UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

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

For the quarterly period ended September 30, 2020

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	01803	Burlington, Massachusetts (Zip Code)
(Address of principal executive office)		

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

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

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

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

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

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

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

As of November 12, 2020, the Registrant had 27,320,959 common shares, $0.0001 par value per share, outstanding.

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, in particular, our lead product candidate, FUROSCIX. We cannot give any assurance that we will receive regulatory approval for this product candidate or any other product candidates, which is necessary before they can be commercialized.
- If we are not able to obtain required regulatory approvals, we will not be able to commercialize FUROSCIX, and our ability to generate revenue will be materially impaired.
- If we fail to produce FUROSCIX, if approved, in the volumes that we require on a timely basis, we may face delays in our commercialization efforts.
- We intend to utilize the 505(b)(2) pathway for the regulatory approval of FUROSCIX, and an NDA submitted under Section 505(b)(2) may subject us to a patent infringement lawsuit that would delay or prevent the review or approval of FUROSCIX.
- COVID-19 may materially and adversely affect our business and our financial results, including the pending approval of FUROSCIX and our intended commercial launch of FUROSCIX, if approved.
- 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, if approved, 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 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 product candidates, if approved, which could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.
- The commencement and completion of clinical trials can be delayed or prevented for a number of reasons. Clinical failure may occur at any stage of clinical development, and the results of our clinical trials may not support our proposed indications for our product candidates.
- 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 below and in the other information set forth in this Quarterly Report, 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 Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our expectations regarding the timing of the U.S. Food and Drug Administration's, or FDA's, review of the FUROSCIX® new drug application, or NDA, with the SmartDose drug delivery system and potential approval by the FDA, including any delays in review or approval related to COVID-19;
- the likelihood of approval by the FDA of our regulatory filings for FUROSCIX using our next generation delivery device;
- the timing or likelihood of other regulatory filings and approvals;
- the outcome of any bridging studies, clinical trials or human factors studies that may be required by the FDA for approval of any of our product candidates;
- the commercialization of FUROSCIX, if approved, including launch preparation, ability to interact with physicians, patient access to FUROSCIX, manufacturing and supply chain, including any delays related to COVID-19 in our ongoing Health Economics and Outcomes Research study and future planned Phase 4 studies of FUROSCIX incorporating the SmartDose drug delivery system to support the pricing and access to our product candidates;
- the pricing and reimbursement of FUROSCIX or any other of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of FUROSCIX or any other of our product candidates for which we receive marketing approval;
- the initiation, timing, progress and results of our research and development programs, including future preclinical and clinical studies;
- our ability to advance any other product candidates into, and successfully complete, clinical studies and obtain regulatory approval for them;
- our ability to identify additional product candidates;
- the implementation of our strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering FUROSCIX or any other of our product candidates and technology;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- our ability to manufacture, or the ability of third parties to deliver, sufficient quantities of components and drug product for commercialization of FUROSCIX or any other of our product candidates;
- our ability to maintain and establish collaborations;
- our financial performance;
- developments relating to our competitors and our industry, including the impact of government regulation; and
- other risks and uncertainties, including those listed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2019.

In some cases, forward-looking statements can be identified by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those set forth in Item 1A, "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the Securities and Exchange Commission on March 24, 2020, as well as in our subsequent filings with the Securities and Exchange Commission. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, then 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 Quarterly Report on Form 10-Q.

SCPHARMACEUTICALS INC.

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PART I — FINANCIAL INFORMATION

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	December 31, 2019	September 30, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 72,624	$ 44,278
Short term investments	-	70,061
Prepaid expenses	2,619	1,091
VAT receivable	310	112
Other current assets	94	146
Total current assets	75,647	115,688
Restricted cash	182	182
Property and equipment, net	127	102
Right-of-use lease assets - operating, net	1,179	910
Deposits and other assets	148	78
Total assets	$ 77,283	$ 116,960
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,142	$ 839
Accrued expenses	3,688	5,910
Lease obligation - operating, short term	407	448
Total current liabilities	5,237	7,197
Term loan, long term	18,915	19,170
Lease obligation - operating, long term	943	600
Derivative liability	765	-
Other liabilities	58	178
Total liabilities	25,918	27,145
Commitments and contingencies (Note 11)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding	-	-
Common stock, $0.0001 par value; 150,000,000 shares authorized as of September 30, 2020; 19,418,955 and 27,320,459 shares issued and outstanding as of December 31, 2019 and September 30, 2020, respectively	2	3
Additional paid-in capital	180,818	243,684
Accumulated deficit	(129,455)	(153,880)
Accumulated other comprehensive gain	-	8
Total stockholders' equity	51,365	89,815
Total liabilities and stockholders' equity	$ 77,283	$ 116,960

