant to Section 7.8 of the Loan and Security Agreement; and (c) neither the MSC Subsidiary Formation nor Borrower's ownership of the stock of Securities Corp shall constitute, in and of itself, an "Event of Default" under the Loan and Security Agreement.

SECTION 3 Amendments to the Loan and Security Agreement.

(a) The Loan and Security Agreement shall be amended as follows effective as of the Amendment Effective Date:

(i) New Definitions. The following definitions are added to Section 1.3 in their proper alphabetical order:

"**MSC Subsidiary**" means a wholly owned Subsidiary incorporated in the Commonwealth of Massachusetts or the State of Delaware for the purpose of holding Investments as a Massachusetts security corporation under 830 CMR 63.38B.1 of the Massachusetts tax code and applicable regulations (as the same may be amended, modified or replaced from time to time).

"**Pledge Agreement**" means that certain Pledge Agreement dated as of the Second Amendment Effective Date, between Borrower and Solar, as amended, amended and restated, supplemented or otherwise modified from time to time.

"**Second Amendment Effective Date**" means December 12, 2018.

(ii) Amended and Restated Definition. The following definitions are hereby amended and restated as follows:

"**Guarantor**" is any Person (including all direct or indirect Subsidiaries of Borrower other than MSC Subsidiary; provided that Borrower shall have maintained compliance with Section 7.15 at all times) providing a Guaranty of the Obligations in favor of Collateral Agent for the benefit of the Secured Parties.

"**Loan Documents**" are, collectively, this Agreement, each Control Agreement, the Perfection Certificates, each Compliance Certificate, the ACH Letter, each Loan Payment Request Form, any Guarantees, the Exit Fee Agreement, the Pledge Agreement, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, any agreements creating or perfecting rights in the Collateral (including all insurance certificates and endorsements, landlord consents and bailee consents) and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent, as applicable, in connection with this Agreement; all as amended, restated, or otherwise modified.

(iii) Section 7 is hereby amended by inserting a new Section 7.15 at the end thereof as follows:

7.15 MSC Investment Covenant. Permit, at any time that MSC Subsidiary has any assets or liabilities, Qualified Cash to be less than 110% of the then aggregate outstanding Obligations.

(iv) Exhibit D to the Loan and Security Agreement is hereby amended and restated in its entirety in the form attached hereto as Exhibit A.

(b) **References Within Loan and Security Agreement**. Each reference in the Loan and Security Agreement to "this Agreement" and the words "hereof," "herein," "hereunder," or words of like import, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment.

SECTION 4 Conditions of Effectiveness. The effectiveness of this Amendment shall be subject to the satisfaction of each of the following conditions precedent:

(a) Fees **and Expenses**. The Borrower shall have paid (i) all invoiced costs and expenses then due in accordance with Section 6(e), and (ii) all other fees, costs and expenses, if any, due and payable as of the Amendment Effective Date under the Loan and Security Agreement.

(b) **This** Amendment. Collateral Agent shall have received this Amendment, executed by the Borrower.

(c) **Pledge Agreement**. Collateral Agent shall have received that certain Pledge Agreement dated as of the date hereof, between Borrower and Solar, executed by the Borrower.

(d) **Officer's Certificate**. Collateral Agent shall have received a certificate of an officer of the Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Agreement, in form acceptable to Collateral Agent and the Lenders.

(e) **Representations and Warranties; No Default**. On the Amendment Effective Date, after giving effect to the amendment of the Loan and Security Agreement contemplated hereby:

(i) The representations and warranties contained in Section 5 shall be true and correct on and as of the Amendment Effective Date as though made on and as of such date; and

(ii) There exist no Events of Default or events that with the passage of time would result in an Event of Default.

SECTION 5 Representations and Warranties. To induce the Lenders to enter into this Amendment, the Borrower hereby confirms, as of the date hereof, (a) that the representations and warranties made by it in Section 5 of the Loan and Security Agreement and in the other Loan Documents are true and correct in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; (b) that there has not been and there does not exist a Material Adverse Change; and (c) that the information included in the Perfection Certificate delivered to Collateral Agent on the Effective Date remains true and correct in all material respects. For the purposes of this Section 5, (i) each reference in Section 5 of the Loan and Security Agreement to "this Agreement," and the words "hereof," "herein," "hereunder," or words of like import in such Section, shall mean and be a reference to the Loan and Security Agreement as amended by this Amendment, and (ii) any representations and warranties which relate solely to an earlier date shall not be deemed confirmed and restated as of the date hereof (provided that such representations and warranties shall be true, correct and complete in all material respects as of such earlier date).

SECTION 6 Miscellaneous.

