# 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, 2022**

**OR**

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

**For the transition period from- to**

**Commission File Number 001-38293**

# SCPHARMACEUTICALS INC.

**(Exact name of registrant as specified in its Charter)**

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

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

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common stock, par value $0.0001 | SCPH | The Nasdaq Global Select Market |

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

**None**
**(Title of class)**

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the 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, 2022) was $75,626,427. The number of shares of the registrant's common stock, par value $0.0001 per share, outstanding as of March 21, 2023 was 35,769,073.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement relating to its 2023 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The registrant's definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2022.

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**Summary of the Material and Other Risks Associated with Our Business**

Our business is subject to numerous material and other risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We are heavily dependent on the success of our product candidates and our approved product, FUROSCIX® (furosemide injection). We have only one approved product and we cannot give any assurance that we will receive regulatory approval for any other product candidates, which is necessary before they can be commercialized.
- If we fail to produce FUROSCIX in the volumes that we require on a timely basis, we may face delays in our commercialization efforts.
- 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.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell FUROSCIX, we may be unable to generate any revenue.
- 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 success.
- 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 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.
- Our success depends on our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of supplies, components and drug product for commercialization of FUROSCIX or any of our product candidates, if approved, including our ability to monitor quality control issues related to the production of FUROSCIX and on-body infusors in the volumes that will be required on a timely basis.
- 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.
- If we fail to comply with our obligations under our existing and any future intellectual property license with third parties, we could lose license rights that are important to our business.
- We may be subject to product liability lawsuits related to our products and product candidates, if approved, which could divert our resources, result in substantial liabilities and reduce the commercial potential of our products and product candidates.
- The ongoing and evolving COVID-19 pandemic may materially and adversely affect our business and our financial results, including the activities supporting our commercial launch of FUROSCIX.
- Our failure to successfully identify, develop and market additional product candidates could impair our ability to grow.
- We depend heavily on our executive officers, directors and principal consultants and the loss of their services would materially harm our business.

The material and other risks summarized above should be read together with the text of the full risk factors set forth in Part I, Item 1A. “Risk Factors” and in the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains express or implied forward-looking statements within the meaning of the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical fact contained in this Annual Report are forward-looking statements, including, but not limited to, statements about the marketing and commercialization of FUROSCIX, the timing or likelihood of regulatory filings and approvals, our plans to develop and commercialize our product candidates, the timing of our ongoing or planned clinical trials, the clinical utility of FUROSCIX or our product candidates, expectations surrounding the pricing, reimbursement or pharmacoeconomic benefit of FUROSCIX, expectations surrounding manufacturing capabilities and supply chain matters, our commercialization capabilities and strategy, the sufficiency of our cash, cash equivalents, restricted cash and short-term investments and our ability to raise additional capital to fund our operations, our future financial performance, the anticipated impact of the COVID-19 pandemic and general economic conditions on our business, and the plans and objectives of management for future operations, capital needs and capital expenditures. In some cases, forward-looking statements can be identified by terminology such as “may,” “will,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology.

The forward-looking statements in this Annual Report on Form 10-K are only predictions. We have based these forward-looking statements on our management’s beliefs and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, you should not place undue reliance on forward-looking statements because they 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. Important factors that may cause actual results to differ materially from current expectations include those described under Part I, Item 1A. “Risk Factors” 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.

As used in this Annual Report on Form 10-K, unless otherwise stated or the context requires otherwise, references to “scPharmaceuticals Inc.,” the “Company,” “we,” “us,” and “our,” refer to scPharmaceuticals Inc. and its subsidiary on a consolidated basis.

## PART I

### Item 1. Business.

### OVERVIEW

We are a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. Our strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or IV, delivery. By moving delivery away from the high-cost healthcare settings typically required for IV administration, we believe our technology has the potential to reduce overall healthcare costs and advance the quality and convenience of care. Our approved product, FUROSCIX, consists of our novel formulation of furosemide delivered via West Pharmaceutical Services, Inc.'s, or West's, on-body infusor, which delivers an 80 mg dose. On October 10, 2022, we announced that the U.S. Food and Drug Administration, or FDA, approved FUROSCIX for the treatment of congestion due to fluid overload in adults with New York Heart Association, or NYHA, Class II/III chronic heart failure. FUROSCIX is the first and only FDA-approved subcutaneous loop diuretic that delivers IV equivalent diuresis at home. IV equivalence was established in a clinical study in which FUROSCIX demonstrated 99.6% bioavailability (90% CI: 94.8%-104.8%) and 8-hour urine output of 2.7 L which was similar to subjects receiving intravenous furosemide. We estimate that there is a $6.9 billion total market opportunity for FUROSCIX in the United States. The commercial launch of FUROSCIX commenced in the first quarter of 2023.

Heart failure affects 7.2 million adults in the United States who collectively experience approximately 4 million heart failure events annually. An estimated 59% of hospital admissions for heart failure are directly attributable to volume overload. Approximately 80% of heart failure patients discharged from hospital schedule a follow-up appointment and 25-30% of patients are readmitted to hospital post-discharge within 30 days. Repeat hospitalization for heart failure has been associated with increased mortality, with first-time discharges having a median survival (50% mortality) of 2.4 years, decreasing to 0.6 years following a fourth hospitalization. Our proprietary formulation of furosemide administered subcutaneously via an on-body infusor, which we refer to together as FUROSCIX, is intended to help alleviate the signs and symptoms associated with congestion due to fluid retention in patients with NYHA Class II/III chronic heart failure, such as fatigue and shortness of breath. FUROSCIX is designed to offer alternative outpatient intervention for heart failure patients who display reduced responsiveness to oral diuretics in non-emergency situations and do not require hospitalization.

We believe FUROSCIX will allow heart failure patients to receive IV-strength diuresis outside the high-cost hospital setting. At a price of $822 per dose, we estimate the average cost of treatment with FUROSCIX for each heart failure exacerbation (comprising four doses of FUROSCIX) to be approximately $3,300. Prevention of hospital admission and reduced readmission rates would result in reducing the estimated 15 million days patients with heart failure spend in the hospital each year. By decreasing the number of admissions and readmissions to hospitals, we believe we can drive significant cost savings to payers and hospitals.

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

Beyond furosemide and ceftriaxone, we aim to leverage our subcutaneous formulation expertise to develop and seek approval of additional product candidates.

## OUR PLATFORM AND OTHER PIPELINE PROGRAMS

### FUROSCIX to Treat Congestion in Patients with Heart Failure

Heart failure is a chronic disease resulting from impairment of the heart's ability to pump blood and is one of the most common causes of hospital admissions in patients over 65 with at least 1-2 million hospitalizations in the United States annually. Patients with heart failure are prone to retaining sodium and water in their blood stream and, as this accumulates, it can distribute to tissues. This extra fluid settling in the lungs, ankles and abdomen can cause 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 cause of hospitalization for patients with heart failure.

Oral loop diuretics, such as furosemide, are the mainstay for the management and prevention of congestion in patients with heart failure. However, during periods of worsening congestion in heart failure, the bioavailability of oral furosemide is reduced and becomes highly variable. To overcome the limitation of oral furosemide in this setting, two strategies are typically employed. First, the furosemide dose is typically doubled, and/or additional oral diuretics (thiazide diuretics) are incorporated to attempt to overcome the blunted pharmacological response to these agents. Second, if this fails, clinicians often rely on giving IV diuretics, either in the hospital, an outpatient heart failure clinic or an infusion center, if available. Approximately 800,000 patients with symptoms of heart failure are admitted to the hospital by an emergency physician annually and we believe 50% of these admissions may be potentially avoided if patients could receive timely, effective treatment for symptomatic congestion outside of the hospital setting.

In addition to potentially unnecessary hospitalizations, it has been estimated that up to 50% of patients hospitalized for an episode of acute decompensated heart failure are discharged on oral diuretics with persistent signs and symptoms of congestion. The presence of congestion at discharge has been associated with an increased risk of 30-day all-cause mortality and rehospitalization for heart failure. The American College of Cardiology Foundation and the American Heart Association Task Force on Practice guidelines recommend that patients hospitalized for heart failure have a post discharge follow up visit within 14 days of hospital discharge. Since symptoms of congestion generally worsen over several days or weeks, patients with heart failure may receive FUROSCIX at discharge when congestion has not fully resolved or at the first signs of worsening congestion post hospitalization.

FUROSCIX therefore offers an alternative outpatient route of administration of furosemide for NYHA Class II/III chronic heart failure patients to alleviate the signs and symptoms associated with congestion when responsiveness to oral diuretics is reduced and hospitalization is not indicated in order to potentially avoid unnecessary hospitalizations.

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

We believe that FUROSCIX provides a safe and effective solution that will enable IV-strength diuresis outside of the high-cost hospital setting. We believe FUROSCIX can potentially 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.

We believe subcutaneous FUROSCIX has the potential to:

- *Reduce hospital admission rates*: Since symptoms of congestion generally worsen over several days or weeks, there is a window of opportunity to intervene. We believe FUROSCIX could in certain instances avoid a hospitalization by providing IV-strength diuresis in an outpatient setting such as the physician's office, a heart failure clinic or at home. It is estimated that 90% of patients presenting to the emergency department with worsening heart failure are admitted to the hospital and approximately 50% of those patients could potentially be safely discharged after demonstrating effective diuresis with parenteral therapy during a brief period of observation.

- *Reduce patient readmission*: We believe FUROSCIX could reduce the incidence of readmission for heart failure patients by providing IV-strength diuresis in the home post-hospital discharge. It is estimated that 30-50% of patients that are hospitalized for acute decompensated heart failure that are transitioned to oral furosemide prior to being discharged from the hospital have persistent symptoms of congestion at discharge. Persistent congestion may reduce the absorption of oral furosemide reducing the diuretic effect. As a result, patients are often readmitted to the hospital to receive IV furosemide. We believe FUROSCIX can break this cycle by providing IV-strength diuresis to patients shortly after discharge to reduce the rate of readmissions for decompensated heart failure.

FUROSCIX offers an outpatient therapeutic option to deliver IV-strength furosemide to potentially avoid the need for unnecessary, expensive hospitalizations which in turn could improve patients' quality of life with minimal interruption of daily living.

**Clinical Development of FUROSCIX**

On October 10, 2022, we announced that the FDA approved FUROSCIX for the treatment of congestion due to fluid overload in adults with New York Heart Association Class II/III chronic heart failure. FUROSCIX is not indicated for emergency situations or in patients with acute pulmonary edema. FUROSCIX is a drug-device combination product and was approved pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, in reliance on the FDA's previous findings of safety and efficacy for the Listed Drug Furosemide (Injection, USP, 10 mg/mL; NDA 18667; Hospira, Inc.), which is indicated for intravenous (IV) and intramuscular (IM) injection for the treatment of edema in adult patients with congestive heart failure, cirrhosis of the liver and renal disease, including nephrotic syndrome. FUROSCIX is the first and only FDA-approved subcutaneous loop diuretic that delivers IV equivalent diuresis at home.

FUROSCIX (Furosemide Injection, 80 mg/10 mL) is a novel, pH neutral formulation of furosemide that is administered via a subcutaneous infusion using a proprietary, wearable, pre-programmed on-body drug delivery system. Other currently available furosemide injection products are alkaline, with a pH of 8.0 – 9.3. Subcutaneous administration of IV/IM furosemide, USP formulation has been associated with local skin reactions, some severe, requiring discontinuation of treatment and local treatment of the complication which has been attributed to the alkaline pH of the furosemide formulation, volume of fluid administered and the rapid injection.

***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 FUROSCIX in 17 patients with heart failure. In this study, FUROSCIX was delivered subcutaneously via the B. Braun Perfusor Space Infusion Pump. This study also evaluated diuresis and the urinary sodium excretion over eight hours and 24 hours post-dosing as the pharmacodynamic endpoints.

*Treatment arms*

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

*Comparative pharmacokinetic results*

This study demonstrated bioequivalence in the concentration of drug delivered over time based upon the area under the curve, or AUC, between our subcutaneous formulation of furosemide and IV furosemide. Although the maximum concentration, or $C_{max}$, 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 observed difference in $C_{max}$ between IV injection and subcutaneous furosemide is attributable to the two bolus IV injections administered at the initiation of IV therapy. Nevertheless, the 5-hour infusion of FUROSCIX resulted in nearly complete bioavailability compared to two bolus IV injections of furosemide.

*Comparative pharmacodynamic results*

Total mean urine outputs for subcutaneous versus IV administration were 102% (2654 mL vs 2641 mL; p = 0.83) and 103% (3630 mL vs 3538 mL; p = 0.71) at 8 and 24 hours, respectively. Total mean urine sodium excretion for subcutaneous versus IV administration were 97.3% (284 mmol vs 292 mmol; p = 0.78) and 97.4% (341 mmol vs 350 mmol; p = 0.80), at 8 and 24 hours, respectively. The total urine sodium excretion and urine output were comparable between our subcutaneous formulation of furosemide and IV furosemide.

***Human Factors Summary***

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

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

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

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

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

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

**FREEDOM-HF** - **F**uroscix **Re**al-World **E**valuation for **D**ecreasing H**o**spital Ad**m**issions in **H**eart **F**ailure

FREEDOM-HF was a health economic study designed to support the commercial reimbursement of FUROSCIX. Further, this multicenter, prospective adaptive clinical trial was designed to evaluate differences in heart failure and overall costs between subjects receiving FUROSCIX outside the hospital and patients receiving intravenous furosemide in the hospital setting for 30-days after being discharged from the emergency department. Differences in costs were determined from a propensity-matched control arm derived from Truven Health Analytics Market Scan databases. The study was designed to enroll up to 75 subjects in the FUROSCIX cohort to detect a statistically significant difference in 30-day overall and heart-failure related costs. The study began enrollment in the fourth quarter of 2020 and completed enrollment in May 2021.

Based on the results from a planned, prespecified interim analysis conducted to confirm the final sample size, and following input from statisticians, principal investigators, payer advisors and Health Economics and Outcomes Research experts, enrollment was closed on May 17, 2021, prior to the enrollment target of 34 patients. This decision was made due to the statistically significant reduction observed in 30-day heart failure-related costs in patients who received FUROSCIX in the interim analysis. The final analysis included 24 subjects treated with FUROSCIX and 66 matched comparators based on seven variables associated with hospitalization. On July 13, 2021, we announced preliminary top-line results from FREEDOM-HF, demonstrating that average 30-day heart failure-related costs were reduced by $17,753 per study subject in the FUROSCIX arm compared to historically matched comparators ($p < 0.0001$). In September 2021, we announced additional results from FREEDOM-HF, demonstrating that average 30-day total healthcare costs were reduced by $30,568 per study subject in the FUROSCIX arm compared to historically matched comparators ($p < 0.0001$). Since the price for FUROSCIX was not established at the time of study completion, the difference in costs did not include the cost of FUROSCIX. These results support our hypothesis that treating heart failure patients presenting to the emergency department with worsening congestion with FUROSCIX outside of the hospital setting has the potential to dramatically reduce the significant costs associated with hospital admissions and readmissions.

We conducted an analysis of additional secondary endpoints in FREEDOM-HF which provided additional insights into the clinical effectiveness of FUROSCIX. In this analysis, it was determined that patients who received FUROSCIX had a median reduction of heart failure peptide biomarkers from study entry to first visit, and to last visit, of 42.3% and 28%, respectively ($p \leq 0.01$). In addition, patients who received FUROSCIX had a 12.8-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) Summary Score 30 days after study entry.

These results have been presented at the Heart Failure Society of America Annual meeting in September 2021 in Denver, Colorado and at the Technology and Heart Failure Therapeutics Conference in February 2022 in New York, NY.