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

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2020	2019	2020
Operating expenses:				
Research and development	$ 4,293	$ 5,119	$ 16,314	$ 14,404
General and administrative	1,996	3,319	6,158	8,359
Total operating expenses	6,289	8,438	22,472	22,763
Loss from operations	(6,289)	(8,438)	(22,472)	(22,763)
Other income (expense)	83	19	61	(13)
Interest income	397	36	1,350	281
Interest expense	(398)	(655)	(1,121)	(1,930)
Net loss	$ (6,207)	$ (9,038)	$ (22,182)	$ (24,425)
Net loss per share — basic and diluted	$ (0.33)	$ (0.33)	$ (1.19)	$ (1.03)
Weighted average common shares outstanding — basic and diluted	18,584,327	27,319,465	18,580,192	23,644,580
Other comprehensive loss:				
Unrealized gain on short term investments	$ -	$ 8	$ -	$ 8
Comprehensive loss	$ (6,207)	$ (9,030)	$ (22,182)	$ (24,417)

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

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share amounts)
(Unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN	ACCUMULATED	OTHER COMPREHENSIVE	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	CAPITAL	DEFICIT	INCOME	EQUITY
At December 31, 2019	19,418,955	$ 2	$ 180,818	$ (129,455)	$ —	$ 51,365
Net loss	—	—	—	(7,092)	—	(7,092)
Issuance of common stock under at-the-market offering net of commissions and issuance costs (Note 10)	1,502,892	—	10,253	—	—	10,253
Issuance of common stock upon exercise of stock options	30,143	—	154	—	—	154
Vesting of restricted stock	29,890	—	(84)	—	—	(84)
Stock-based compensation	—	—	508	—	—	508
At March 31, 2020	20,981,880	2	191,649	(136,547)	—	55,104
Net loss	—	—	—	(8,295)	—	(8,295)
Common stock offering, net of commissions and issuance costs (Note 10)	6,220,589	1	50,147	—	—	50,148
Issuance of common stock upon exercise of stock options	85,528	—	561	—	—	561
Vesting of restricted stock	—	—	(80)	—	—	(80)
Stock-based compensation	—	—	621	—	—	621
At June 30, 2020	27,287,997	3	242,898	(144,842)	—	98,059
Net loss	—	—	—	(9,038)	—	(9,038)
Issuance costs	—	—	40	—	—	40
Issuance of common stock upon exercise of stock options	500	—	2	—	—	2
Vesting of restricted stock	31,962	—	—	—	—	—
Stock-based compensation	—	—	744	—	—	744
Unrealized gain on short term investments	—	—	—	—	8	8
At September 30, 2020	27,320,459	$ 3	$ 243,684	$ (153,880)	$ 8	$ 89,815
At December 31, 2018	18,569,289	$ 2	$ 175,201	$ (96,459)	$ —	$ 78,744
Net loss	—	—	—	(8,719)	—	(8,719)
Issuance of common stock upon exercise of stock options	11,141	—	18	—	—	18
Stock-based compensation	—	—	355	—	—	355
At March 31, 2019	18,580,430	2	175,574	(105,178)	—	70,398
Net loss	—	—	—	(7,255)	—	(7,255)
Stock-based compensation	—	—	326	—	—	326
At June 30, 2019	18,580,430	2	175,900	(112,433)	—	63,469
Net loss	—	—	—	(6,207)	—	(6,207)
Issuance of common stock under at-the-market offering net of commissions and issuance costs (Note 10)	40,300	—	256	—	—	256
Issuance of common stock upon exercise of stock options	9,000	—	35	—	—	35
Stock-based compensation	—	—	333	—	—	333
At September 30, 2019	18,629,730	$ 2	$ 176,524	$ (118,640)	$ —	$ 57,886