(a) **Loan Documents Otherwise Not Affected; Reaffirmation**. Except as expressly amended pursuant hereto or referenced herein, the Loan and Security Agreement and the other Loan Documents shall remain unchanged and in full force and effect and are hereby ratified and confirmed in all respects. The Lenders' and Collateral Agent's execution and delivery of, or acceptance of, this Amendment shall not be deemed to create a course of dealing or otherwise create any express or implied duty by any of them to provide any other or further amendments, consents or waivers in the future. The Borrower hereby reaffirms the grant of security under Section 4.1 of the Loan and Security Agreement and hereby reaffirms that such grant of security in the Collateral secures all Obligations under the Loan and Security Agreement, including without limitation any Term Loans funded on or after the Amendment Effective Date, as of the date hereof.

(b) **Conditions**. For purposes of determining compliance with the conditions specified in Section 4, each Lender that has signed this Amendment shall be deemed to have consented to, approved or accepted or to be satisfied with, each document or other matter required thereunder to be consented to or approved by or acceptable or satisfactory to a Lender unless Collateral Agent shall have received notice from such Lender prior to the Amendment Effective Date specifying its objection thereto.

(c) **Release**. In consideration of the agreements of Collateral Agent and each Lender contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Borrower, on behalf of itself and its successors, assigns, and other legal representatives, hereby fully, absolutely, unconditionally and irrevocably releases, remises and forever discharges Collateral Agent and each Lender, and its successors and assigns, and its present and former shareholders, affiliates, subsidiaries, divisions, predecessors, directors, officers, attorneys, employees, agents and other representatives (Agent, Lenders and all such other persons being hereinafter referred to collectively as the "**Releasees**" and individually as a "**Releasee**"), of and from all demands, actions, causes of action, suits, covenants, contracts, controversies, agreements, promises, sums of money, accounts, bills, reckonings, damages and any and all other claims, counterclaims, defenses, rights of set-off, demands and liabilities whatsoever of every name and nature, known or unknown, suspected or unsuspected, both at law and in equity, which Borrower, or any of its successors, assigns, or other legal representatives may now or hereafter own, hold, have or claim to have against the Releasees or any of them for, upon, or by reason of any circumstance, action, cause or thing whatsoever which arises at any time on or prior to the day and date of this Amendment, including, without limitation, for or on account of, or in relation to, or in any way in connection with the Loan Agreement, or any of the other Loan Documents or transactions thereunder or related thereto. Borrower understands, acknowledges and agrees that

the release set forth above may be pleaded as a full and complete defense and may be used as a basis for an injunction against any action, suit or other proceeding which may be instituted, prosecuted or attempted in breach of the provisions of such release. Borrower agrees that no fact, event, circumstance, evidence or transaction which could now be asserted or which may hereafter be discovered shall affect in any manner the final, absolute and unconditional nature of the release set forth above.

(d) **No Reliance**. The Borrower hereby acknowledges and confirms to Collateral Agent and the Lenders that the Borrower is executing this Amendment on the basis of its own investigation and for its own reasons without reliance upon any agreement, representation, understanding or communication by or on behalf of any other Person.

(e) **Costs and Expenses**. The Borrower agrees to pay to Collateral Agent within ten (10) days of its receipt of an invoice (or on the Amendment Effective Date to the extent invoiced on or prior to the Amendment Effective Date), the reasonable documented out-of-pocket costs and expenses of Collateral Agent and the Lenders party hereto, and the reasonable documented fees and disbursements of counsel to Collateral Agent and the Lenders party hereto (including allocated costs of internal counsel), in connection with the negotiation, preparation, execution and delivery of this Amendment and any other documents to be delivered in connection herewith on the Amendment Effective Date or after such date.

(f) **Binding Effect**. This Amendment binds and is for the benefit of the successors and permitted assigns of each party.

(g) Governing Law. THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF NEW YORK (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE STATE OF NEW YORK), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL.

(h) **Complete Agreement; Amendments; Exit Fee Agreement**. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Amendment and the Loan Documents merge into this Amendment and the Loan Documents. For the avoidance of doubt and notwithstanding anything to the contrary in this Amendment, Borrower (a) reaffirms its obligations under the Exit Fee Agreement, including without limitation its obligation to pay the Exit Fee (as defined in the Exit Fee Agreement) if and when due thereunder, and (b) agrees that the defined term "Loan Agreement" as defined in the Exit Fee Agreement shall on and after the Amendment Effective Date mean the Loan and Security Agreement as amended by this Amendment and as may be amended, restated or modified from time to time on or after the Amendment Effective Date.

(i) **Severability of Provisions.** Each provision of this Amendment is severable from every other provision in determining the enforceability of any provision.

(j) **Counterparts**. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile, portable document format (.pdf) or other electronic transmission will be as effective as delivery of a manually executed counterpart hereof.