**AT HOME-HF PILOT - A**voiding **T**reatment in the **H**ospital with Fur**o**scix for the **M**anagement of Cong**e**stion in **H**eart **F**ailure – A Pilot Study

AT-HOME-HF PILOT was a multicenter, randomized pilot clinical trial designed to evaluate the clinical outcomes and safety of FUROSCIX compared to a "treatment as usual" approach in patients presenting to a heart failure clinic with chronic heart failure and fluid overload requiring augmented diuretic therapy. The objective of this pilot study was to evaluate prospective endpoints that could inform the design and sample size of a clinical trial that could be used to seek expansion of the indication for FUROSCIX to include a reduction of hospitalizations for heart failure or inclusion in treatment guidelines. The primary endpoint was a 30-day hierarchal composite of cardiovascular death, heart failure hospitalizations, emergency department visits for heart failure and % change of NT-proBNP at day seven from baseline, utilizing the Finkelstein-Schoenfeld win ratio. The Finkelstein-Schoenfeld win ratio is a statistical method used to compare composite outcomes for every pair in a clinical trial from the treatment and control group. Pre-defined secondary endpoints were evaluated from baseline across the 30-day study period and included the number of days alive and heart failure event free, global assessment via visual analog scale, composite clinical congestion score, 5- and 7-point Likert dyspnea scores, health-related quality of life measured by the Kansas City Cardiomyopathy Questionnaire, or KCCQ-12, serum creatinine, weight, six-minute walk test and ReDS® (Remote Dielectric Sensing) lung fluid measurement. The study compared FUROSCIX to a "treatment as usual" approach, was descriptive only and did not include a powered statistical hypothesis test. The study completed enrollment in the first quarter of 2022. The study enrolled 51 subjects, of which 34 received FUROSCIX and 17 received "treatment as usual".

In July 2022, we announced top-line results from the AT HOME-HF Phase 2 Pilot study demonstrating a positive trend in the Finkelstein-Schoenfeld win ratio in the FUROSCIX group compared to the "treatment as usual" group across multiple analysis populations. Subjects randomized to FUROSCIX had a 37% reduction in the risk of a heart failure hospitalization relative to patients randomized to "treatment as usual" at day 30. All pre-defined secondary endpoints measuring symptoms of congestion, quality of life and functional status favored the FUROSCIX group and included a two kilogram greater weight loss at day three and a 12-point increase in the KCCQ-12 summary score at day 7 and day 30. There were 11 subjects that experienced 21 adverse events during the 30-day study period that were determined by the investigator to be related to FUROSCIX. The most common related adverse event was infusion site pain that was mild in severity. There was one serious adverse event (dehydration) that was assessed by the investigator as possibly related to FUROSCIX, which resolved. During the 30-day study period, there was one death (sudden cardiac death) in the FUROSCIX group which occurred on study day 30 and was assessed by the investigator to be not related to FUROSCIX.

In September 2022, we announced that subjects in the AT HOME-HF study who received FUROSCIX demonstrated augmented decongestion compared with patients receiving enhanced oral diuretics as demonstrated by:

- Improved diuresis as measured by a greater reduction in body weight from baseline at study day 3 (2.8 kg vs 0.8 kg, p=0.035);
- Improvement from baseline in mean 5-point dyspnea score at day 3 (-0.5 vs. 0.1, p=0.019);
- Greater number of patients with markedly or moderately better shortness of breath based on 7-point dyspnea at day 3 (44% vs 6%, p=0.006);

- Clinically relevant improvement from baseline in quality of life as measured by Kansas City Cardiomyopathy questionnaire – 12 (KCCQ-12) summary score at study days 7 and 30 of 8.9 points and 9.3 points, respectively; and
- An increase of 55.8 meters in the average six-minute walk distance at day 30 (36.7 vs -19.1 meters, p=.012).

The win-ratio for the hierarchical endpoint of cardiovascular death, heart failure hospitalization, urgent ED/clinic visit for heart failure and the percentage change in NT-proBNP from baseline at day seven was 1.11 (95% Confidence Interval: 0.48-2.50) favoring the FUROSCIX group.

During the 30-day study period, subjects in the FUROSCIX group spent an average of 23.2 days heart failure event free compared to 14.3 in subjects receiving enhanced oral diuretics.

In the FUROSCIX group, 14.7% of subjects had a serum potassium level that was less than 3.5 mEq/L during the 30-day study and was managed effectively with oral potassium supplements.

The results of the AT HOME-HF study showed that subjects receiving subcutaneous FUROSCIX demonstrated augmented decongestion, as evidenced by a greater reduction in body weight, better dyspnea scores, greater exercise capacity and improvement of health-related quality of life compared with patients receiving enhanced oral diuretics, or standard treatment, in a Phase 2 pilot study.

**Commercialization**

The commercial launch of FUROSCIX commenced in the first quarter of 2023. We plan to commercialize FUROSCIX in the United States by building and utilizing our own commercial infrastructure. We currently intend to focus our commercial efforts on the United States market, which we believe represents the largest market opportunity for FUROSCIX. In addition, we plan to seek collaborations with third-party partners outside of the United States to distribute our products in foreign markets, if approved by the relevant foreign regulatory authorities.

We believe that we can effectively commercialize FUROSCIX in the United States with an initial specialty sales force of approximately 40 field-based sales representatives. We intend to initially pursue a highly-concentrated target market, which consists of approximately 400 hospitals, associated clinics and office-based practices that, collectively account for approximately 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 and increasing patient comfort were ranked as important potential attributes of FUROSCIX by the health plans and pharmacy benefit managers that were surveyed.

We intend to build a highly concentrated commercial infrastructure focused on distribution, promotion and customer support to healthcare providers in our key hospital targets and in office-based practices. Our target call points within these hospitals and practices will include heart failure specialists, cardiologists, 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, 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, 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 as the ability to treat in the home setting, prevention of hospitalization, and avoidance of IV placement, while the lowest perceived barriers to adoption identified in the survey were the preference to monitor in a hospital setting, sufficiency of current medications and hospital guidelines or protocols. In addition, based on a last two patient exercise conducted in our quantitative market research with healthcare professionals, when given the option to change their prior treatment choice to FUROSCIX, 65% of healthcare practitioners in a clinic setting and 40% in a hospital setting responded that they would prescribe our product candidate. We expect to supplement our outside sales force with inside sales representatives and people in the medical science, nursing and reimbursement fields to support the proper training and utilization of FUROSCIX.

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

Eligible patients with heart failure may receive FUROSCIX at the initial worsening signs and symptoms when the response to oral diuretics is not adequate. In addition, patients can receive FUROSCIX after discharge, if they still are exhibiting some signs and symptoms of congestion despite their oral diuretic regimen. FUROSCIX is packaged as individual, single use only on-body infusor kits. In April 2016, we held a meeting with the Centers for Medicare and Medicaid Services, or CMS, at which CMS stated that coverage and reimbursement of FUROSCIX may be available under Medicare Part D as a transition of care drug.

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

**Our Pipeline Programs**

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

- *scCeftriaxone*: We have submitted an investigational new drug application, or IND, for a subcutaneous form of Ceftriaxone, 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 our Ceftriaxone formulation, which we refer to as scCeftriaxone. We are currently evaluating a suitable on-body delivery system to administer scCeftriaxone.
- *scCarbapenem*: We have completed several IND-enabling studies for our subcutaneous Carbapenem program, which we refer to as scCarbapenem, an antibiotic currently used intravenously for the treatment of infections caused by gram-negative organisms.

***Ceftriaxone***

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

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

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

### *Additional Product Programs*

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

### Our FUROSCIX On-Body Infusor

The FUROSCIX On-Body Infusor is a drug-device combination product consisting of FUROSCIX (furosemide injection, 80 mg per 10 mL), a novel, pH neutral furosemide formulation optimized for subcutaneous administration and contained in a prefilled, Crystal Zenith® cartridge, and a proprietary wearable, pre-programmed on-body delivery system, the FUROSCIX On-Body Infusor, based on West's proprietary on-body infusor. The FUROSCIX On-Body Infusor is applied to the abdomen via a medical grade adhesive and delivers a subcutaneous infusion of FUROSCIX through a pre-programmed, biphasic delivery profile over 5 hours.

## MANUFACTURE OF OUR PRODUCTS AND 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 FUROSCIX and our product candidates. 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 in an effort to ensure conformity with the specifications, policies and procedures for our product candidates.

We believe that our current third-party manufacturers have capacity of FUROSCIX in quantities sufficient to meet our expected commercial needs and to accommodate the manufacturing of materials for future clinical trials of candidates in our pipeline.

In order to meet projected global demand for FUROSCIX, we plan to support an increase in production capacity at West's and our pharmaceutical manufacturing partners' facilities.

## INTELLECTUAL PROPERTY

### Proprietary protection

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, manufacturing and process discoveries and other know-how, to operate without infringing the proprietary rights of others, and to prevent others from infringing on our proprietary rights. We and our partners have been building and continue to build our intellectual property portfolio relating to our product candidates and

technology. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and certain foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also intend to rely on trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us or our partners in the future will be commercially useful in protecting our technology.

**Patent rights**

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

***Furosemide formulations***

As of February 8, 2023, we own a patent family directed to the composition of matter of our subcutaneous formulation of furosemide and methods of treating edema, hypertension or heart failure using the formulation of furosemide having a concentration of about 2 mg/mL to about 20 mg/mL. This patent family includes U.S. Patent Nos. 9,884,039 and 11,433,044, directed to methods of treatment, U.S. Patent No. 10,272,064, directed to liquid pharmaceutical formulations, one pending U.S. patent application, one granted patent in each of Canada, China and Europe, two granted patents in Japan, one pending patent application in Europe, and seven granted patents and five pending patent applications in other countries outside of the United States. Patents that issue from this patent family are generally expected to expire in 2034, excluding any additional term in the United States for patent term adjustment. U.S. Patent Nos. 9,884,039; 10,272,064; and 11,433,044 are scheduled to expire in April 2034.

We also own a patent family directed to compositions of matter of liquid pharmaceutical formulations containing an increased concentration of furosemide and methods of treating congestion, edema, fluid overload, or hypertension using these formulations of furosemide. This patent family includes U.S. Patent Nos. 11,497,755; 11,559,535; and 11,571,434 directed to liquid pharmaceutical formulations, two pending U.S. patent applications, one pending patent application in each of Canada, China, Europe and Japan, and 12 pending patent applications in other countries outside of the United States. Patents that issue from this patent family are generally expected to expire in 2040, excluding any additional term in the United States for patent term adjustment. U.S. Patent Nos. 11,497,755; 11,559,535; and 11,571,434 are scheduled to expire in January 2040.

**Trade secret and other protection**

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

**Other intellectual property rights**

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

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

## COMPETITION

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. Some of these companies are developing therapies that are directly competitive to our approach, and others are more generally developing therapies to treat heart failure. These companies include but are not limited to: Abbott Laboratories, Amgen, AstraZeneca, Bayer, Bioheart, Boston Scientific, Boehringer Ingelheim, GlaxoSmithKline, Johnson & Johnson, Eli Lilly and Company, Merck & Co., Medtronic, Novartis, Pfizer, Roche, Sanofi, Sarfez Pharmaceuticals, Servier Pharmaceuticals, SQ Innovation and Takeda Pharmaceutical Company. 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 foreign 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

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing.

### *U.S. drug development process*

In the United States, the FDA regulates drugs, medical devices and drug-device combination products under the FDCA and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice regulations, or GLPs, and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations, or GCPs, to evaluate the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a New Drug Application, or NDA, after completion of all pivotal trials;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice requirements, or cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. An IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the trial includes an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. 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 about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials must be conducted under protocols detailing the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and a separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries, including clinicaltrials.gov.

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

- Phase 1: The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and appropriate dosage.
- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

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

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. 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 drug. In addition, 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.

***U.S. review and approval process***

The results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission, or ten months from the date of receipt for a drug that is not a new molecular entity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional clinical trial or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or

withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory 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. In addition, the FDA may require a sponsor to conduct Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. The FDA may also place other conditions on approval 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.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

***Regulation of Combination Products in the United States***

Certain products may be comprised of components, such as drug components and device components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

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

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of the FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination

product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

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

***Orphan drug designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. However, competitors, 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. Orphan exclusivity also could block the approval of a competing product for seven years if a competitor obtains approval of the “same drug,” as defined by the FDA, or if a product candidate is determined to be contained within the competitor’s product for the same disease or condition. In addition, if an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

***Expedited development and review programs***

The FDA has a number of programs intended to expedite the development or review of a marketing application for a new drug. For example, the fast track designation program is intended to expedite or facilitate the process for developing and reviewing product candidates that meet certain criteria. Specifically, investigational drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. With regard to a fast track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.
A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive

FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.
Any product candidate submitted to the FDA for approval, including a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. An NDA is eligible for priority review if the product candidate is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals. For non-new molecular entity NDAs, these six- and ten-month review periods are measured from the date that the FDA receives the application.

In addition, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials. Drugs receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory trials in a timely manner or if such trials fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition of accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***Post-approval requirements***

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. 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 and regulations. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy that are consistent with FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

***Marketing exclusivity***

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, 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, for example new indications, dosages or strengths of an existing drug. 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 ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity 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 preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor

conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials.

***Other U.S. 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, 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. These laws include but are not limited to, the Anti-Kickback Statute, the federal False Claims Act, the federal Physician Payments Sunshine Act, and other state and federal laws and regulations.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Moreover, 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 False Claims Act.

In addition, the Civil Monetary Penalties 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 also created additional 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. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to health care professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Certain foreign countries and U.S. states also mandate implementation of commercial compliance programs,

impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to health care professionals and entities.

Violations of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, reporting obligations and integrity oversight, exclusion from participation in federal and state healthcare programs and imprisonment.

**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 EU, 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.

***Healthcare Reform***

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, or AMP, beginning January 1, 2024. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship

between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated.

Payment methodologies may also be subject to changes in healthcare legislation and regulatory challenges. For example, in order for a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price, or ASP, plus 6 percent to ASP minus 22.5 percent on specified covered outpatient drugs, or SCODs, but did so without issuing a formal notice of proposed rulemaking, which was subsequently challenged in court. In June 2022, the U.S. Supreme Court held that although the Department of Health and Human Services, or HHS, has authority to set reimbursement rates based on average price and discretion to "adjust" the price up or down, HHS may not vary the reimbursement rates by hospital group unless it conducts a survey of hospitals' acquisition costs. Accordingly, the U.S. Supreme Court held that HHS's changes to the 2018 and 2019 reimbursement rates for 340B hospitals were unlawful. Based on the foregoing, CMS issued a final rule, effective January 1, 2023, pursuant to which CMS will pay 340B hospitals under Medicare Part B for certain outpatient drugs at the drug's ASP, plus 6%, the same rate used for non-340B hospitals. It is unclear how future changes to the payment methodology may affect pharmaceutical manufacturers and hospitals who purchase their products now and in the future.

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.

We expect that the 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, lower reimbursement, and new payment methodologies. This could lower the price that we receive for any approved product. Any denial in coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payors, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our product candidates, if approved.

***Data Privacy and Security Laws***

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

***Cybersecurity***

In the normal course of business, we may collect and store personal information and certain sensitive company information, including proprietary and confidential business information, trade secrets, intellectual property, information regarding trial participants in connection with clinical trials, sensitive third-party information and employee information. While we have certain cybersecurity measures in place, our security measures cannot guarantee that a significant cyberattack will not occur. A successful attack on our information technology systems could have significant consequences to the business. While we devote resources to our security measures to protect our systems and information, these measures cannot provide absolute security. See "Risk Factors –

General Risk Factors" for additional information about the risks to our business associated with a breach or compromise to our information technology systems.

**Human Capital Management**

As of March 21, 2023, we had 96 full-time employees, including 10 in technical operations and product development, 14 in clinical development and medical affairs, regulatory affairs, and quality assurance, 20 in commercial, 40 sales representatives and 12 in finance, general administrative and executive administration. All of our employees are located in the U.S., and none are represented by a labor union or are parties to a collective bargaining agreement. We believe our efforts in managing our workforce have been effective.

*Recruitment, Retention and Culture*

We recognize that our future success depends on our ability to attract, develop and retain key personnel, maintain our strong company culture, and ensure diversity and inclusion in our Board of Directors, management and broader workforce. We launched FUROSCIX in February 2023 after successfully building an experienced commercial team and expanded commercial organization to support our future growth. During this period of expansion, we remain committed to our core values and key human capital-related objectives including effectively recruiting, retaining, incentivizing and integrating our existing and new employees, maintaining and growing a diverse and inclusive workforce, and ensuring a robust culture of compliance. A testament to our strong culture is our third year in a row earning a spot in the Boston Business Journal's Best Places to Work list for companies of our size.

*Diversity, Equity and Inclusion (DEI)*

Diversity, equity and inclusion are fundamental to our success and future innovation. We are intentional about including diverse points of view, perspectives, experiences, backgrounds and ideas in our decision-making and hiring processes and practices. For example, the consideration of individuals from underrepresented groups was a key hiring factor during the expansion of the commercial part of our organization.