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

SCPHARMACEUTICALS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	**2020**
Cash flows from operating activities		
Net loss	$ (22,182)	$ (24,425)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	29	25
Amortization expense - right-of-use leased assets - operating	241	270
Accretion of discount on investments	-	45
Stock-based compensation	1,014	1,873
Non-cash interest expense	260	380
Fair value adjustment to derivative liability	3	30
Changes in operating assets and liabilities		
Prepaid expenses and other assets	1,088	1,671
Accounts payable, accrued expenses and other liabilities	3,940	1,618
Net cash used in operating activities	(15,607)	(18,513)
Cash flows from investing activities		
Purchases of short term investments	-	(70,161)
Net cash used in investing activities	-	(70,161)
Cash flows from financing activities		
Proceeds from common stock offering, net	-	50,187
Proceeds from at-the-market offering, net	70	10,388
Proceeds from term loan, net of costs	9,568	-
Proceeds from the exercise of vested stock options	53	717
Payment of term loan exit fee	-	(800)
Settlements of restricted stock units for tax withholding obligations	-	(164)
Net cash provided by financing activities	9,691	60,328
Net decrease in cash, cash equivalents and restricted cash	(5,916)	(28,346)
Cash, cash equivalents and restricted cash at beginning of period	89,660	72,806
Cash, cash equivalents and restricted cash at end of period	$ 83,744	$ 44,460
Supplemental cash flow information		
Interest paid	$ 925	$ 1,471
Taxes paid	$ 296	$ 144
Supplemental non-cash information		
Issuance of derivative in connection with modification of term loan	$ 763	$ -
Transfer of issuance costs from other noncurrent assets to equity	$ 3	$ -

The accompanying notes are an integral part of these unaudited condensed 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 condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information 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 condensed consolidated financial statements reflect the operations of the Company and its wholly-owned subsidiary, scPharmaceuticals Securities Corporation. Certain information and disclosures normally included in financial statements in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and related notes for the year ended December 31, 2019 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of September 30, 2020, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and nine months ended September 30, 2019 and 2020 and condensed consolidated statements of cash flows for the nine months ended September 30, 2019 and 2020 are unaudited. The unaudited condensed consolidated financial statements have been prepared on a basis consistent with that used to prepare the Company's audited annual financial statements and include, in the opinion of management, adjustments, consisting of normal recurring items, necessary for the fair statement of the condensed consolidated financial statements. The operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results expected for the full year ending December 31, 2020.

Liquidity

As of September 30, 2020, the Company had an accumulated deficit of approximately $153.9 million. Management expects to continue to incur operating losses for the foreseeable future. The Company has financed its operations to date from proceeds from the sale of common stock, preferred stock and the incurrence of debt.

As of September 30, 2020, the Company had cash, cash equivalents, restricted cash, and marketable securities of $114.5 million. The Company believes that its existing cash, cash equivalents, restricted cash and marketable securities will be sufficient to meet its cash commitments for at least the next 12 months after the date that the interim condensed consolidated financial statements are issued.

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 reported periods. Actual results could differ from those estimates.

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's cash and cash equivalent accounts, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts.

As of September 30, 2020, the Company classified $182,000 as restricted cash related to a letter of credit issued as a security deposit in connection with the Company's lease of its corporate office facilities (Note 11). Cash, cash equivalents and restricted cash consists of the following (in thousands):

	December 31, 2019	September 30, 2020
Cash and cash equivalents	$ 72,624	$ 44,278
Restricted cash	182	182
Cash, cash equivalents and restricted cash	$ 72,806	$ 44,460

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and available-for-sale securities. 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 marketable securities consist of United States Treasury securities, mortgage-backed securities, corporate debt securities and commercial paper. 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.

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 may 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.

Income Taxes

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

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. The tax benefits recorded are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is "more likely than not" to be realized following resolution of any uncertainty related to the tax benefit, assuming that the matter in question will be raised by the tax authorities. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense. At September 30, 2020, the Company had no such accruals.

Recently Issued Accounting Standards

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820) ("ASU 2018-13"). ASU 2018-13 modifies fair value disclosure requirements, specifically around level transfers and valuation of Level 3 assets and liabilities. ASU 2018-13 is effective for financial statements issued for annual and interim periods beginning after December 15, 2019 for all entities. The Company adopted ASU 2018-13 on January 1, 2020 and there has not been any impact to its financial statements.