(k) **Loan Documents**. This Amendment and the documents related thereto shall constitute Loan Documents.

IN WITNESS WHEREOF, the parties hereto have duly executed this Amendment, as of the date first above written.

BORROWER:

SCPHARMACEUTICALS INC.,
as Borrower

By: /s/ John Tucker
Name: John Tucker
Title: Chief Executive Officer and President

[Signature Page to Second Amendment to Loan and Security Agreement (scPharma/Solar)]

COLLATERAL AGENT AND LENDER:

SOLAR CAPITAL LTD.,
as Collateral Agent and a Lender

By: /s/ Anthony J. Storino
Name: Anthony J. Storino
Title: Vice President

LENDER:

SILICON VALLEY BANK,
as a Lender

By: /s/ Lauren Cole
Name: Lauren Cole
Title: Vice President

[Signature Page to Second Amendment to Loan and Security Agreement (scPharma/Solar)]

EXHIBIT A

EXHIBIT D

Compliance Certificate

TO: SOLAR CAPITAL LTD., as Collateral Agent and Lender
SILICON VALLEY BANK, as Lender

FROM: SCPHARMACEUTICALS INC.

The undersigned authorized officer ("**Officer**") of SCPHARMACEUTICALS INC. ("**Borrower**"), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement dated as of May 23, 2017, by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "**Loan Agreement**;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending _covenants with all required except as noted below;

(b) There are no defaults or Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.

(d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	Complies
1)	Financial statements	Monthly within 30 days		Yes No N/A
2)	Annual (CPA Audited) statements	Within 180 days after FYE		Yes No N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within earlier 30 days of approval or 60 days of FYE), and when revised		Yes No N/A
4)	A/R & A/P agings	If applicable		Yes No N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing		Yes No N/A
6)	Compliance Certificate	Monthly within 30 days		Yes No N/A
7)	IP Report	When required		Yes No N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		**$** _	Yes No N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period		**$** _	Yes No N/A

Deposit and Securities Accounts

(Please list all accounts; attach separate sheet if additional space needed)

	Institution Name	Account Number	New Account?	Account Control Agreement in place?
1)			Yes No	Yes No
2)			Yes No	Yes No
3)			Yes No	Yes No
4)			Yes No	Yes No

Financial Covenants

Minimum Liquidity Requirement	(A) Qualified Cash	(B) A/P not paid within 90 days from invoice date	Complies with Minimum Liquidity Requirement (Is (B) plus $10,000,000 less than (A))?
			Yes No N/A

MSC Investment Covenant	(A) Qualified Cash	(B) Aggregate outstanding Obligations	Complies with MSC Investment Covenant (Is (A) at least 110% of (B))1?
			Yes No N/A

1 MSC Investment Covenant only applicable at any time that MSC Subsidiary has any assets or liabilities.

Other Matters

1)	Have there been any changes in Key Persons since the last Compliance Certificate?	Yes	No
2)	Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement?	Yes	No
3)	Have there been any new or pending claims or causes of action against Borrower that involve more than Two Hundred Fifty Thousand Dollars ($250,000.00)?	Yes	No
4)	Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.	Yes	No
5)	Has Borrower or any Subsidiary entered into or amended any Material Agreement? If yes, please explain and provide a copy of the Material Agreement(s) and/or amendment(s).	Yes	No
6)	Has Borrower provided the Collateral Agent with all notices required to be delivered under Sections 6.2(a) and 6.2(b) of the Loan Agreement?	Yes	No

Exceptions

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

SCPHARMACEUTICALS INC.

By:
Name:
Title:
Date:

COLLATERAL AGENT USE ONLY

Received by:	Date:
Verified by:	Date:
Compliance Status:	Yes No

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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 Form S-8 and the Registration Statement (No. 333-229120) on Form S-3 of scPharmaceuticals Inc. of our report dated March 21, 2019, relating to the financial statements of scPharmaceuticals Inc., appearing in this Annual Report on Form 10-K of scPharmaceuticals Inc. for the year ended December 31, 2018.

/s/ RSM US LLP

Boston, Massachusetts

March 21, 2019

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 21, 2019

By: /s/ John H. Tucker

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

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, Rachael Nokes, 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 21, 2019

By: /s/ Rachael Nokes

Rachael Nokes
Principal Accounting Officer

Exhibit 32.1

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

In connection with the Annual Report of scPharmaceuticals Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 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 21, 2019

By: /s/ John H. Tucker

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

Exhibit 32.2

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

In connection with the Annual Report of scPharmaceuticals Inc. (the "Company") on Form 10-K for the year ended December 31, 2018 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 21, 2019

By: /s/ Rachael Nokes
Rachael Nokes
Principal Accounting Officer