As of March 21, 2023, approximately 33% of our Board of Directors self-identified as female. As of March 21, 2023, approximately 11% of our Board of Directors were individuals from underrepresented groups, i.e., those self-identifying as Black or African American, Hispanic or Latinx, Asian, or being of two or more races. Two members of our Board of Directors are military veterans.

*Compensation and Benefits*

We have designed a broad-based compensation and benefits program that is designed to attract, retain and motivate our employees and believe that our efforts have been successful in this regard. In addition to base salaries and annual bonuses, these programs include a 401(k) plan with generous eligibility and matching features, healthcare and insurance benefits, equity awards, educational assistance and an employee stock purchase plan. Furthermore, benefits are extended to domestic partners.

We are committed to ensuring fair and equitable pay for all of our employees including across genders and underrepresented groups. Our Board of Directors and senior leadership team strongly support this commitment.

**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.

**Available Information**

We file electronically with the Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov. We make available on our website at www.scpharmaceuticals.com, under "Investor Relations," free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. The information contained in

the websites referenced in this Annual Report on Form 10-K is not incorporated by reference into this Annual Report on Form 10-K.

## INFORMATION ABOUT OUR EXECUTIVE OFFICERS AND DIRECTORS

The following information with respect to our Board of Directors and executive officers is presented as of the date of this Annual Report on Form 10-K:

| Name | Age | Position at scPharmaceuticals | Principal Employment |
|---|---|---|---|
| **Executive Officers** | | | |
| John H. Tucker | 60 | President, Chief Executive Officer and Director | Same |
| Rachael Nokes | 48 | Chief Financial Officer | Same |
| **Non-Employee Directors** | | | |
| Jack A. Khattar | 61 | Chairman of the Board and Director | President and Chief Executive Officer of Supernus Pharmaceuticals, a public pharmaceutical company |
| William T. Abraham, M.D. | 63 | Director | Chief Medical Officer of V-Wave Ltd., a privately held medical device company, and College of Medicine Distinguished Professor at The Ohio State University |
| Mette Kirstine Agger | 58 | Director | Chief Executive Officer and Strategic Advisor of Ersum Biotech |
| Minnie Baylor-Henry | 75 | Director | President of B-Henry & Associates, a regulatory and compliance strategy consulting company |
| Sara Bonstein | 42 | Director | Chief Financial Officer of Insmed Incorporated, a public biopharmaceutical company |
| Frederick Hudson | 77 | Director | Former Partner of KPMG, LLP |
| Leonard D. Schaeffer | 77 | Director | Partner of North Bristol Partners LLC, a privately held consulting company |
| Klaus Veitinger, M.D., Ph. D. | 61 | Director | Venture Partner of OrbiMed Advisors LLC, a healthcare investment firm |

## 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 Products and Product Candidates

Risks Related to Approval and Commercialization of our Products and Product Candidates

***We are heavily dependent on the success of our product candidates and our approved product, FUROSCIX. We cannot give any assurance that we will receive regulatory approval for any 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 our approved product, FUROSCIX, which we announced in October 2022 was approved by the U.S. Food and Drug Administration, or FDA. A substantial majority of our resources have also been focused on the commercial launch of FUROSCIX in the United States, which commenced in the first quarter of 2023. Our business and future success are substantially dependent on our ability to successfully commercialize FUROSCIX for the treatment of congestion due to fluid overload in adults with New York Heart Association Class II/III chronic heart failure. All of our product candidates are in early 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 commercialize FUROSCIX.

We are not permitted to market any of our product candidates in the United States until we receive approval of a new drug application, or NDA, from the U.S. Food and Drug Administration, or FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. There can be no assurance that the FDA will approve any of our product candidates, which is necessary before they can 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. The time required to obtain approval by the FDA and comparable foreign regulatory 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. 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. We cannot predict whether we will obtain regulatory approval to commercialize any of our 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.

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 foreign regulatory authorities. The FDA or other foreign 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 foreign 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 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 a product candidate'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 our product candidates, our business will be materially harmed and the price of our common stock will be adversely affected.

***There is no assurance that our commercialization efforts with respect to FUROSCIX will be successful or that we will be able to generate revenues at the levels or within the timing we expect or at the levels or within the timing necessary to support our goals.***

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 foreign regulatory authorities outside the United States. Failure to obtain marketing approval for FUROSCIX outside the United States will prevent us from commercializing it in those jurisdictions.

Our ability to successfully commercialize FUROSCIX and any of our products candidates, if approved, 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 successfully commercialize FUROSCIX or any of our product candidates, if approved, in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business.

***Even though we obtained 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.

Risks Related to Clinical Development

***Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.***

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or early clinical trials of a product candidate may not predict the results of later clinical trials of the product candidate, and interim results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an Investigational New Drug Application, or IND, or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- Obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;

- obtaining approval from one or more institutional review boards, or IRBs, or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice, or GCP, requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current Good Manufacturing Practice, or cGMP, regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Moreover, 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 comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority 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 comparable foreign regulatory authority 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 comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted

***We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites;
- the risk that patients enrolled in clinical trials will drop out of such trials before completion; and
- delays or difficulties in enrollment and completion of studies due to the COVID-19 pandemic.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

***Our products and 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. The most common adverse events observed in clinical trials of FUROSCIX included the following administration site and skin reactions: erythema, bruising, edema and infusion site pain. 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. Clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such products (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such products;
- regulatory authorities may require the addition of labeling statements, such as a Risk Evaluation or Mitigation Strategy, or REMS, "boxed" warning or a contraindication;
- we may be required to change the way such products are distributed or administered, conduct additional clinical trials or change the labeling of the products;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to recall or remove such products from the marketplace; or
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; or
- we may fail to secure acceptance of our product candidates from physicians, healthcare payers, patients and the medical community; and

- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected products, and could substantially increase the costs of commercializing our products and significantly impact our ability to successfully commercialize our products and generate revenues. Any of these occurrences may harm our business, financial condition and prospects.

***Interim, "topline" and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose interim, topline, or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline, or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition

***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 products beyond FUROSCIX. We are exploring various therapeutic opportunities for our pipeline and product programs for use with West's proprietary on-body infusor. 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 foreign regulatory authorities.

Risks Related to Acceptance, Sales, Marketing and Competition

***The commercial success of FUROSCIX and any 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 FUROSCIX or 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 FUROSCIX or our product candidates over alternative treatments, such as oral and IV formulations;
- relative convenience as well as ease of administration of FUROSCIX or our product candidates compared to existing treatments;
- any labeling restrictions placed upon FUROSCIX or any product candidate in connection with its approval;
- the prevalence and severity of the adverse side effects of FUROSCIX or our product candidates;
- the clinical indications for which FUROSCIX or any 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 FUROSCIX or any 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.

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 approved product, FUROSCIX, we may be unable to generate any revenue.***

We are in the process of establishing sufficient infrastructure for the sales, marketing or distribution of FUROSCIX and for 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, we must continue to build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services.

We have established an initial sales force to promote FUROSCIX to hospital networks, healthcare providers and third-party payers in the United States. 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.

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 FUROSCIX and our product candidates, if approved, 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 in order to educate physicians about our product candidates, once approved; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

In addition, we intend to establish collaborations to commercialize our product candidates, if approved by the relevant regulatory authorities, outside of the United States. Therefore, our future success will depend, in part, on our ability to enter into and maintain collaborative relationships for such efforts, the collaborator's strategic interest in the product and such collaborator's ability to successfully market and sell the product. We cannot assure you

that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

***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 FUROSCIX and our product candidates, if approved.***

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

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

If the FDA approves a competitor's application for a product candidate or drug-device combination product before our application for a similar product candidate or drug-device combination product, and grants such competitor a period of exclusivity, the FDA may take the position that it cannot approve our 505(b)(2) application for a similar product candidate until the exclusivity period expires. Additionally, even if our 505(b)(2) application for any of our product candidates 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 FUROSCIX and our product candidates will compete may limit market acceptance of FUROSCIX and 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 FUROSCIX and the established use of IV furosemide may limit the potential for FUROSCIX to receive widespread acceptance.

Risks Related to the COVID-19 Pandemic

***The ongoing and evolving COVID-19 pandemic may materially and adversely affect our business and our financial results, including the activities supporting our commercial launch of FUROSCIX.***

The ongoing and evolving COVID-19 pandemic may continue to have a negative impact on the global economy which could impact our business and results of operations. The continued spread of COVID-19, and any current or new variants of the virus, could adversely impact our operations. For instance, the COVID-19 pandemic may negatively affect the operations of third-party suppliers, which could result in delays or disruptions in the supply of FUROSCIX and our product candidates. Furthermore, COVID-19 may delay enrollment in any future clinical trials due to prioritization of hospital resources toward the pandemic and restrictions in travel. Some patients may be unwilling to enroll in future clinical trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, any governmental measures that are implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns, could negatively affect our business. For instance, encouraging all employees to work remotely may disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration or potential resurgence of the pandemic, the severity of new variants of COVID-19 or the effectiveness of actions to contain and treat COVID-19. To date, the third parties that perform our manufacturing, assembly, packaging and testing of our products have experienced delays relating to supply chain logistics but have remained operational. An extended period of global supply chain and economic disruption may continue to impact us and could materially affect our business, results of operations, access to sources of liquidity and financial condition. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

***Disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed, reviewed, approved or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs, medical devices and biologics or modifications to approved drugs, and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business

Risks Related to Manufacturing, Supply and Use

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

We do not currently own or operate manufacturing facilities for the production of FUROSCIX or any of our product candidates. We currently depend on third parties to manufacture our product candidates, including the drug formulation and device components for FUROSCIX, and continue to rely on such third parties to produce the final commercial product. 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. Any delays in the manufacturing of finished drug product or device components could delay our commercial supply, which could delay, prevent or limit our ability to generate revenue and continue our business. Moreover, 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 or foreign regulatory authorities 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 drug-device combination products need to comply with both pharmaceutical current good manufacturing practice requirements, or cGMPs, and the FDA's cGMP requirements for medical devices, known as the Quality System Regulation, or QSR, which is 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 FUROSCIX and our product candidates may be unable to comply with these cGMP and QSR requirements and with other FDA and foreign regulatory requirements. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. 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 FUROSCIX or 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 FUROSCIX or 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 FUROSCIX or our product candidates, entail higher costs or even prevent us from effectively commercializing FUROSCIX or our product candidates.

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

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

For example, in our Phase 3 product design clinical validation 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 our first generation device, 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 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.

## Risks Related to Our Financial Position and Capital Requirements

Risks Related to Past Financial Condition

***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 $28.0 million and $36.8 million for the years ended December 31, 2021 and 2022, respectively. In addition, our accumulated deficit as of December 31, 2022 was $226.5 million. Absent the realization of sufficient revenues from product sales, if any, of FUROSCIX or 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 FUROSCIX.

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

- build our sales, marketing, distribution and other commercial infrastructure and manufacture commercial inventory of FUROSCIX;
- initiate and continue research, preclinical and clinical development efforts for any current or future product candidates;
- seek to identify additional product candidates;
- seek regulatory and marketing approvals for 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, scientific and sales and marketing 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 until we are able to 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 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 have not yet demonstrated an ability to 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 generate substantial revenue from FUROSCIX and may never be profitable.***

Our ability to become profitable depends upon our ability to generate revenue. Our commercial launch of FUROSCIX commenced in the first quarter of 2023, and there is no assurance that we will generate substantial revenues from FUROSCIX.

Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- continue to obtain commercial quantities of FUROSCIX at acceptable cost levels;
- obtain third-party coverage or adequate reimbursement for FUROSCIX;
- achieve market acceptance of FUROSCIX 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.

We expect to incur significant sales and marketing costs as we commercialize FUROSCIX. Even if we 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 substantial product revenue, we will not become profitable and may be unable to continue operations without continued funding.

Risks Related to Future Financial Condition

***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. In addition, we may incur significant commercialization expenses for FUROSCIX or any of our product candidates, if approved, 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 commercialization efforts.

We plan to continue to use our existing unrestricted cash primarily for development activities related to the advancement and commercialization of FUROSCIX, automation necessary to increase capacity for our delivery technology, research and development, and for working capital and other general corporate purposes. We will be required to expend significant funds in order to commercialize FUROSCIX, as well as other product candidates we may seek to develop. In any event, our existing unrestricted cash may not be sufficient to fund all of the efforts that we plan to undertake, including the development of any of our product candidates. Accordingly, we may be required to obtain further funding through public or private equity offerings, debt financings, royalty-based financing arrangements, collaborations and licensing arrangements or other sources. 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. In addition, we maintain our cash and cash equivalents at a number of financial institutions, and our deposits at one or more of these institutions may exceed federally insured limits. Market conditions can impact the viability of one or more of these institutions and, in the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

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

- the outcome, timing and costs of completing development and seeking regulatory approvals for product candidates that we may develop;
- the costs of commercialization activities for FUROSCIX and any of our product candidates that receive marketing approval, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue, if any, received from commercial sales of FUROSCIX or any of our current and future product candidates;
- the pricing and reimbursement of FUROSCIX and of any of our 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;
- costs associated with any adverse market conditions or other macroeconomic factors; and
- the costs of operating as a public company.

***The terms of our credit facility place restrictions on our operating and financial flexibility, and 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 October 2022, we entered into a Credit Agreement and Guaranty, or the Credit Agreement, with, among others, funds managed by Oaktree Capital Management, L.P., or Oaktree. The Credit Agreement establishes a $100.0 million term loan facility, consisting of (i) $50.0 million, or the Tranche A Loan, funded at closing, (ii) $25.0 million, or the Tranche B Loan, that we may borrow in up to two draws on or prior to September 30, 2024, and (iii) $25.0 million, or the Tranche C Loan, that we may borrow on or prior to December 31, 2024; provided, in the case of the Tranche B Loan and the Tranche C Loan, that we have achieved certain net sales revenue milestone targets described in the Credit Agreement. We used a portion of the proceeds from the Tranche A Loan to prepay all outstanding loans under our prior loan and security agreement with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank. All obligations under our secured credit facility are secured by substantially all of our existing property and assets (including our intellectual property assets), subject to certain exceptions. This debt financing may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

The Credit Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring us to (i) maintain certain levels of cash and cash equivalents in accounts subject to a control agreement in favor of Oaktree of at least $15.0 million at all times commencing from November 13, 2022 and increasing to $20.0 million of cash and cash equivalents in such controlled accounts after we borrow the Tranche B Loan, and (ii) meet minimum quarterly net sales revenue targets described in the Credit Agreement. In addition, the Credit Agreement contains customary events of default that entitle Oaktree to accelerate our indebtedness under the Credit Agreement to become immediately due and payable. Under the Credit Agreement, an event of default will occur if, among other things, we fail to make payments under the Credit Agreement (subject to specified periods), we or our subsidiaries breach any of the covenants under the Credit Agreement (subject to specified cure periods with respect to certain breaches), a material adverse change occurs, we, our subsidiaries or our respective assets become subject to certain legal proceedings, such as bankruptcy proceedings, we and/or our subsidiaries are unable to pay our debts as they become due or default on contracts with third parties which would permit the holder of indebtedness in excess of a certain threshold to accelerate the maturity of such indebtedness or that could cause a material adverse change..

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.

## Risks Related to Government Regulation

### Risks Related to Ongoing Regulatory Obligations

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our products and product candidates are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. In the U.S., we are not permitted to market our product candidates in the U.S. until we receive regulatory approval of an NDA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe available nonclinical or clinical data support the safety or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain

regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;

- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. Additionally, the FDA regulates FUROSCIX as a combination product that consists of both a drug and a medical device, and we may develop product candidates that are similarly regulated as combination products. Developing and obtaining regulatory approval for combination products can pose unique challenges because they involve components that are regulated under different types of regulatory requirements and potentially by different FDA centers. As a result, such product candidates may raise regulatory, policy and review management challenges. Differences in regulatory pathways for each component of a combination product can impact the regulatory processes for all aspects of product development and management, including clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, user fees and post approval modifications. 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.