3. Net Loss per Share

Net Loss per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2020	2019	2020
Net loss	$ (6,207)	$ (9,038)	$ (22,182)	$ (24,425)
Weighted-average shares used in computing net loss per share	18,584,327	27,319,465	18,580,192	23,644,580
Net loss per share, basic and diluted	$ (0.33)	$ (0.33)	$ (1.19)	$ (1.03)

The Company's potentially dilutive securities, which include stock options and unvested restricted stock units, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2020	2019	2020
Stock options to purchase common stock	1,424,018	2,183,217	1,424,018	2,183,217
Unvested restricted stock units	160,900	80,450	160,900	80,450
Total	1,584,918	2,263,667	1,584,918	2,263,667

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.

The following table summarizes the Company's investments, by category, as of September 30, 2020 (in thousands):

Investments - Current:	September 30, 2020
Debt securities - available-for-sale	$ 70,061
Total	$ 70,061

A summary of the Company's available-for-sale classified investments as of September 30, 2020 consisted of the following (in thousands):

	At September 30, 2020			
Investments - Current:	Cost Basis	Accumulated Unrealized Gains	Accumulated Unrealized Losses	Fair Value
United States Treasury securities	$ 39,710	$ 5	$ -	$ 39,715
Mortgage-backed securities	4,498	1	-	4,499
Corporate debt securities	12,063	2	-	12,065
Commercial paper	13,782	-	-	13,782
Total	$ 70,053	$ 8	$ -	$ 70,061

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of September 30, 2020 consisted of the following (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	$ 70,053	$ 70,061
Total	$ 70,053	$ 70,061

5. Property and Equipment

Purchased property and equipment consist of the following (dollars in thousands):

	ESTIMATED USEFUL LIFE	December 31, 2019	September 30, 2020
Office equipment	5 years	$ 10	$ 10
Office furniture	7 years	116	116
Computer equipment	3 years	8	8
Leasehold improvements	Life of lease	95	95
		229	229
Less: Accumulated depreciation		(102)	(127)
Property and equipment, net		$ 127	$ 102

Depreciation expense for the three months ended September 30, 2019 and September 30, 2020 was $10,000 and $8,000, respectively.

Depreciation expense for the nine months ended September 30, 2019 and September 30, 2020 was $29,000 and $25,000, respectively.

6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2019	September 30, 2020
Contract research and development	$ 2,001	$ 3,308
Employee compensation and related costs	1,250	1,636
Consulting and professional service fees	296	811
Interest	91	85
State taxes	49	70
Other	1	-
Total accrued expenses	$ 3,688	$ 5,910

7. Stock-Based Compensation

Stock Options

The Company's 2017 Stock Option and Incentive Plan (the "2017 Stock Plan") became effective in November 2017, upon the closing of the Company's initial public offering and will expire in October 2027. Under the 2017 Stock Plan, the Company may grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units ("RSUs") and other stock-based awards. The Company's 2014 Stock Incentive Plan (the "2014 Stock Plan") was terminated in November 2017 upon the completion of the Company's initial public offering and no further options were granted under the 2014 Stock Plan. At September 30, 2020, there were 703,136 options outstanding under the 2014 Stock Plan.

As of September 30, 2020, there were 3,891,429 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 265,203 options that have been forfeited from the 2014 Stock Plan.

At September 30, 2020, there were 2,312,300 options available for issuance under the 2017 Stock Plan, 1,480,081 options outstanding and 80,450 RSUs outstanding. 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 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:

	Nine Months Ended September 30,	
	2019	2020
Risk-free interest rate	1.61%-2.51%	0.33% - 1.71%
Expected dividend yield	0%	0%
Expected life	5.5-6.1 years	5.5-6.6 years
Expected volatility	72%-74%	72%-75%
Weighted-average grant date fair value	$ 2.17	$ 4.25

The following table summarizes information about stock option activity during the nine months ended September 30, 2020 (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, 2019	1,439,518	$ 6.09		
Granted	923,700	6.63		
Exercised	(116,171)	6.17		
Forfeited	(63,830)	9.77		
Outstanding, September 30, 2020	2,183,217	$ 6.20	7.97	$ 4,278
Vested and exercisable, September 30, 2020	1,015,997	$ 5.72	6.76	$ 2,649
Vested and expected to vest, September 30, 2020	1,812,650	$ 6.11	7.70	$ 3,827

Of the options granted in the nine months ended September 30, 2020, 226,110 were performance-based options. Vesting of these performance-based options is contingent on the occurrence of certain regulatory and commercial milestones. The Company is recognizing the expense as straight-line over the expected performance achievement term.

The following table summarizes information about RSU activity during the nine months ended September 30, 2020:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
Outstanding, December 31, 2019	160,900	$ 3.25
Granted	—	—
Vested	(80,450)	3.25
Forfeited	—	—
RSUs outstanding at September 30, 2020	80,450	$ 3.25

The number of RSUs vested includes shares of common stock withheld on behalf of employees to satisfy the minimum statutory tax withholding requirements. As a result of a regulatory milestone, 31,962 common shares were issued on July 2, 2020.

Unrecognized compensation expense related to unvested options as of September 30, 2020 was $2.6 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 2.3 years. Unrecognized compensation expense related to unvested RSUs as of September 30, 2020 was $105,000 and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 0.3 years.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2019 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2020	2019	2020
Research and development	$ 75	$ 213	$ 215	$ 534
General and administrative	258	531	799	1,339
Total	$ 333	$ 744	$ 1,014	$ 1,873

8. Fair Value of Financial Instruments

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

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

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

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

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

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

The following table summarizes the Company's assets as of September 30, 2020 that are measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents	$ 43,006	$ 43,006	$ —	$ —
Total cash equivalents	43,006	43,006	—	—
United States Treasury securities	39,715	39,715	—	—
Mortgage-backed securities	4,499	—	4,499	—
Corporate debt securities	12,065	—	12,065	—
Commercial paper	13,782	—	13,782	—
Investments	70,061	39,715	30,346	—
Total	$ 113,067	$ 82,721	$ 30,346	$ —

9. Term Loan

In May 2017, the Company entered into a loan and security agreement (the "2017 Loan Agreement"), with Solar Capital Ltd. and Silicon Valley Bank (together, the "Lenders"), for $10.0 million. The 2017 Loan Agreement had a maturity date of May 1, 2021. Debt

issuance costs for the 2017 Loan Agreement were to be amortized to interest expense over the remaining term of the 2017 Loan Agreement using the effective-interest method.

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

For the three and nine months ended September 30, 2019, the Company recorded $53,000 and $169,000, respectively, related to the amortization of debt discount associated with the 2017 Loan Agreement.

The 2017 Loan Agreement allowed the Company to voluntarily prepay all (but not less than all) of the outstanding principal at any time. A prepayment premium of 1% would be assessed on the outstanding principal. A final payment fee of $250,000 was due upon the earlier to occur of the maturity date or prepayment of such borrowings. The final payment fee was increased to $325,000 in the First Amendment to the 2017 Loan Agreement. For the three and nine months ended September 30, 2019, the Company recorded $23,000 and $80,000, respectively, related to the amortization of the final payment fee associated with the 2017 Loan Agreement.

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

The interest rate under the 2019 Loan Agreement is the higher of (i) LIBOR plus 7.95% or (ii) 10.18% and there is an interest-only period until September 30, 2021. The rate at September 30, 2020 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 an Exit Agreement in connection with the 2019 Loan Agreement which provides for an aggregate payment of 4% of the loan commitment, or $800,000, to the lenders upon the occurrence of an exit event (the "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 is re-measured at each balance sheet date and any changes in estimated fair value is recorded as other income (expense). The Company paid the Exit Fee during the nine months ended September 30, 2020 in conjunction with the Company's public offering, which was deemed to be an exit event pursuant to the Exit Agreement (Note 10). Prior to the public offering, the Company recorded $30,000 in non-cash expense as a fair value adjustment to the derivative liability in 2020.