Even if we eventually complete clinical trials and receive approval of a NDA or comparable foreign marketing application for any of our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects

***Even though FDA has approved FUROSCIX, we will remain subject to significant post-marketing regulatory requirements and oversight.***

In October 2022, the FDA approved FUROSCIX for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. In connection with this approval, or any other approvals we may obtain for any of our product candidates, we are required to submit reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product. In addition, approved labeling for our products may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the approved labeling for FUROSCIX includes contraindications for patients with anuria, hypersensitivity to furosemide and hepatic cirrhosis or ascites, and is not approved for use in emergency situations or in patients with acute pulmonary edema. The FDA may also require a REMS in order to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products are subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with current good manufacturing practices, or cGMPs, and GCPs for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority

discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize FUROSCIX and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. In addition, the FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could impair our business. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

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

Successful sales of FUROSCIX and any product candidates that receive regulatory approval depend on the availability of adequate coverage and reimbursement rates 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. Coverage and adequate reimbursement rates from governmental healthcare programs 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 rates might not be sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high, thereby discouraging their use of our products. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our 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 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. 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 may apply formulary controls (e.g., prior authorization or step therapy requirements, higher co-payments) to restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payers, whether foreign or domestic, and whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the United States, no uniform policy for coverage and reimbursement of products exists among third-party payers. The Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, decides whether and to what extent products will be covered and reimbursed under Medicare. Third-party payers often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. Reimbursement by a third-party payer may depend upon a number of factors, including the third-party payer's determination that a medication is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Therefore, coverage of and reimbursement rates 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 will be applied consistently or obtained in the first instance.

There may also be delays in obtaining coverage for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, for example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services. We may also increasingly be required to provide discounts on our products to governmental healthcare programs, commercial payers and health maintenance organizations.

Further, we believe that future coverage and reimbursement rates will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage 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.

***If the FDA does not conclude that our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

In October 2022, the FDA approved our NDA for FUROSCIX through the Section 505(b)(2) regulatory pathway, and we plan to develop additional product candidates for which we plan to seek approval under the 505(b)(2) regulatory pathway, The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the submissions of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our future product candidates by potentially decreasing the amount of nonclinical and/or clinical data that we would need to generate in order to obtain FDA approval.

If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway for our product candidates, we may need to conduct additional nonclinical studies and/or 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 such product candidates, and complications and risks associated with such product candidates, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway could result in new competitive products reaching the market more quickly than any product candidates we developed, which could 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 any product candidates we develop will receive the requisite approval for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to certain requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of a new product. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to streamlined product development or earlier approval.

***If the FDA or other foreign regulatory authorities approve generic products that compete with FUROSCIX or any of our product candidates, the sales of FUROSCIX or 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 foreign 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 FUROSCIX or any of our product candidates, 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, FUROSCIX or our product candidate (and in some cases even this limited bioequivalence testing can be waived by the FDA). Competition from generic equivalents to FUROSCIX or any of our product candidates could substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in FUROSCIX and our product candidates.

***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 offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain 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.

Our business is heavily regulated and therefore involves significant interaction with public officials, which may in the future include officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers would be subject to regulation under the FCPA. Recently the Securities and Exchange Commission, or SEC, and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws.

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 anti-bribery and anti-corruption laws, and other laws governing international business practices, may result in substantial fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of heightened monitoring by governmental authorities, and prohibitions on the conduct of our business. The 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.

***We may be liable if the FDA or other U.S. enforcement agencies determine we have engaged in the off-label promotion of our products or have disseminated false or misleading labeling, advertising or promotional materials.***

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for FUROSCIX is limited to the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure, and includes limitations prohibiting use in emergency situations or patients with pulmonary edema.

Our promotional materials and training methods must comply with the FDA and other applicable laws and regulations, including laws and regulations prohibiting marketing claims that promote the off-label use of our products or that omit material facts or make false or misleading statements about the safety or efficacy of our products. Healthcare providers may use our products, if approved, off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. The FDA also could conclude that a claim is misleading if it determines that there are inadequate nonclinical and/or clinical data supporting the claim, or if a claim fails to reveal material facts about the safety or efficacy of our products. If the FDA determines that our promotional labeling or advertising materials promote an off-label use or make false or misleading claims, it could request that we modify our promotional materials or training content or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines and criminal penalties.

It is also possible that other federal, state or foreign enforcement authorities might take action if they determine that our promotional or training materials promote an unapproved use or make false or misleading claims, which could result in significant fines or penalties. The FDA or another regulatory agency could disagree with the manner in which we advertise and promote our products. Violations of the FDCA may also lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws, which may lead to costly penalties and may adversely impact our business. Recent court decisions have impacted FDA's enforcement activity regarding off-label promotion in light of First Amendment considerations; however, there are still significant risks in this area, in part due to the potential for False Claims Act exposure. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

***Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of any product candidates and commercialize FUROSCIX and may 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 any of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell FUROSCIX or any product candidates for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

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

Among the provisions of the ACA of importance to our products and 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 certain drugs and biologics 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 potential liability under federal healthcare fraud and abuse laws, including the False Claims Act, or FCA, and the Anti-Kickback Statute, or AKS;
- 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 340B drug pricing program;
- new requirements to annually report to CMS certain data on payments and other transfers of value to physicians and teaching hospitals;
- 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.

There have been a number of significant changes to the ACA and its implementation, as well as judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers pursuant to the Budget Control Act of

2011, which began in 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. The American Taxpayer Relief Act of 2012, 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. These laws and similar future initiatives may result in additional reductions in Medicare and other healthcare funding, which could have an adverse effect on customers for FUROSCIX or our product candidates, if approved, and, accordingly, our financial operations.

There also 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. In March 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. For the 2018 and 2019 fiscal years, CMS altered the reimbursement formula from Average Sale Price, or ASP, plus 6 percent to ASP minus 22.5 percent on specified covered outpatient drugs, or SCODs, but did so without issuing a formal notice of proposed rulemaking, which was subsequently challenged in court. In June 2022, the U.S. Supreme Court held that although the Department of Health and Human Services, or HHS, has authority to set reimbursement rates based on average price and discretion to "adjust" the price up or down, HHS may not vary the reimbursement rates by hospital group unless it conducts a survey of hospitals' acquisition costs. Accordingly, the U.S. Supreme Court held that HHS's changes to the 2018 and 2019 reimbursement rates for 340B hospitals were unlawful. Based on the foregoing, CMS issued a final rule, effective January 1, 2023, pursuant to which CMS will pay 340B hospitals under Medicare Part B for certain outpatient drugs at the drug's ASP, plus 6%, the same rate used for non-340B hospitals. It is unclear how future changes to the payment methodology may affect pharmaceutical manufacturers and hospitals who purchase their products now and in the future.

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

***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, including 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 principal 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. The laws that will affect our operations include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- False claims laws, which prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental healthcare programs. 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 false claims laws. Further, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits persons or entities from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows, or should know, it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal physician sunshine requirements under ACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Centers for Medicare & Medicaid Services information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable 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; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that our business practices, including our arrangements with physicians and other healthcare providers, some of whom received stock options as compensation for services provided, may be subject to challenge under current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. 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. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, 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.

***Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.***

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, results of operation, and financial condition.

In the U.S., the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder, or collectively HIPAA, imposes privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California

Consumer Privacy Act of 2018, or CCPA went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act, or CPRA, passed in California, and it significantly amends the CCPA. It imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions went into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia, Colorado, Connecticut and Utah, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Furthermore, the Federal Trade Commission, or FTC, and many state Attorneys General continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

We are also or may become subject to rapidly evolving data protection laws, rules and regulations in foreign jurisdictions. For example, in Europe, the European Union General Data Protection Regulation, or GDPR, went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the European Economic Area, or EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States; in July 2020, the Court of Justice of the European Union, or CJEU limited how organizations could lawfully transfer personal data from the European Union, or EU, and the EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses, or SCCs. In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. European court and regulatory decisions subsequent to the CJEU decision of July 16, 2020 have taken a restrictive approach to international data transfers. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, after the end of the transition period following the United Kingdom's departure from the EU, we are also subject to the United Kingdom data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

## Risks Related to Our Intellectual Property

Risks Related to Protecting our Intellectual Property

***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 products and 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 products and product candidates that are important to our business; we also may 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 products and 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 products and product candidates. In addition, the patent portfolio licensed to us is, or may be, licensed to third parties, such as outside our field, and such third parties may have certain enforcement rights. Thus, patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against another licensee or in administrative proceedings brought by or against another licensee in response to such litigation or for other reasons.

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

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

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

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

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

Patent applications are generally maintained in confidence until publication. In the United States, for example, patent applications are typically maintained in secrecy for up to 18 months after their filing date. Similarly, publication of discoveries in scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we were the first to file patent applications on our products and product candidates. Any of the foregoing could harm our competitive position, business, financial condition, results of operations, and prospects.

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 products and 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 there is a risk that 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 formulations and compounds of our products and product candidates, the methods used to manufacture them, 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 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;
- we may not be the first to make the inventions covered by each of our patents and pending patent applications;
- we may not be the first to file patent applications for these inventions;
- 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 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 candidate for follow-on indications.

We also may rely on trade secrets to protect our technologies or product candidates, 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, there is a risk that 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 patent 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 product candidates for an adequate amount of time and if we do not obtain protection under the Hatch-Waxman Act and similar non-U.S. legislation for extending the term of patents covering each of our products and product candidates, our business may be materially harmed.***

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, if available, 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 (or Hatch-Waxman Act) permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication. 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 biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries 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 including patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and uses a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in litigation in a U.S. federal court. If any of our or our licensors’ patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent rights to us.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that

would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

For example, a European Unified Patent Court (UPC) is scheduled to come into force during 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time and may adversely affect our ability to enforce our European patents or defend the validity thereof. We may decide to opt out our European patents and patent applications from the UPC. If certain formalities and requirements are not met, however, our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

***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. There is a risk that 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.

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

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 the 505(b)(2) NDA 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 the 505(b)(2) NDA. Otherwise, a 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 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 the product candidate, has expired. These factors, among others, may limit our ability to gain approval of or successfully commercialize our product candidates.

Risks Related to Intellectual Property Claims or Litigation

***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 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 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.

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

Filing, prosecuting, enforcing and defending patents on our products and 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 products and product candidates.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India,

China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Moreover, such proceedings could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

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

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

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

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

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the formulations, 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 products and 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 products or 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 products or product candidates, or methods of use or of making 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 or product candidate. 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 or product candidate. 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 products or 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, 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, products or product candidates. 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.

## Risks Related to Our Reliance on Third Parties

### Risks Related to Third Party Performance

***Use of third parties to manufacture our products and 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 products and 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 products and product candidates, and our furosemide formulation, as well as the device components of our drug-device combination products and 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 and related supplies and packaging. 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 infusor 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 product candidates, 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 or if our third-party manufactures fail to comply with applicable regulations, we may need to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. 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.

If any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our product supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations, and may need to obtain prior FDA approval with respect to any manufacturing changes for any approved products. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another foreign regulatory authority. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our products and product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our approved product, FUROSCIX, is a drug-device combination product that is 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 cGMP requirements 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.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSR requirements or comparable foreign regulatory requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other foreign regulatory authorities, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities for our products. 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 could cause significant delays in our operating timelines and 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 QSR requirements and comparable foreign regulatory requirements. 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 or comparable foreign regulatory requirements. Any failure to comply with cGMP or QSR requirements or other FDA 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.

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

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

Further, although our reliance on these third parties for clinical development activities limits our control over these activities, we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of one of our product candidates, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory authorities require 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 IRBs. Similar requirements apply in other jurisdictions, such as the EU. 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 or comparable foreign regulatory authorities 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 or comparable foreign regulatory authorities 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.

Risks Related to Third Party Contracts

***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 an on-body infusor. 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 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 Employee Matters, Managing Growth and Business Operations

### Risks Related to Employee Matters

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

As of March 21, 2023, we had 96 full-time employees. Our focus on the development and commercialization of FUROSCIX has required us to optimize cash utilization and to manage and operate our business in a lean manner. There can be no assurance that we will be able to hire and/or retain adequate staffing levels to commercialize FUROSCIX or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

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

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

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

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

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

***Our company lacks experience commercializing products, which may have a material adverse effect on our business.***

We are transitioning from a company with a development focus to a company capable of supporting commercial activities. We have completed building our initial sales force and began the commercial launch of FUROSCIX in February 2023. Since FUROSCIX is our first commercial product approved, we have not yet demonstrated an ability to commercialize a product candidate or to obtain marketing approval for a product candidate outside of the U.S. Therefore, our clinical development, and commercialization processes and our regulatory approval process in the U.S. or countries outside of the U.S. may involve more inherent risk, take longer, and cost more than it would if we were a company with a more significant operating history and had experience obtaining approval and marketing approval for and commercializing a product candidate.

***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, contract research organizations, principal investigators, suppliers and vendors may engage in fraud or other misconduct, including intentional, reckless and/or negligent conduct that fails to comply with FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, to provide true, complete and 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.

We have adopted a Code of Business Conduct and Ethics to aid our directors, officers, employees and certain designated agents in making ethical and legal decisions when conducting business on our behalf and performing their day-to-day duties. However, 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 private person or governmental agency 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.

Risks Related to Business Operations and Growth

***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 commercialization and development of FUROSCIX or 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 products and product candidates.

***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, 2022, we had federal net operating loss carryforwards of $17.5 million, which expire at various dates through 2037, and $64.6 million, which may be carried forward indefinitely. At December 31, 2022, we had available state net operating loss carryforwards of $72.6 million, which expire at various dates through 2042 and $300,000, which may be carried forward indefinitely. If not utilized, the net operating loss carryforwards will expire. At December 31, 2022, we had federal and state research and development tax credit carryforwards of $4.3 million and $1.0 million, respectively. If not utilized, the research and development credits expire at various dates through 2042. Our ability to use our U.S. federal and state net operating loss and tax credit carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income. 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.

**General Risk Factors**

***Our business and operations may suffer in the event of information technology system failures, cyberattacks or deficiencies in our cybersecurity.***

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information.

Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack and damage or interruption from computer viruses and malware (e.g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information.

Further, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate

incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss, corruption or unauthorized disclosure of our trade secrets, personal information or other proprietary or sensitive information or other similar disruptions. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of personal information, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws. We could also incur liability, including litigation exposure, penalties and fines, and we could become the subject of regulatory action or investigation. Our competitive position could be harmed and the further development and commercialization of our products and services could be delayed. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems.

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

The risk that we may be sued on product liability claims is inherent in the development of 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 products and product candidates. Product liability claims might be brought against us by consumers, healthcare providers or others coming into contact with our products and 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.

***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.***

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.

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

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including, for example, severely diminished liquidity and credit availability, rising interest and inflation rates, crises involving banking and financial institutions, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers, CMOs, or other third-party providers may not survive an economic downturn or recession. As a result, our business, results of operations and price of our common stock may be adversely affected.

## Risks Related to Ownership of Our Common Stock

***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:

- regulatory actions with respect to our product candidates, including any delays related to COVID-19;
- the pricing, reimbursement and commercialization of FUROSCIX 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 products or 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.

***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 and the development of our 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, products 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

***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 restrict or preclude us from paying dividends. For example, under our Credit Agreement with Oaktree, we are restricted from paying any dividends or making any distributions on account of our capital stock if we are in, or expected to be, in default. 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, 2022, 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 61.7% 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.

***We are a "smaller reporting company," as defined in the Exchange Act, and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.***

We are a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700.0 million measured on the last business day of our second fiscal quarter, which we refer to as a low-revenue smaller reporting company.

Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as a low-revenue smaller reporting company, which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as a smaller reporting company we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may 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 and may decline.

***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. 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 continue 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 a low-revenue smaller reporting company, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not smaller reporting companies, including, but not limited to, not being required to comply with the auditor attestation requirement of Section 404. Once we are no longer a low-revenue smaller reporting 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, especially for so long as our independent registered public accounting firm is not required to provide an attestation report on the effectiveness of such internal controls over financial reporting. 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 Exchange Act. 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.

***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.

***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.

***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.

***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.

***Our bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for any state law claim for (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; or (4) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America are the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, or the rules and regulations promulgated thereunder, and of all suits in equity and actions at law brought to enforce any liability or duty created by the Securities Act or the rules and regulations thereunder. In addition, our bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our Common Stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court and other states have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on us and/or our stockholders who assert that the provision is invalid or unenforceable. The Court of Chancery of the State of Delaware or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

**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 2023. We lease 2,037 square feet in Salem, New Hampshire. The term of the lease for our Salem, New Hampshire facility extends through August 2023. Our facilities house 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.

**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 and Holders

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

As of March 21, 2023, there were 24 holders of record of our common stock, 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 and the securities authorized for issuance thereunder is set forth in Part III, Item 12 of this Annual Report on Form 10-K.

#### Recent Sales of Unregistered Securities

None.

#### Issuer Purchases of Equity Securities

None.

### Item 6. [RESERVED]

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

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

### OVERVIEW

We are a pharmaceutical company focused on developing and commercializing products that have the potential to optimize the delivery of infused therapies, advance patient care and reduce healthcare costs. Our strategy is designed to enable the subcutaneous administration of therapies that have previously been limited to intravenous, or IV, delivery. By moving delivery away from the high-cost healthcare settings typically required for IV administration, we believe our technology has the potential to reduce overall healthcare costs and advance the quality and convenience of care. Our approved product, FUROSCIX, consists of our novel formulation of furosemide delivered via West Pharmaceutical Services, Inc.'s on-body infusor, which delivers an 80 mg dose. On October 10, 2022, we announced that the U.S. Food and Drug Administration, or FDA, approved FUROSCIX for the treatment of congestion due to fluid overload in adults with New York Heart Association Class II/III chronic heart failure. FUROSCIX is the first and only FDA-approved subcutaneous loop diuretic that delivers IV equivalent diuresis at home. IV equivalence was established in a clinical study in which FUROSCIX demonstrated 99.6% bioavailability (90% CI: 94.8%-104.8%) and 8-hour urine output of 2.7 L which was similar to subjects receiving intravenous furosemide. We estimate that there is a $6.9 billion total market opportunity for FUROSCIX in the United States. The commercial launch of FUROSCIX commenced in the first quarter of 2023.

We have funded our operations from inception through December 31, 2022 primarily through the sale of shares of our common stock and the incurrence of debt and, prior to that, through the private placement of our preferred stock. Our first product, FUROSCIX, was approved for sale in October 2022 and we had not generated any revenue from product sales as of December 31, 2022.

For the years ended December 31, 2021 and 2022, our net losses were $28.0 million and $36.8 million, respectively. We have not been profitable since inception, and as of December 31, 2022, our accumulated deficit was $226.5 million. We expect to continue to incur net losses for the foreseeable future as we support the commercialization efforts of FUROSCIX in the United States, including building our sales and marketing organization, continuing research and development efforts, engaging in scale-up manufacturing and seeking regulatory approval for new product candidates and enhancements. Our financial results may fluctuate from quarter to quarter and will depend on, among other factors, the net sales of FUROSCIX, the scope and progress of our research and development efforts and timing of certain expenses.

### COMPONENTS OF OUR RESULTS OF OPERATIONS

#### *Research and Development Expenses*

Research and development ("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;
- cost of pre-approval pharmaceutical batch manufacturing; 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 approved product 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:

- 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 ("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.

With the approval of FUROSCIX, we anticipate that our G&A expenses will increase as we continue to build our corporate and commercial infrastructure to support the commercial launch of FUROSCIX in the United States.

## RESULTS OF OPERATIONS

***Comparison of Years Ended December 31, 2021 and 2022***

The following table summarizes our results of operations for the years ended December 31, 2021 and 2022 (in thousands):

| (in thousands) | YEAR ENDED DECEMBER 31, 2021 | 2022 | INCREASE (DECREASE) |
|---|---|---|---|
| Operating expenses: | | | |
| Research and development | $ 16,039 | $ 15,533 | $ (506) |
| General and administrative | 9,784 | 20,624 | 10,840 |
| Total operating expenses | 25,823 | 36,157 | 10,334 |
| Loss from operations | (25,823) | (36,157) | 10,334 |
| Other income | 315 | 1,418 | 1,103 |
| Interest income | 49 | 1,203 | 1,154 |
| Interest expense | (2,575) | (3,302) | 727 |
| Net loss | $ (28,034) | $ (36,838) | $ 8,804 |

*Research and development expenses.* R&D expenses decreased $0.5 million to $15.5 million during the year ended December 31, 2022, compared to $16.0 million during the year ended December 31, 2021. This decrease was primarily attributable to a $2.3 million decrease in contract services for clinical and medical affairs, a $0.6 million decrease in quality and regulatory consulting costs and a $0.3 million decrease in device development costs. The decrease was partially offset by a $1.6 million increase in pharmaceutical development costs, a $0.9 million increase in employee-related costs, and a $0.2 million increase in patent costs.

*General and administrative expenses.* G&A expenses increased $10.8 million to $20.6 million during the year ended December 31, 2022, compared to $9.8 million during the year ended December 31, 2021. This increase was primarily attributable to a $6.8 million increase in employee-related costs, a $3.5 million increase in commercial preparation costs, and a $0.5 million increase in legal and public company related costs.

*Other income.* Other income was $1.4 million for the year ended December 31, 2022, compared to $0.3 million during the year ended December 31, 2021. The increase in income of $1.1 million was primarily attributable to the fair value adjustment to the derivative liability in 2022.

*Interest income.* Interest income increased $1.2 million to $1.2 million during the year ended December 31, 2022 compared to $49,000 during the year ended December 31, 2021. This increase was primarily attributable to higher interest rates on and larger investment balances in our financial instruments during the year ended December 31, 2022.

*Interest expense.* Interest expense increased $727,000 from the year ended December 31, 2021 to $3.3 million during the year ended December 31, 2022. This increase was due to higher term loan balances in the fourth quarter of 2022 as a result of the Oaktree Agreement (as defined below), combined with the amortization of the debt discount associated with the instrument.

## LIQUIDITY AND CAPITAL RESOURCES

### *Overview*

We have funded our operations from inception through December 31, 2022 primarily through the sale of shares of our common stock, through the private placement of our preferred stock and the incurrence of debt. From inception through December 31, 2022, we had received net cash proceeds of $92.7 million from our initial public offering; $56.7 million from sales of our preferred stock; $48.6 million from borrowings under our previous term loan with SLR Investment Corp. and Silicon Valley Bank and our current term loan under the Oaktree Agreement in 2022, net; $13.5 million from sales of convertible notes; $50.2 million from our public offering of common stock in 2020; $46.6 million from our public offering of common stock in 2022; $14.4 million from the sale of common stock in our 2019 at-the-market offering; and $1.1 million from the sale of common stock in our 2021 at-the-market offering. As of December 31, 2022, we had cash, cash equivalents and restricted cash of $71.2 million and short-term investments of $47.1 million. Our cash and cash equivalents are maintained at a number of financial institutions in amounts that may exceed federally insured limits.

On March 23, 2021, we entered into an Open Market Sale Agreement (the "2021 ATM Agreement") with Cowen and Company LLC ("Cowen") to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to $50.0 million, through an at-the-market equity offering program under which Cowen will act as our sales agent. As of December 31, 2022, we had received $1.1 million of net proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

On October 13, 2022, we entered into the Oaktree Agreement which established a $100.0 million term loan facility, consisting of (i) $ 50.0 million funded immediately, (ii) $25.0 million that we may borrow in up to two draws on or prior to September 30, 2024 and (iii) $25.0 million that we may borrow on or prior to December 31, 2024.

We expect to incur substantial additional expenditures in the near future to support our ongoing activities and our commercialization of FUROSCIX. We believe our existing unrestricted cash is sufficient to fund our operations through at least the next 12 months from the date of this Annual Report on Form 10-K. We expect our costs and expenses to increase in the future as we continue 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. In connection with such development plans and activities, if we determine that we need additional cash resources, we would seek to access such funds either pursuant to our 2021 ATM Agreement or through a combination of public or private equity offerings or debt financings. Additionally, we continue to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the costs and expenses of establishing our U.S. sales and marketing infrastructure;
- the degree of success we experience in commercializing FUROSCIX;
- the revenue generated by sales of FUROSCIX and of other product candidates that may be approved;
- the pricing and reimbursement of FUROSCIX 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 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. For example, the trading prices for our and other biopharmaceutical companies' securities have been highly volatile as a result of macroeconomic conditions, developments in our industry and the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our securities and any such sales may be on unfavorable terms. Additionally, our ability to raise capital may be further impacted by global macroeconomic conditions including, for example, as a result of international political conflict, supply chain issues and rising inflation and interest rates.

**Oaktree Loan and Security Agreement**

On October 13, 2022 (the "Closing Date"), we entered into a Credit Agreement and Guaranty (the "Oaktree Agreement") with, among others, the lenders from time to time party thereto (the "Lenders") and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders (in such capacity, the "Agent"). The Oaktree Agreement establishes a $ 100.0 million term loan facility, consisting of (i) $50.0 million (the "Tranche A Loan") funded immediately, (ii) $25.0 million (the "Tranche B Loan") that we may borrow in up to two draws on or prior to September 30, 2024 and (iii) $25.0 million (the "Tranche C Loan" and, together with the Tranche A Loan and the Tranche B Loan, collectively, the "Term Loan") that we may borrow on or prior to December 31, 2024; provided, in the case of the Tranche B Loan and the Tranche C Loan, that we have achieved certain net sales revenue milestone targets described in the Oaktree Agreement. The Term Loan has a maturity date of October 13, 2027 (the "Maturity Date"). We used a portion of the proceeds of the Term Loan to prepay all outstanding loans under our existing credit facility with SLR Investment Corp. and Silicon Valley Bank and intend to use the remainder of the proceeds to support our commercialization efforts for FUROSCIX and other working capital and general corporate purposes, including the payment of fees and expenses associated with the Oaktree Agreement.

Borrowings under the Term Loan will bear interest at a rate per annum equal to three-month term Secured Overnight Financing Rate ("SOFR") (subject to a 1.00% floor and a 3.00% cap), plus an applicable margin of 8.75%, payable monthly in arrears. From and after achieving $100.0 million in trailing 12-month net sales of FUROSCIX, the applicable margin shall be reduced from 8.75% to 8.25% through the Maturity Date. For the first two years, we may elect to pay up to 3.00% of interest in-kind. We are also permitted to make quarterly interest-only payments until the third anniversary of the Closing Date, after which we will be required to make quarterly payments of interest, plus repay 5.00% of the outstanding principal of the Term Loan in quarterly installments until maturity (subject to certain exceptions).

The Oaktree Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring us to (i) maintain certain levels of cash and cash equivalents in accounts

subject to a control agreement in favor of the Agent of at least $15.0 million at all times commencing from 30 days after the Closing Date and increasing to $20.0 million of cash and cash equivalents in such controlled accounts after we borrow the Tranche B Loan and (ii) meet minimum quarterly net sales revenue targets described in the Oaktree Agreement.

In connection with the Oaktree Agreement, we issued the Lenders warrants to purchase an aggregate of 516,345 shares of our common stock at an exercise price of $5.40 per share. The warrants are immediately exercisable, and the exercise period will expire 7 years from the date of issuance.

Prepayments of the loan, in whole or in part, will be subject to a prepayment fee which declines each year until the fourth anniversary date of the Closing Date, after which no prepayment fee is required. We are also required to pay an exit fee upon any payment or prepayment equal to 2.0% of the aggregate principal amount of the loans funded under the Oaktree Agreement.

In addition, the Oaktree Agreement contains customary events of default that could cause our indebtedness to become immediately due and payable. The lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect as defined under the Oaktree Agreement. Upon the occurrence and for the duration of an event of default, an additional interest rate equal to 2.0% per annum could apply to all obligations owed under the Oaktree Agreement. Among other loan covenant requirements, the Oaktree Agreement also requires the Company to provide an audit opinion of its annual financial statements not subject to any "going concern" or like qualification or exception.

**SLR Investment Corp. and Silicon Valley Bank Term Loan**

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

In September 2019, we replaced the 2017 Loan Agreement with a new $20.0 million term loan with the Lenders (the “2019 Loan Agreement”). The restructured four-year term loan facility allowed for an expansion of the 2017 Loan Agreement. Some of the proceeds from the 2019 Loan Agreement were used to pay off the 2017 Loan Agreement including the final fee of $325,000. The 2019 Loan Agreement extended the term of the credit facility until September 17, 2023.

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

We entered into an Exit Agreement in connection with the 2019 Loan Agreement which provided for an aggregate payment of 4% of the loan commitment, or $800,000, to the lenders upon the occurrence of an exit event (the “Exit Fee”). We paid the Exit Fee during the year ended December 31, 2020 in conjunction with our public offering, which was deemed to be an exit event pursuant to the Exit Agreement.

The 2019 Loan Agreement allowed us to voluntarily prepay all (but not less than all) of the outstanding principal at any time. A prepayment premium of 3% or 1% through the one-year anniversary and the two-year anniversary, respectively, would be assessed on the outstanding principal. After the two-year anniversary, a 0.5% prepayment premium would be assessed on the outstanding principal. A final payment fee of $500,000 was due upon the earlier to occur of the maturity date or prepayment of such borrowings.

In connection with the Oaktree Agreement, we paid off all unpaid borrowings under the 2019 Loan Agreement on October 13, 2022, including the $500,000 final fee and a prepayment premium of $46,000.

***2021 At-the-Market Issuance Sales Agreement***

On March 23, 2021, we entered into the 2021 ATM Agreement with Cowen with respect to an at-the-market offering program (the "2021 ATM Program") under which we could offer and sell shares of our common stock (the "2021 ATM Shares"), having an aggregate offering price of up to $50.0 million through Cowen as our sales agent. The offering and sale of 2021 ATM Shares are made pursuant to our shelf registration statement on Form S-3, which was declared effective by the SEC on April 29, 2021 (the “2021 Registration Statement”). We agreed to pay Cowen a commission up to 3.0% of the gross sales proceeds of such 2021 ATM Shares.

During the year ended December 31, 2022, we sold a total of 181,553 2021 ATM Shares under the 2021 ATM Program, in the open market, at a weighted average gross selling price of $6.33 per share for net proceeds of $1.1 million.

**Sale of Common Stock**

In November 2022, we completed an underwritten public offering of 6,620,000 shares of our common stock (the “2022 Offering Shares”), pursuant to the 2021 Registration Statement. The 2022 Offering Shares were sold at an offering price of $5.25 per share. In addition, a prefunded warrant to purchase up to 2,905,000 shares of common stock at a purchase price of $5.249 per underlying share was issued as part of the transaction. Net proceeds of the offering were $46.6 million, after deducting underwriting discounts, commissions and offering expenses.

## CASH FLOWS

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

| | YEAR ENDED DECEMBER 31, | |
|---|---|---|
| (in thousands) | 2021 | 2022 |
| Net cash (used in) provided by: | | |
| Operating activities | $ (27,151) | $ (34,577) |
| Investing activities | 32,130 | (45,859) |
| Financing activities | (2,530) | 77,229 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | $ 2,449 | $ (3,207) |

***Net Cash Used in Operating Activities***

During the year ended December 31, 2022, net cash used in operating activities was $34.6 million, consisting primarily of a net loss of $36.8 million and a $0.4 million increase in net operating assets. This was offset by non-cash charges of $2.6 million. The non-cash charges primarily consisted of stock-based compensation expense, amortization of right-of-use leased assets, the fair value adjustment to the derivative liability and non-cash interest expense related to amortization of debt discount associated with the 2019 Loan Agreement and Oaktree Agreement.

During the year ended December 31, 2021, net cash used in operating activities was $27.2 million, consisting primarily of a net loss of $28.0 million and a $2.6 million increase in net operating assets. This was offset by non-cash charges of $3.5 million. The non-cash charges primarily consisted of 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 2019 Loan Agreement.

***Net Cash Provided By (Used in) Investing Activities***

During the year ended December 31, 2022, net cash used in investing activities was $45.9 million, consisting primarily of purchases of short-term investments, net of maturities.

During the year ended December 31, 2021, net cash provided by investing activities was $32.1 million, consisting primarily of maturities of short-term investments, net of purchases.

***Net Cash (Used in) Provided by Financing Activities***

During the year ended December 31, 2022, net cash provided by financing activities was $77.2 million, consisting primarily of net proceeds of $47.3 million from the Oaktree Agreement, $46.6 million from the November 2022

public offering, net proceeds of $1.1 million from the 2021 ATM Program and $0.2 million in proceeds from stock option exercises and purchases of shares through the employee stock purchase plan. The proceeds were offset by the $18.0 million payment on the 2019 Loan Agreement, including the final fee, and $54,000 in tax obligations from the settlement of restricted stock units.

During the year ended December 31, 2021, net cash used in financing activities was $2.5 million, consisting primarily of principal payments on the 2019 Loan Agreement.