As of September 30, 2020, unpaid borrowings under the 2019 Loan Agreement totaled $20.0 million. For the three and nine months ended September 30, 2020, the Company recorded $94,000 and $260,000, respectively, related to the amortization of debt discount associated with the 2019 Loan Agreement. For the three and nine months ended September 30, 2019, the Company recorded $5,000 related to the amortization of debt discount associated with the 2019 Loan Agreement.

The 2019 Loan Agreement allows the Company to voluntarily prepay all (but not less than all) of the outstanding principal at any time. A prepayment premium of 3% or 1% through the one-year anniversary and the two-year anniversary, respectively, would be assessed on the outstanding principal. After the two-year anniversary, a 0.5% prepayment premium would be assessed on the outstanding principal. A final payment fee of $500,000 is due upon the earlier to occur of the maturity date or prepayment of such borrowings. For the three and nine months ended September 30, 2020, the Company recorded $40,000 and $120,000, respectively, related to the amortization of the final payment fee associated with the 2019 Loan Agreement. For the three and nine months ended September 30, 2019, the Company recorded $6,000 related to the amortization of the final payment fee associated with the 2019 Loan Agreement.

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

The 2019 Loan Agreement includes restrictions on, among other things, the Company's ability to incur additional indebtedness, change the name or location of the Company's business, merge with or acquire other entities, pay dividends or make other

distributions to holders of its capital stock, make certain investments, engage in transactions with affiliates, create liens, sell assets or pay subordinated debt.

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

	September 30, 2020
Face value	$ 20,000
Less: discount	(830)
Total	$ 19,170
Less: current portion	-
Total	$ 19,170

As of September 30, 2020, future principal payments due under the 2019 Loan Agreement are as follows (in thousands):

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

10. Stockholders' Equity

At-the-Market Issuance Sales Agreement

On August 23, 2019, the Company entered into an Open Market Sale Agreement℠ ("ATM Agreement"), with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program under which the Company could offer and sell shares of its common stock (the "ATM Shares"), having an aggregate offering price of up to $15.0 million through Jefferies as its sales agent. The offering and sale of ATM Shares were made pursuant to the Company's shelf registration statement on Form S-3, which was declared effective by the SEC on February 11, 2019 (the "Registration Statement"). The Company agreed to pay Jefferies a commission equal to 3.0% of the gross sales proceeds of such ATM Shares.

During the three months ended September 30, 2019, the Company sold a total of 40,300 ATM Shares under the ATM Agreement, in the open market, at a weighted average gross selling price of $6.63 per share for net proceeds of $259,000. During the three months ended September 30, 2019, the Company incurred $189,000 of legal, accounting and other costs to establish and activate the ATM program. The Company charged $3,000 of these costs against additional paid in capital upon issuance of shares during the three months ended September 30, 2019.

During the three months ended March 31, 2020, the Company sold a total of 1,502,892 ATM Shares under the ATM Agreement, in the open market, at a weighted average gross selling price of $7.13 per share for net proceeds of $10.4 million, which completed the program. The Company charged $135,000 in costs related to establishing and activating the program against additional paid in capital upon issuance of shares in 2020.

Sale of Common Stock

In May 2020, the Company completed an underwritten public offering of 5,780,347 shares of its common stock (the "2020 Offering Shares"), pursuant to the Registration Statement. The 2020 Offering Shares were sold at an offering price of $8.65 per share, resulting in net proceeds of $46.6 million, after deducting underwriting discounts, commissions and offering expenses. In addition, the underwriters of the offering were granted the option for a period of 30 days to purchase up to an additional 867,052 shares of common stock at $8.65 per share. In June 2020, the underwriters exercised their option and purchased an additional 440,242 shares of common stock at $8.65 per share, resulting in additional net proceeds to the Company of $3.6 million, after deducting underwriting discounts, commissions and offering expenses.

11. Commitments and Contingencies

Operating Leases

The Company leases office facilities and equipment under long-term, non-cancelable operating lease agreements. The leases expire at various dates through 2022 and do not include renewal options.