## CONTRACTUAL OBLIGATIONS

The following table summarizes our contractual obligations as of December 31, 2022 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 | 2023 | 2024 and 2025 | 2026 and 2027 | After 2027 |
| Operating lease obligations [1] | $ 606 | $ 596 | $ 10 | $ — | $ — |
| Term loan | 51,000 | — | 2,500 | 48,500 | — |
| Total | $ 51,606 | $ 596 | $ 2,510 | $ 48,500 | $ — |

(1) Consists of obligations under multi-year, non-cancelable building and equipment leases for our facilities in Salem, New Hampshire, and Burlington, Massachusetts. The building leases expire on August 31, 2023 and November 30, 2023, respectively.

We have drawn down an aggregate of $50.0 million from the Oaktree Agreement as of December 31, 2022. Our contractual commitments under the Oaktree Agreement as of December 31, 2022 consist of an aggregate of $78.3 million in repayment obligations, inclusive of related interest amounts and final fee in the amount of $1.0 million. See "—Oaktree Loan and Security Agreement" for additional information regarding the Oaktree Agreement.

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

Due to the discontinuation of use of our first generation device in 2019, we have received notice of termination costs related to the program. Certain of our vendors have claimed or billed for additional costs for which we believe we are not obligated. At this time, we have determined that the possibility of additional costs is remote.

## CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, revenue, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

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

### *Stock-Based Compensation Expense*

We are required to determine the fair value of equity incentive awards and recognize compensation expense for all equity incentive awards, including employee stock options and restricted stock units. We recognize this

expense over the requisite service period. In addition, we recognize stock-based compensation expense in the statements of operations based on awards expected to vest and, therefore, the amount of expense has been reduced for estimated forfeitures. We use the ratable straight-line method for expense attribution.

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

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

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

***Research and Development Expenses***

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

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

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

***Derivative Liability***

We evaluate our financial instruments for embedded features and bifurcate those features from the host instrument that meet the definition of a derivative if (i) the economic characteristics and risks of the embedded feature are not clearly and closely related to the host instrument, (ii) the hybrid instrument that embodies both the embedded feature and the host contract is not remeasured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (iii) a separate instrument with the same terms as the embedded feature would be considered a derivative instrument subject to the accounting requirements of derivative instruments.

We use judgment in determining the fair value of embedded features that are bifurcated from the host instrument and accounted for as derivative instruments at the date of issuance and at every balance sheet date thereafter. The valuation method used in the determination of fair value is based on the type of derivative instrument. At each balance sheet date, we remeasure our derivative instruments at fair value with adjustments to fair value recognized within other income (expense).

In connection with the Oaktree Agreement, we identified a number of derivatives that required bifurcation from the term loan as a compound derivative liability. The fair value of the embedded derivative liability was estimated using a hybrid between the discounted cash flow and Monte Carlo simulation methods, which required significant judgement. Assumptions included estimates of volatility, market yield, probability and timing of change in control, probability and timing of a going concern qualification, and net sales projections. We recorded an initial fair value of approximately $8.9 million at inception of the Oaktree Agreement and a fair value of $7.5 million as of December 31, 2022. The change in fair value of $1.3 million between inception and December 31, 2022 was recognized as a gain within other income on our consolidated statement of operations and comprehensive loss.

**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, 2022, our aggregate outstanding indebtedness was $50.0 million, which bears interest per annum equal to three-month term SOFR (subject to a 1.00% floor and a 3.00% cap), plus applicable margin of 8.75%. 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.

We do not believe that inflation has had a material effect on our business. However, if our costs, in particular costs related to manufacture and supply, were to become subject to significant inflationary pressures, it may adversely impact our business, operating results and financial condition.

## Item 8. Consolidated Financial Statements and Supplementary Data.

## Index to Consolidated Financial Statements

## Report of Independent Registered Public Accounting Firm

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

**Opinion on the Financial Statements**
We have audited the accompanying consolidated balance sheets of scPharmaceuticals Inc. and its subsidiary (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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

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

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

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

**Accounting Assessment and Valuation of Derivative Liability**

On October 13, 2022, the Company entered into a $100.0 million term loan consisting of $50.0 million of debt funded immediately with additional borrowings in up to two draws of $25.0 million each, as described in Notes 9 and 10 to the consolidated financial statements. The Company concluded that the term loan contained embedded derivatives and determined that the embedded derivatives required bifurcation as one compound derivative liability. The Company recorded the derivative liability on its consolidated balance sheet at its fair value of approximately $8.9 million on October 13, 2022 and $7.5 million as of December 31, 2022. The Company also recorded a gain on its consolidated statement of operations and comprehensive loss of approximately $1.3 million to reflect the change in fair value of the derivative liability during the year ended December 31, 2022. To estimate the fair value of the derivative liability at both October13, 2022 and December 31, 2022, the Company utilized a combination of a valuation model that discounts forecasted future cash flows expected to be generated and a valuation model that reflects the use of multiple probabilities.

We identified the initial accounting assessment and the valuation of the derivative liability as a critical audit matter because of the complexity of evaluating the accounting for the embedded derivatives and the complexity of the valuation models, including the judgements made by management in estimating the fair value of the derivative liability. The valuation models used in determining the fair value of the derivative liability include inputs subject to management's judgment, including estimates of volatility, market yield, probability of a change of control or fundamental change, probability of a going concern qualification and net sales projections. This required subjective auditor judgment and an increased level of effort when performing audit procedures, including the involvement of valuation professionals with specialized skills and knowledge.

Our audit procedures related to the Company’s evaluation and valuation of the derivative liability included the following, among others:

- Inspected the terms of all relevant term loan legal documents supporting the transaction and ensured agreement to the source data used by management in determining the appropriate accounting treatment for the embedded features and the resulting derivative valuation
- Assessed the Company’s technical accounting assessment regarding the existence of embedded derivatives that may require separate accounting under the applicable accounting guidance
- Evaluated significant assumptions used to calculate the fair value of the derivative liability including the estimate of the probability of a change of control or fundamental change, probability of a going concern qualification and net sales projections
- With the assistance of our fair value specialists, we tested the appropriateness of the methodology used in estimating the fair value of the embedded derivatives, including evaluating the reasonableness of the estimates for volatility and market yield and tested the mathematical accuracy of the resulting valuations

/s/ RSM US LLP

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

Boston, Massachusetts
March 22, 2023

**SCPHARMACEUTICALS INC.**

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

| | DECEMBER 31, 2021 | DECEMBER 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 74,268 | $ 71,061 |
| Short-term investments | 1,010 | 47,125 |
| Restricted cash | 182 | 182 |
| Inventory | — | 1,230 |
| Prepaid expenses | 2,791 | 2,282 |
| Deposits and other current assets | 24 | 1,428 |
| Total current assets | 78,275 | 123,308 |
| Property and equipment, net | 69 | 54 |
| Right-of-use lease assets - operating, net | 410 | 566 |
| Deposits and other assets | 283 | 267 |
| Total assets | $ 79,037 | $ 124,195 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 544 | $ 1,518 |
| Accrued expenses | 3,995 | 5,289 |
| Term loan, short-term | 9,805 | — |
| Lease obligation - operating, short-term | 476 | 567 |
| Other current liabilities | 26 | 42 |
| Total current liabilities | 14,846 | 7,416 |
| Term loan, long-term | 7,354 | 36,794 |
| Derivative liability | — | 7,517 |
| Lease obligation - operating, long-term | — | 7 |
| Other liabilities | 367 | 28 |
| Total liabilities | 22,567 | 51,762 |
| 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, 2022; 27,366,707 and 34,257,916 shares issued and outstanding at December 31, 2021 and December 31, 2022, respectively | 3 | 3 |
| Additional paid-in capital | 246,166 | 298,934 |
| Accumulated deficit | (189,698) | (226,536) |
| Accumulated other comprehensive (loss) income | (1) | 32 |
| Total stockholders' equity | 56,470 | 72,433 |
| Total liabilities and stockholders' equity | $ 79,037 | $ 124,195 |

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, | |
|---|---|---|
| | 2021 | 2022 |
| Operating expenses: | | |
| Research and development | $ 16,039 | $ 15,533 |
| General and administrative | 9,784 | 20,624 |
| Total operating expenses | 25,823 | 36,157 |
| Loss from operations | (25,823) | (36,157) |
| Other income | 315 | 1,418 |
| Interest income | 49 | 1,203 |
| Interest expense | (2,575) | (3,302) |
| Net loss | $ (28,034) | $ (36,838) |
| Net loss per share, basic and diluted | $ (1.02) | $ (1.30) |
| Weighted—average common shares outstanding, basic and diluted | 27,351,730 | 28,358,502 |
| | | |
| Other comprehensive loss: | | |
| Unrealized (loss) gain on short-term investments | $ (2) | $ 33 |
| Comprehensive loss | $ (28,036) | $ (36,805) |

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

## SCPHARMACEUTICALS INC.

### Consolidated Statements of Stockholders' Equity

(in thousands, except share data)

| | COMMON STOCK | | ADDITIONAL PAID-IN CAPITAL | ACCUMULATED DEFICIT | OTHER COMPREHENSIVE INCOME (LOSS) | TOTAL STOCKHOLDERS' EQUITY |
|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | | | | |
| **At December 31, 2020** | 27,325,959 | 3 | 243,830 | (161,664) | 1 | 82,170 |
| Net loss | — | — | — | (28,034) | — | (28,034) |
| Issuance of common stock upon exercise of stock options | 2,501 | — | 9 | — | — | 9 |
| Issuance of common stock purchased through employee stock purchase plan | 11,253 | — | 42 | — | — | 42 |
| Vesting of restricted stock | 26,994 | — | (81) | — | — | (81) |
| Stock-based compensation | — | — | 2,366 | — | — | 2,366 |
| Unrealized loss on short term investments | — | — | — | — | (2) | (2) |
| **At December 31, 2021** | 27,366,707 | 3 | 246,166 | (189,698) | (1) | 56,470 |
| Net loss | — | — | — | (36,838) | — | (36,838) |
| Issuance of common stock under at-the-market offering, net of issuance costs (Note 11) | 181,553 | — | 1,114 | — | — | 1,114 |
| Issuance of common stock and pre-funded warrants in common stock offering, net of issuance costs (Note 11) | 6,620,000 | — | 46,645 | — | — | 46,645 |
| Issuance of common stock upon exercise of stock options | 11,756 | — | 44 | — | — | 44 |
| Issuance of common stock purchased through employee stock purchase plan | 45,938 | — | 173 | — | — | 173 |
| Vesting of restricted stock | 31,962 | — | (54) | — | — | (54) |
| Issuance of warrants (Note 11) | — | — | 2,008 | — | — | 2,008 |
| Stock-based compensation | — | — | 2,838 | — | — | 2,838 |
| Unrealized gain on short term investments | — | — | — | — | 33 | 33 |
| **At December 31, 2022** | 34,257,916 | $ 3 | $ 298,934 | $ (226,536) | $ 32 | $ 72,433 |

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, | |
|---|---|---|
| | 2021 | 2022 |
| **Cash flows from operating activities** | | |
| Net loss | $ (28,034) | $ (36,838) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation expense | 34 | 37 |
| Amortization expense - right-of-use leased assets - operating | 404 | 431 |
| Accretion on short-term investments | 124 | (244) |
| Stock-based compensation | 2,366 | 2,838 |
| Non-cash interest expense | 554 | 884 |
| Fair value adjustment to derivative liability | — | (1,335) |
| Changes in operating assets and liabilities | | |
| Inventory | — | (1,230) |
| Prepaid expenses and other assets | (234) | (887) |
| Accounts payable, accrued expenses and other liabilities | (2,365) | 1,767 |
| Net cash flows used in operating activities | (27,151) | (34,577) |
| **Cash flows from investing activities** | | |
| Purchases of property and equipment | (9) | (21) |
| Maturities of short-term investments | 41,150 | 21,700 |
| Purchases of short-term investments | (9,011) | (67,538) |
| Net cash flows provided by (used in) investing activities | 32,130 | (45,859) |
| **Cash flows from financing activities** | | |
| Proceeds from common stock offering, net of underwriter discounts and offering costs | — | 46,645 |
| Proceeds from at-the-market offering, net | — | 1,120 |
| Proceeds from the exercise of stock options | 9 | 44 |
| Proceeds from employee stock purchase plan | 42 | 173 |
| Proceeds from term loan | — | 47,301 |
| Principal payments on term loan | (2,500) | (17,500) |
| Payment of term loan final fee | — | (500) |
| Settlement of restricted stock units for tax withholding obligations | (81) | (54) |
| Net cash flows (used in) provided by financing activities | (2,530) | 77,229 |
| Net increase (decrease) in cash | 2,449 | (3,207) |
| Cash, cash equivalents and restricted cash, beginning of year | 72,001 | 74,450 |
| Cash, cash equivalents and restricted cash, end of year | $ 74,450 | $ 71,243 |
| **Supplemental cash flow information** | | |
| Interest paid | $ 2,043 | $ 2,555 |
| Taxes paid | 206 | 190 |
| **Supplemental disclosure of non-cash activities** | | |
| Transfer of issuance costs from other noncurrent assets to equity | — | 6 |

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

## 1. Description of Business and Basis of Presentation

### *Description of Business*

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

### *Basis of Presentation*

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

### *Liquidity*

At December 31, 2022, the Company had cash, cash equivalents, restricted cash and investments of $118.4 million and working capital of $115.9 million. During the year ended December 31, 2022, the Company incurred a net loss totaling $36.8 million and used cash in operating activities totaling $34.6 million. The Company expects to continue to incur losses and use cash in operating activities in 2023.

In October 2022, the Company entered into a Credit Agreement and Guaranty (the "Oaktree Agreement") with, among others, the lenders from time to time party thereto (the "Lenders") and Oaktree Fund Administration, LLC, in its capacity as administrative agent for the Lenders (Note 10). In November 2022, the Company completed an underwritten public offering with net proceeds of $46.6 million (Note 11). In addition, the Company currently has an at-the-market offering program with Cowen and Company, LLC that has $48.9 million in capacity remaining at December 31, 2022 (Note 11).

The Company believes that, based on its current development plans and activities, its resources 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 the determination of fair value of financial instruments, accruals related to development costs and clinical activities, and the establishment of the tax valuation allowance. Actual results could differ from those estimates.

***Foreign Currency Transactions***

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

***Cash, Cash Equivalents and Restricted Cash***

Cash, cash equivalents and restricted cash consists of bank deposits, certificates of deposit and money market accounts with financial institutions. Cash equivalents are carried at cost which approximates fair value due to their short-term nature and which the Company believes do not have a material exposure to credit risk. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents. The Company places its cash and cash equivalents with institutions with high credit quality. However, at certain times such cash and cash equivalents may be in excess of Federal Deposit Insurance Corporation and Securities Investor Protection Corporation insurance limits. The Company has not experienced any losses with respect to these accounts.

As of December 31, 2021 and 2022, 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 (in thousands):

| | December 31, 2021 | December 31, 2022 |
|---|---|---|
| Cash and cash equivalents | $ 74,268 | $ 71,061 |
| Restricted cash | 182 | 182 |
| Cash, cash equivalents and restricted cash | $ 74,450 | $ 71,243 |

***Concentration of Credit Risk***

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company's short-term investments consist of commercial paper, United States Treasury securities and United States Government Agency securities. The Company has adopted an investment policy that limits the amounts the Company may invest in any one type of investment and requires all investments held by the Company to hold a minimum rating, thereby reducing credit risk exposure.

***Investments***

The Company invests excess cash balances in available-for-sale debt securities. The Company determines the appropriate classification of these securities at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. The Company reports available-for-sale investments at fair value at each balance sheet date and includes any unrealized gains and losses in accumulated other comprehensive income (loss), a component of stockholders' equity. Realized gains and losses are determined using the specific identification method and are included in other income (expense). If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other than temporary," including the intention to sell and, if so, marks the investment to market through a charge to the Company's consolidated statements of operations and comprehensive loss.

***Inventory***

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-process and finished goods. The Company began capitalizing inventory costs following U.S. Food and Drug Administration ("FDA") approval of FUROSCIX on October 7, 2022. Inventory is sold on a first in, first out ("FIFO") basis. The Company periodically reviews inventory for expiry and obsolescence and writes it down accordingly, if necessary.

Prior to FDA approval of FUROSCIX, the Company expensed all inventory-related costs, including that used for clinical development, to research and development ("R&D") costs in the period incurred.