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, 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 of the operating lease liabilities as of September 30, 2020 (in thousands):

Year ended:	
December 31, 2020	$ 134
December 31, 2021	537
December 31, 2022	496
Total minimum lease payments	1,167
Less imputed interest	(119)
Total	$ 1,048

	Nine Months Ended September 30,	
	2019	2020
Lease cost:		
Operating lease cost	$ 368	$ 365
Short-term lease cost	6	-
Sublease income	(38)	(38)
Total lease cost	$ 336	$ 327
Other information		
Cash paid for amounts included in the measurement of lease liabilities	$ 384	$ 391
Operating cash flows from operating leases	$ (21)	$ (32)
Weighted-average remaining lease term - operating leases	3.2 years	2.2 years
Weighted-average discount rate - operating leases	10.1%	10.1%

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

Research and Development Agreements

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

Contingencies

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

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

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

Due to the discontinuation of use of the sc2Wear Infusor, the Company has received notice of termination costs related to the program. The Company has accrued all costs for which it either believes it is contractually liable or for which the Company has negotiated settlement agreements in good faith. However, certain of the Company's vendors have claimed or billed for additional

costs for which the Company believes it is not obligated. At this time, the Company estimates that additional termination costs, if any, will be immaterial to the Company's financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and the results of operations should be read in conjunction with our financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") and our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2019 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section in our Annual Report and in this Quarterly Report, our actual results could differ materially from the results described in or implied by, the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

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

We resubmitted our new drug application, or NDA, for FUROSCIX, with the U.S. Food and Drug Administration, or FDA, on June 30, 2020. The resubmission was a response to a Complete Response Letter, or CRL, from the FDA with respect to our NDA submitted in August 2017, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required device modifications necessary to advance FUROSCIX using the existing technology, we decided to transition to our next generation device. The resubmission incorporated our next generation device which is being developed through a partnership with West Pharmaceutical Services, Inc., or West, using its proprietary, wearable, SmartDose® drug delivery system (SmartDose is a registered trademark of West Pharma. Services IL, Ltd., a subsidiary of West, in the United States and other jurisdictions). On July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of December 30, 2020 for completion of its review of the NDA. We have received a General Advice Letter from the FDA indicating that West's facility in Scottsdale, Arizona will need to undergo a routine pre-approval inspection. We are actively working with the FDA to address this inspection prior to the PDUFA target action date.

We began enrollment for FREEDOM-HF, a prospective clinical trial evaluating overall and heart failure-related costs for subjects treated with FUROSCIX for 30 days post-discharge from the emergency department compared to patients who remain in the hospital for 24 to 72 hours following hospitalization. Data is expected in the second quarter of 2021 to support the planned commercial launch of FUROSCIX, if approved.

We have funded our operations from inception through September 30, 2020 primarily through the sale of shares of our common stock and, prior to that, through the private placement of our preferred stock and the incurrence of debt. We do not have any products approved for sale and have not generated any revenue from product sales.

As of September 30, 2020, we had an accumulated deficit of $153.9 million. We expect to continue to incur net losses for the foreseeable future as we develop the infrastructure to commercialize our products, if approved, in the United States, including building our sales and marketing organization, continue research and development efforts, engaging in scale-up manufacturing and seeking regulatory approval for new product candidates and enhancements. We will need additional funding to pay expenses related to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition.

IMPACT OF COVID-19

A new strain of novel coronavirus which causes a severe respiratory disease ("COVID-19") was identified in 2019, and subsequently declared a pandemic by the World Health Organization, affecting the populations of the United States as well as the rest of the world. In response to the pandemic, we transitioned our workforce to work from home in March 2020. In July 2020, we opened our offices for limited access to employees integrating all recommendations for workplace safety, including appropriate protocols to ensure social-distancing. The health of our employees remains a top priority and we are continuing to monitor the impact of COVID-19 and government regulations.

To date, the third parties that perform our manufacturing, assembly, packaging and testing of our products have generally remained operational. The extent of the impact of the COVID-19 pandemic on the timing of the FDA's review of the FUROSCIX NDA and our operational and financial performance will depend on future developments, including the duration, severity and spread of the pandemic, related restrictions on travel and transportation and other actions that may be taken by governmental authorities, including the ability of the FDA to inspect facilities required for approval of our NDA, the impact to the business of our

suppliers or customers, and other items identified under “Risk Factors” below, all of which are uncertain and cannot be predicted. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition.