***Leases***

The Company determines if an arrangement is a lease at inception. Operating leases are included in right-of-use ("ROU") lease assets, current portion of lease obligations, and long term lease obligations on the Company's balance sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease asset excludes lease incentives. The Company's lease terms include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

***Debt Issuance Costs***

Debt issuance costs are amortized to interest expense using the effective interest rate method over the term of the debt. Debt issuance costs paid to the lender and third parties are reflected as a discount to the debt in the consolidated balance sheets.

***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 Accounting Standard Codification ("ASC") 740 *Income Taxes* ("ASC 740"). 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, 2021 and 2022, the Company had no such accruals.

***Stock-Based Compensation***

Stock-based compensation expense for stock options is recognized based on the grant-date fair value using the Black-Scholes valuation model. Restricted stock units are valued at the fair market value per share of the Company's common stock on the date of grant. The Company recognizes compensation expense only for those stock-based awards expected to vest after considering expected forfeitures. Cumulative compensation expense is at least equal to the compensation expense for vested awards. Stock-based compensation is recognized on a straight-line basis over the service period of each award.

***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.

***Recently Issued Accounting Standards***

In June 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments-Credit Losses : Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. The ASU will be effective for the Company's fiscal year beginning January 1, 2023. The Company is currently evaluating the impact of the adoption of ASU 2016-13 and does not expect adoption to have a material effect on the Company’s consolidated financial statements or disclosures.

**3. 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. Basic and diluted weighted average shares of common stock outstanding for the year ended December 31, 2022 include the weighted average effect of outstanding pre-funded warrants for the purchase of shares of common stock for which the remaining unfunded exercise price is $0.001 per share.

Dilutive common stock equivalents are comprised of unexercised stock options outstanding under the Company’s equity plan, unexercised warrants 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, 2021 | December 31, 2022 |
| Net loss | $ (28,034) | $ (36,838) |
| Weighted—average common shares outstanding, basic and diluted | 27,351,730 | 28,358,502 |
| Net loss per share, basic and diluted | $ (1.02) | $ (1.30) |

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, 2021 | December 31, 2022 |
| Stock options to purchase common stock | 2,662,752 | 4,008,177 |
| Warrants to purchase common stock | — | 516,345 |
| Unvested restricted stock | 42,250 | — |
| | 2,705,002 | 4,524,522 |

**4. Investments**

Cash in excess of the Company’s immediate requirements is invested in accordance with the Company’s investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

A summary of the Company's available-for-sale classified investments as of December 31, 2021 and 2022 consisted of the following (in thousands):

| | At December 31, 2021 | | | |
|---|---|---|---|---|
| **Investments - Current:** | **Cost Basis** | **Accumulated Unrealized Gains** | **Accumulated Unrealized Losses** | **Fair Value** |
| Corporate debt securities | $ 1,011 | $ - | $ (1) | $ 1,010 |
| Total | $ 1,011 | $ - | $ (1) | $ 1,010 |

| | At December 31, 2022 | | | |
|---|---|---|---|---|
| **Investments - Current:** | **Cost Basis** | **Accumulated Unrealized Gains** | **Accumulated Unrealized Losses** | **Fair Value** |
| Commercial paper | $ 16,741 | $ - | $ - | $ 16,741 |
| United States Treasury securities | 15,768 | 7 | - | 15,775 |
| United States Government Agency securities | 14,584 | 25 | - | 14,609 |
| Total | $ 47,093 | $ 32 | $ - | $ 47,125 |

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of December 31, 2022 consisted of the following (in thousands):

| | **Amortized Cost** | **Fair Value** |
|---|---|---|
| Due in one year or less | $ 47,093 | $ 47,125 |
| Total | $ 47,093 | $ 47,125 |

**5. Inventory**

The Company's inventory balance consists of the following (in thousands):

| | As of December 31, | |
|---|---|---|
| | **2021** | **2022** |
| Raw materials | $ — | $ 1,201 |
| Work-in-process | — | 29 |
| Finished goods | — | — |
| | $ — | $ 1,230 |

Inventory is stated at the lower of cost and net realizable value and consists of raw materials, work-in-process and finished goods. The Company began capitalizing inventory costs following FDA approval of FUROSCIX in October 2022 and has not recorded any significant inventory write-downs since that time. The Company currently uses a limited number of third-party contract manufacturing organizations ("CMOs") to produce its inventory.

**6. Property and Equipment**

Purchased property and equipment consist of the following as of December 31, 2021 and 2022 (in thousands):

| | **ESTIMATED USEFUL LIFE** | **2021** | **2022** |
|---|---|---|---|
| Office equipment | 5 years | $ 10 | $ 6 |
| Office furniture | 7 years | 126 | 126 |
| Computer equipment | 3 years | 8 | 15 |
| Leasehold improvements | Life of lease | 95 | 95 |
| | | 239 | 242 |
| Less: Accumulated depreciation | | (170) | (188) |
| Property and equipment, net | | $ 69 | $ 54 |

Depreciation expense for the years ended December 31, 2021 and 2022 was $34,000 and $37,000, respectively.

## 7. Accrued Expenses

Accrued expenses at December 31, 2021 and 2022 consist of (in thousands):

| | 2021 | 2022 |
|---|---|---|
| Employee compensation and related costs | $ 1,152 | $ 2,754 |
| Contract research and development | 2,350 | 1,827 |
| Consulting and professional service fees | 265 | 603 |
| State taxes | 5 | 49 |
| Financing related costs | 60 | 29 |
| Interest | 154 | 16 |
| Other | 9 | 11 |
| Total accrued expenses | $ 3,995 | $ 5,289 |

## 8. Income Taxes

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

Accordingly, the Company had no net income tax provision or benefit during the years ended December 31, 2021 and 2022. Components of the net deferred tax assets at December 31, 2021 and 2022 are as follows (in thousands):

| | 2021 | 2022 |
|---|---|---|
| Deferred tax assets: | | |
| Federal net operating loss carryforwards | $ 12,813 | $ 17,252 |
| State net operating loss carryforwards | 3,630 | 4,585 |
| Research and development tax credits | 3,719 | 4,214 |
| Accrued liabilities | 327 | 677 |
| Stock-based compensation | 1,087 | 1,329 |
| Depreciation and amortization | 247 | 324 |
| Capitalized research and development costs | 29,529 | 30,976 |
| Lease liabilities | 129 | 146 |
| Other | 29 | — |
| Total deferred tax assets | 51,510 | 59,503 |
| Deferred tax liabilities: | | |
| Right-of-use lease assets | (111) | (144) |
| Other | — | (273) |
| Total deferred tax liabilities | $ (111) | $ (417) |
| Valuation allowance | $ (51,399) | $ (59,086) |
| Net deferred tax assets | $ — | $ — |

At December 31, 2022, the Company had available federal net operating loss carryforwards of $17.5 million, which expire at various dates through 2037, and $64.6 million, which may be carried forward indefinitely. At December 31, 2022, the Company had available state net operating loss carryforwards of $72.6 million, which expire at various dates through 2042, and $300,000, 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, 2021 and 2022 since it is more likely than not that these future tax benefits will not be realized. During 2022, the valuation allowance increased by $7.7 million.

At December 31, 2022, the Company had federal and state research and development credit carryforwards of $4.3 million and $1.0 million, respectively. The net credit carryforwards may be used to offset future income taxes and expire at various dates through 2042. 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.

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, 2021 and 2022 are as follows:

| | 2021 | 2022 |
|---|---|---|
| Federal income tax at statutory rate | 21.00% | 21.00% |
| State income tax, net of federal benefit | 5.97% | 4.28% |
| Research and development credits | 3.16% | 1.39% |
| Book compensation related to stock options | 0.03% | (0.80)% |
| Change in income tax rate | 0.45% | (4.93)% |
| Other | (0.93)% | (0.09)% |
| Increase in valuation allowance | (29.68)% | (20.87)% |
| Effective tax rate | —% | (0.02)% |

The Company files tax returns in the United States, Massachusetts and other states. The tax years 2018 through 2022 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily the United States federal and Massachusetts. 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):

| | 2021 | 2022 |
|---|---|---|
| Beginning uncertain tax benefits | $ 774 | $ 977 |
| Prior year - increases | — | — |
| Current year - decreases | — | — |
| Current year - increases | 203 | 129 |
| Ending uncertain tax benefits | $ 977 | $ 1,106 |

**9. Fair Value of Financial Instruments**

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

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

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

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

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

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

The following tables summarize the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

| | As of December 31, 2021 | | | |
|---|---|---|---|---|
| | TOTAL | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Assets:** | | | | |
| Cash equivalents | $ 72,449 | $ 72,449 | $ — | $ — |
| Total cash equivalents | 72,449 | 72,449 | — | — |
| Corporate debt securities | 1,010 | — | 1,010 | — |
| Investments | 1,010 | — | 1,010 | — |
| Total | $ 73,459 | $ 72,449 | $ 1,010 | $ — |

| | As of December 31, 2022 | | | |
|---|---|---|---|---|
| | TOTAL | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Assets:** | | | | |
| Cash equivalents | $ 65,875 | $ 65,875 | $ — | $ — |
| Total cash equivalents | 65,875 | 65,875 | — | — |
| Commercial Paper | 16,741 | — | 16,741 | — |
| United States Treasury securities | 15,775 | 15,775 | — | — |
| United States Government Agency securities | 14,609 | — | 14,609 | — |
| Investments | 47,125 | 15,775 | 31,350 | — |
| Total | $ 113,000 | $ 81,650 | $ 31,350 | $ — |
| **Liabilities:** | | | | |
| Derivative liability | $ 7,517 | $ — | $ — | $ 7,517 |
| Total | $ 7,517 | $ — | $ — | $ 7,517 |

Changes in the fair value of the Company's Level 3 derivative liability for the year ended December 31, 2022 are as follows:

| | |
|---|---|
| At December 31, 2021 | $ — |
| Initial fair value of derivative liability | 8,852 |
| Change in fair value of derivative liability | (1,335) |
| At December 31, 2022 | $ 7,517 |

The Oaktree Agreement contains embedded derivatives requiring bifurcation as a derivative instrument. The derivative liability related to the term loan is recorded and accounted for separately in the consolidated financial statements as one compound derivative liability, see Note 10 for additional details. The fair value of the embedded derivative liabilities associated with the term loan was estimated using a hybrid between the discounted cash flow and Monte Carlo simulation methods. This involves significant Level 3 inputs and assumptions including (i) the estimated probability and timing of a change in control and (2) the probability-weighted net sales of FUROSCIX.

A summary of quantitative information about significant unobservable inputs (Level 3 inputs) used in measuring the Company's derivative liability that are categorized within Level 3 of the fair value hierarchy is as follows:

| | October 13, 2022 | December 31, 2022 |
|---|---|---|
| Net sales discount rate | 23.3% | 22.3% |
| Net sales volatility | 80.0% | 80.0% |
| Risk-free rate | 4.2% | 4.0% |
| Recovery rate | 80.0% | 80.0% |

**10. Debt**

The following table presents the carrying value of the Company's debt balance as of December 31, 2021 and 2022 (in thousands):

| | DECEMBER 31, 2021 | DECEMBER 31, 2022 |
|---|---|---|
| Face value of term loans | $ 17,500 | $ 50,000 |
| Unamortized debt discount | (341) | (13,206) |
| Total debt, net | $ 17,159 | $ 36,794 |
| Less: short-term debt | (9,805) | — |
| Long-term debt | $ 7,354 | $ 36,794 |

**Oaktree Agreement**

On October 13, 2022 (“Closing Date”), the Company entered into a Credit Agreement and Guaranty (the “Oaktree Agreement”) with Oaktree Fund Administration, LLC as administrative agent, and the lenders party thereto (collectively “Oaktree”) to borrow up to $100.0 million in three tranches with a maturity date of October 13, 2027.

The first tranche of $50.0 million was drawn immediately, with $9.8 million of the proceeds used to repay in full the outstanding loan and fees under the 2019 Loan Agreement with SLR Investment Corp. and Silicon Valley Bank and $2.7 million in fees and expenses incurred in connection with the financing, leaving $37.5 million in available proceeds from the first tranche. The ability to draw the remaining $50.0 million is contingent upon reaching certain net sales revenue milestone targets prior to September 30, 2024 and December 31, 2024, respectively.

The term loan initially bears interest at the three-month term Secured Overnight Financing Rate (“SOFR”) plus an applicable margin of 8.75% (with a SOFR floor of 1.00% and a 3.00% cap). Once FUROSCIX achieves at least $100.0 million in trailing 12-month net sales, the applicable margin will step down to 8.25%. The Company is required to make quarterly interest-only payments until the third anniversary of the Closing Date, after which the Company is required to make quarterly amortizing payments, with the remaining balance of the principal plus accrued and unpaid interest due at maturity.

In connection with entering into the Oaktree Agreement, the Company granted warrants to Oaktree to purchase up to an aggregate of 516,345 shares of the Company’s common stock at an exercise price of $5.40 per share. Upon inception, the Company evaluated the warrants and determined that they met all the requirements for equity classification under ASC 815. This transaction was accounted for as a detachable warrant at its fair value, using the relative fair value method, which is based on a number of unobservable inputs and is recorded as an increase to additional paid-in-capital on the consolidated statement of stockholder’s equity. The relative fair value of the warrants, $2.0 million, was reflected as a discount to the term loan and will be amortized over the life of the term loan using the effective interest method. The Company used the Black-Scholes option pricing model to determine the fair value of the warrants. Assumptions included the fair market value per share of common stock on the valuation date of $5.50, the exercise price per warrant equal to $5.40, the expected volatility of 77%, the risk-free interest rate of 4.11%, the expected term of 7 years and the absence of a dividend. The warrants are immediately exercisable and the exercise period expires on October 13, 2029.

The Company identified a number of embedded derivatives that require bifurcation from the term loan and that were separately accounted for in the consolidated financial statements as one compound derivative liability. Certain of these embedded features include contingent interest rate reset upon event of default, contingent put options, including change in control and going concern provisions, and additional costs as a result of changes in

law. These embedded features met the criteria requiring these to be bifurcated because they were not clearly and closely related to the host instrument in accordance with ASC 815-15 and the derivative liability is presented separately in the condensed consolidated balance sheet as of December 31, 2022. The fair value of the embedded derivative liabilities associated with the term loan was estimated using a hybrid between the discounted cash flow and Monte Carlo simulation methods. This involves significant Level 3 inputs and assumptions including an estimated probability and timing of a change in control. The Company re-evaluates this assessment each reporting period and any changes in estimated fair value is recorded as other income (expense). The initial recognition of the embedded derivative liability upon issuance of the Term Loan was $8.9 million. At December 31, 2022, the fair value of the embedded derivative liability was $7.5 million.

In connection with the issuance of the term loan, the Company recorded a debt discount of $13.6 million, inclusive of debt issuance costs, the derivative liability and the relative fair value of the warrants. The discount will be amortized over the life of the term loan using the effective interest method. For the year ended December 31, 2022, the Company recorded $383,000 related to the amortization of the debt discount associated with the Oaktree Agreement.

Prepayments of the term loan, in whole or in part, will be subject to a prepayment fee which declines each year until the fourth anniversary date of the Closing Date, after which no prepayment fee is required. The Company is also required to pay an exit fee upon any payment or prepayment equal to 2.0% of the aggregate principal amount of the loans funded under the Oaktree Agreement. The Company recorded an additional debt discount of $1.0 million related to the exit fee. For the year ended December 31, 2022, the Company recorded $28,000 related to the amortization of the exit fee associated with the Oaktree Agreement.

The Oaktree Agreement contains customary representations, warranties and affirmative and negative covenants, including financial covenants requiring the Company to (i) maintain unrestricted cash of at least $15.0 million at all times, increasing to $20.0 million upon accessing the second tranche of the term loan and (ii) meet minimum quarterly net sales revenue targets.

In addition, the Oaktree Agreement contains customary events of default that could cause the Company’s indebtedness to become immediately due and payable. The lenders could declare the Company in default under its debt obligation upon the occurrence of any event that the lenders interpret as having a material adverse effect as defined under the Oaktree Agreement. Upon the occurrence and for the duration of an event of default, an additional interest rate equal to 2.0% per annum could apply to all obligations owed under the Oaktree Agreement. Among other loan covenant requirements, the Oaktree Agreement also requires the Company to provide an audit opinion of its annual financial statements not subject to any "going concern" or like qualification or exception.

**SLR Investment Corp. and Silicon Valley Bank Term Loan**

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

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

The interest rate under the 2019 Loan Agreement was the higher of (i) LIBOR plus 7.95% or (ii) 10.18% and there was an interest-only period until September 30, 2021. The rate at December 31, 2022 was 10.18%. Pursuant to the 2019 Loan Agreement, the Company provided a first priority security interest in substantially all of the Company’s assets, including intellectual property, subject to certain exceptions.

The Company entered into the Exit Agreement in connection with the 2019 Loan Agreement which provided for an aggregate payment of 4% of the loan commitment, or $800,000, to the Lenders upon the occurrence of an exit event (the "Exit Fee"). The Company concluded that the exit payment obligation met the definition of a derivative that was required to be accounted for as a separate unit of accounting. The Company recorded the issuance-date fair value of the derivative liability of $763,000 as a debt discount and as a derivative liability in the Company's balance sheet. The derivative liability was re-measured at each balance sheet date and any changes in estimated fair value was recorded as other income (expense). The Company paid the Exit Fee during the year ended December 31, 2020 in conjunction with the Company's public offering, which was deemed to be an exit event pursuant to the Exit Agreement. Prior to its public offering in 2020, the Company recorded $30,000 in non-cash expense as a fair value adjustment to the derivative liability.

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

In connection with the Oaktree Agreement, the Company paid off all unpaid borrowings under the 2019 Loan Agreement on October 13, 2022, including the $500,000 final fee and a prepayment premium of $46,000. For the years ended December 31, 2021, and 2022, the Company recorded $392,000 and $341,000, respectively, related to the amortization of the debt discount associated with the 2019 Loan Agreement. For the years ended December 31, 2021, and 2022, the Company recorded $162,000 and $132,000 related to the amortization of the final payment fee associated with the 2019 Loan Agreement.

As of December 31, 2022, future principal payments due under the Oaktree Agreement are as follows (in thousands):

| | |
|---|---|
| **Year ended:** | |
| December 31, 2023 | $ - |
| December 31, 2024 | - |
| December 31, 2025 | 2,500 |
| December 31, 2026 | 10,000 |
| December 31, 2027 | 37,500 |
| Total minimum principal payments | $ 50,000 |

## 11. Stockholders' Equity

### *Common Stock*

At December 31, 2021 and 2022, the Company had 150,000,000 shares of common stock authorized with a par value of $0.0001. There were 27,366,707 and 34,257,916 shares issued and outstanding at December 31, 2021 and 2022, 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 4,008,177 shares of common stock for the exercise of outstanding options to purchase common stock.

### 2021 At-the-Market Issuance Sales Agreement

On March 23, 2021, the Company entered into an Open Market Sale Agreement℠ (the "2021 ATM Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at-the-market offering program (the "2021 ATM Program") under which the Company could offer and sell shares of its common stock (the "2021 ATM Shares"), having an aggregate offering price of up to $50.0 million through Cowen as its sales agent. The offering and sale

of 2021 ATM Shares are made pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on April 29, 2021 (the "2021 Registration Statement").

The Company agreed to pay Cowen a commission up to 3.0% of the gross sales proceeds of such 2021 ATM Shares. The Company incurred $273,000 of legal, accounting, and other costs to establish and activate the 2021 ATM Program.

During the year ended December 31, 2022, the Company sold a total of 181,553 2021 ATM Shares under the 2021 ATM Agreement, in the open market, at a weighted average gross selling price of $6.33 per share for net proceeds of $1.1 million. The Company charged $6,000 in costs related to establishing and activating the program against additional paid in capital upon issuance of shares in 2022.

**Sale of Common Stock**

In November 2022, the Company completed an underwritten public offering of 6,620,000 shares of its common stock (the "2022 Offering Shares"), pursuant to the 2021 Registration Statement. The 2022 Offering Shares were sold at an offering price of $5.25 per share. In addition, a prefunded warrant to purchase up to 2,905,000 shares of common stock at a purchase price of $5.249 per underlying share was issued as part of the transaction. The pre-funded warrants were accounted for as equity instruments. Net proceeds of the offering were $46.6 million, after deducting underwriting discounts, commissions and offering expenses.

**Preferred Stock**

At December 31, 2021 and 2022, the Company had 10,000,000 shares of preferred stock authorized with a par value of $0.0001 and no shares of preferred stock were issued or outstanding.

## 12. Stock-Based Compensation

***Stock Options***

In October 2017, the board of directors approved the 2017 Stock Option and Incentive Plan (the "2017 Stock Plan") which became effective in November 2017, upon the closing of the Company's IPO. The 2017 Stock Plan will expire in October 2027. Under the 2017 Stock Plan, the Company may grant incentive stock options, non-statutory stock options, restricted stock awards, RSUs and other stock-based awards. The Company's 2014 Stock Incentive Plan (the "2014 Stock Plan") terminated in November 2017 effective upon the completion of the Company's IPO. No additional options will be granted under the 2014 Stock Plan. At December 31, 2022, there were 598,411 options outstanding under the 2014 Stock Plan.

At December 31, 2022, there were 6,105,147 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 359,860 options that have been forfeited from the 2014 Stock Plan.

At December 31, 2022, there were 2,655,289 options available for issuance and 3,409,766 options outstanding under the 2017 Stock Plan. Awards granted under the 2017 Stock Plan have a term of ten years. Vesting of awards under the 2017 Stock Plan is determined by the compensation committee of the board of directors but is generally over one to four-year terms.

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

| | 2021 | 2022 |
|---|---|---|
| Risk-free interest rate | 0.50%—1.25% | 1.67%—4.18% |
| Expected dividend yield | 0% | 0% |
| Expected life | 5.5—6.7 years | 5.5—6.7 years |
| Expected volatility | 72%—74% | 70%—84% |
| Weighted-average grant date fair value | $ 4.18 | $ 3.18 |

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 2021 and 2022 (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, 2020 | 2,224,913 | $ 6.26 | | |
| Granted | 953,506 | 6.57 | | |
| Exercised | (2,501) | 3.81 | | |
| Forfeited | (513,166) | 6.72 | | |
| Outstanding, December 31, 2021 | 2,662,752 | $ 6.28 | | |
| Granted | 1,455,594 | 4.86 | | |
| Exercised | (11,756) | 3.71 | | |
| Forfeited | (98,413) | 6.73 | | |
| Outstanding, December 31, 2022 | 4,008,177 | $ 5.76 | 7.47 | $ 7,147 |
| Vested and exercisable, December 31, 2022 | 1,982,329 | $ 6.15 | 6.01 | $ 3,436 |
| Vested and expected to vest, December 31, 2022 | 3,489,134 | $ 5.81 | 7.25 | $ 6,226 |

The following table summarizes information about RSU activity during 2021 and 2022:

| | RSUs | AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE) |
|---|---|---|
| RSUs outstanding, December 31, 2020 | 80,450 | $ 3.25 |
| Granted | — | — |
| Vested | (38,200) | 3.25 |
| Forfeited | — | — |
| RSUs outstanding, December 31, 2021 | 42,250 | 3.25 |
| Granted | — | — |
| Vested | (42,250) | 3.25 |
| Forfeited | — | — |
| RSUs outstanding, December 31, 2022 | — | $ — |

The number of RSUs vested includes shares of common stock withheld on behalf of employees to satisfy the minimum statutory tax withholding requirements.

During 2021 and 2022, the Company received $9,000 and $44,000, respectively, upon exercise of stock options. The intrinsic value of the options exercised in 2021 and 2022 was $7,000 and $18,000, respectively.

Unrecognized compensation expense related to unvested options as of December 31, 2022 was $4.2 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 2.5 years.

***Employee Stock Purchase Plan***

In October 2017, the board of directors approved the 2017 Employee Stock Purchase Plan ("the ESPP") which became effective in November 2017, upon the closing of the Company's IPO. As part of the ESPP, eligible employees may acquire an ownership interest in the Company by purchasing common stock, at a discount, through payroll deductions. Eligible employees who elected to participate were able to participate in the ESPP beginning September 1, 2021.

During 2021 and 2022, 11,253 and 45,938 shares of common stock were issued under the ESPP, respectively. As of December 31, 2022, there were 1,142,691 shares of common stock available for issuance under the ESPP.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying condensed consolidated statements of operations and comprehensive loss for employees, directors and non-employees during the years ended December 31, 2021 and 2022 as follows (in thousands):

| | 2021 | 2022 |
|---|---|---|
| Research and development | $ 947 | $ 1,050 |
| General and administrative | 1,419 | 1,788 |
| Total | $ 2,366 | $ 2,838 |

**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, 2023, respectively. Rent expense under the operating leases totaled $0.5 million and $0.5 million for the years ended December 31, 2021 and 2022, 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 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, 2022 (in thousands):

| | |
|---|---|
| Year ended: | |
| December 31, 2023 | $ 596 |
| December 31, 2024 | 9 |
| December 31, 2025 | 1 |
| Total minimum lease payments | 606 |
| Less imputed interest | (32) |
| Total | $ 574 |

| | 2021 | 2022 |
|---|---|---|
| **Lease cost:** | | |
| Operating lease cost | $ 482 | $ 505 |
| Short-term lease cost | 20 | 37 |
| Sublease income | (51) | (47) |
| Total lease cost | $ 451 | $ 495 |
| **Other information** | | |
| Cash paid for amounts included in the measurement of liabilities | $ 530 | $ 551 |
| Operating cash flows from operating leases | $ (60) | $ (57) |
| Weighted-average remaining lease term - operating leases | 0.9 years | 0.9 years |
| Weighted-average discount rate - operating leases | 10.1% | 10.1% |

In July 2021, the Company signed a lease agreement for a new office facility located in Salem, New Hampshire. The lease commenced on September 1, 2021 and had an initial term of 12 months with an optional extension term through August 2023. In June 2022, the Company exercised the lease option. The lease is considered short-term and is being recognized on a straight-line basis.

***Research and Development Agreements***

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

***Contingencies***

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

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

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

Due to the discontinuation of use of the first generation device in 2019, the Company has received notice of termination costs related to the program. Certain of the Company's vendors have claimed or billed for additional costs for which the Company believes it is not obligated. The Company has evaluated this contingent liability in accordance with ASC 450, Contingencies, and determined that the possibility of additional costs is remote and no longer probable.

**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, 2021 and 2022, the Company has recognized compensation expense of $198,000 and $340,000, 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.

In the period beginning January 1, 2023 through the date of this Annual Report on Form 10-K, the Company issued and sold an additional 1,511,157 shares of its common stock under the 2021 ATM Agreement at a weighted average gross selling price of $9.30 per share for net proceeds of $13.7 million.

On February 1, 2023, the Board of Directors of the Company adopted the 2023 Employment Inducement Award Plan (the "Inducement Plan") and, subject to the adjustment provisions of the Inducement Plan, reserved 500,000 shares of the Company’s Common Stock for issuance pursuant to equity awards granted under the Inducement Plan.

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

None.

**Item 9A. Controls and Procedures.**

***Limitations on Effectiveness of Controls and Procedures***

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our principal executive and financial 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 (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive and financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level.

***Management's Annual Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management assessed the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on its assessment, management concluded that, as of December 31, 2022, our internal control over financial reporting was effective based on those criteria.

***Attestation Report of the Independent Registered Public Accounting Firm***

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm because we are a non-accelerated filer.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information.**

None.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

Certain information relating to our executive officers and directors is included in Part I, Item 1, of this Annual Report on Form 10-K. The remaining information with respect to this item will be contained in our definitive proxy statement to be filed with the SEC in connection with the 2023 Annual Meeting of Stockholders within 120 days after the conclusion of our fiscal year ended December 31, 2022, or the Proxy Statement, and is incorporated in this Annual Report on Form 10-K by reference.

### Item 11. Executive Compensation.

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

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

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

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

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

### Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is RSM US LLP, Boston, MA, PCAOB Auditor ID 49.

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

## PART IV

**Item 15. Exhibits, Financial Statement Schedules.**

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

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



**(2) Financial Statement Schedules**

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

**(3) Index to Exhibits.**

| Exhibit Number | Description |
|---|---|
| 3.1 | Second Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on November 21, 2017) |
| 3.2 | Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on November 21, 2017) |
| 3.3 | Amendment No. 1 to the Company's Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on June 10, 2020) |
| 3.4 | Amendment No. 2 to the Company's Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on March 12, 2021) |
| 4.1 | Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated December 22, 2016 (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) filed on October 23, 2017) |
| 4.2 | Form of Warrant, dated October 13, 2022, issued by the Registrant to certain lenders, together with a schedule of warrant holders (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on October 14, 2022) |
| 4.3 | Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on November 23, 2022) |
| 4.4 | Description of Registered Securities (incorporated by reference to the Registrant's Annual Report on Form 10-K (File No. 001-38293) filed on March 23, 2021) |
| 10.1# | 2014 Stock Incentive Plan, as amended, and forms of award agreements thereunder (incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) on October 23, 2017) |
| 10.2# | 2017 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017) |

| | |
|---|---|
| 10.3# | Senior Executive Cash Incentive Bonus Plan (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017) |
| 10.4# | 2017 Employee Stock Purchase Plan (incorporated by reference to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017) |
| 10.5*# | 2023 Employment Inducement Award Plan and form of award agreement thereunder |
| 10.6*# | Amended and Restated Non-Employee Director Compensation Policy |
| 10.7# | Form of Indemnification Agreement (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-221077) filed on November 7, 2017) |
| 10.8 | Office Lease Agreement, dated as of June 2, 2017, by and between the Registrant and NEEP Investors Holdings LLC (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-221077) filed on October 23, 2017) |
| 10.9 | Amendment No. 1, dated April 11, 2022, to the Office Lease Agreement, dated as of June 2, 2017, by and between the Registrant and NEEP Investors Holdings LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38293) filed on May 16, 2022) |
| 10.10 | Credit Agreement and Guaranty, dated October 13, 2022, by and among the Registrant, the subsidiary guarantors from time to time party thereto, the lenders from time to time party thereto and Oaktree Fund Administration, LLC, as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38293) filed on October 14, 2022) |
| 10.11*# | Amended and Restated Employment Agreement, by and between the Registrant and John H. Tucker |
| 10.12# | Employment Agreement, by and between the Registrant and Rachael Nokes (incorporated by reference to Exhibit 10.9 to the Registrants Annual Report on Form 10-K (File No. 00138293) filed on March 24, 2020) |
| 10.13† | Development Agreement, by and between the Registrant and West Pharmaceutical Services, Inc., dated January 28, 2019 (incorporated by reference to Exhibit 10.2 to the Registrants Quarterly Report on Form 10-Q (File No. 00138293) filed on May 8, 2019) |
| 10.14† | Supply Agreement, dated August 15, 2020, by and between West Pharmaceutical Services, Inc. and the Registrant (incorporated by reference to Exhibit 10.1 to the Registrants Quarterly Report on Form 10-Q (File No. 00138293) filed on November 16, 2020) |
| 21.1 | Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38293) filed on March 22, 2022) |
| 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* | Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded with the Inline XBRL document |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document |

| | |
|---|---|
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE* | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104* | Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*) |

* Filed herewith.
† Portions of this exhibit have been omitted. Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.
# Indicates a management contract or any compensatory plan, contract or arrangement.
** This certification will not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

**Item 16. Form 10-K Summary.**

Not applicable.

## SIGNATURES

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

**SCPHARMACEUTICALS INC.**

Date: March 22, 2023

By: /s/ John H. Tucker
**John H. Tucker**
**President and Chief Executive 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<br>**John H. Tucker** | Director, President, and Chief Executive Officer (Principal Executive Officer) | March 22, 2023 |
| /s/ Rachael Nokes<br>**Rachael Nokes** | Chief Financial Officer (Principal Financial and Accounting Officer) | March 22, 2023 |
| /s/ Jack A. Khattar<br>**Jack A. Khattar** | Chairman of the Board | March 22, 2023 |
| /s/ Mette Kirstine Agger<br>**Mette Kirstine Agger** | Director | March 22, 2023 |
| /s/ Sara Bonstein<br>**Sara Bonstein** | Director | March 22, 2023 |
| /s/ Minnie V. Baylor-Henry<br>**Minnie V. Baylor-Henry** | Director | March 22, 2023 |
| /s/ Leonard D. Schaeffer<br>**Leonard D. Schaeffer** | Director | March 22, 2023 |
| /s/ Klaus Veitinger, M.D., Ph.D.<br>**Klaus Veitinger, M.D., Ph.D.** | Director | March 22, 2023 |
| /s/ Frederick Hudson<br>**Frederick Hudson** | Director | March 22, 2023 |
| /s/ William T. Abraham, M.D.<br>**William T. Abraham, M.D.** | Director | March 22, 2023 |