COMPONENTS OF OUR RESULTS OF OPERATIONS

Research and Development Expenses

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

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

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

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

General and Administrative Expenses

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

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

Results of Operations

Comparison of Three Months Ended September 30, 2019 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2020 (in thousands):

	Three Months Ended September 30,		Increase
	2019	2020	(Decrease)
Operating expenses:			
Research and development	$ 4,293	$ 5,119	$ 826
General and administrative	1,996	3,319	1,323
Total operating expenses	6,289	8,438	2,149
Loss from operations	(6,289)	(8,438)	2,149
Other income	83	19	(64)
Interest income	397	36	(361)
Interest expense	(398)	(655)	257
Net loss	$ (6,207)	$ (9,038)	$ 2,831

Research and development expenses. R&D expenses were $5.1 million for the three months ended September 30, 2020, compared to $4.3 million for the three months ended September 30, 2019. The increase of $0.8 million was primarily attributable to a $0.9 million increase in clinical study activity, a $0.5 million increase in employee-related costs and a $0.2 million increase in regulatory and patent-related costs, which was partially offset by a $0.5 million decrease in pharmaceutical preparation costs and a $0.3 million decrease in device development costs.

General and administrative expenses. G&A expenses were $3.3 million for the three months ended September 30, 2020, compared to $2.0 million for the three months ended September 30, 2019. The increase of $1.3 million was primarily attributable to a $0.8 million increase in employee-related costs, a $0.2 million increase in costs related to operating as a public company, including director and officer's insurance and investor and public relations costs, and a $0.3 million increase in commercial preparation costs.

Other income. Other income was $19,000 for the three months ended September 30, 2020, compared to $83,000 for the three months ended September 30, 2019. The decrease in income of $64,000 was primarily attributable to decreased foreign currency activity.

Interest income. Interest income was $36,000 for the three months ended September 30, 2020 compared to $397,000 for the three months ended September 30, 2019. The decrease of $361,000 was primarily attributable to lower interest rates on our financial instruments.

Interest expense. Interest expense was $0.7 million for the three months ended September 30, 2020 compared to $0.4 million for the three months ended September 30, 2019. The increase was due to the restructuring of the term loan in September 2019 with Solar Capital Ltd. and Silicon Valley Bank, which increased the principal from $10.0 million to $20.0 million.

Comparison of Nine Months Ended September 30, 2019 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2020 (in thousands):

	Nine Months Ended September 30,		Increase
	2019	2020	(Decrease)
Operating expenses:			
Research and development	$ 16,314	$ 14,404	$ (1,910)
General and administrative	6,158	8,359	2,201
Total operating expenses	22,472	22,763	291
Loss from operations	(22,472)	(22,763)	291
Other income (expense)	61	(13)	74
Interest income	1,350	281	(1,069)
Interest expense	(1,121)	(1,930)	809
Net loss	$ (22,182)	$ (24,425)	$ 2,243

Research and development expenses. R&D expenses were $14.4 million for the nine months ended September 30, 2020, compared to $16.3 million for the nine months ended September 30, 2019. The decrease of $1.9 million was primarily attributable to one-time costs in 2019, including $1.7 million in materials related to the first-generation device and $1.0 million in severance costs, a decrease of $2.2 million in device development costs, and a $0.4 million decrease in pharmaceutical development costs in the nine months ended September 30, 2020. The decrease was partially offset by a $1.7 million increase in clinical study activity, a $1.1 million increase in employee-related costs, a $0.5 million increase in regulatory and patent-related costs, and a $0.1 million increase in contract services for medical affairs.

General and administrative expenses. G&A expenses were $8.4 million for the nine months ended September 30, 2020, compared to $6.2 million for the nine months ended September 30, 2019. The increase of $2.2 million was primarily attributable to a $1.5 million increase in employee-related costs, a $0.5 million increase in costs related to operating as a public company, including director and officer's insurance and investor and public relations costs, a $0.3 million increase in legal costs, and a $0.3 million increase in commercial preparation costs. The increase was partially offset by $0.4 million in severance costs recognized in 2019.

Other income (expense). Other expense was $13,000 for the nine months ended September 30, 2020, compared to other income of $61,000 for the nine months ended September 30, 2019. The increase in expense of $74,000 was primarily attributable to the fair value adjustment to the derivative liability and decreased foreign currency activity.

Interest income. Interest income was $0.3 million for the nine months ended September 30, 2020, compared to $1.4 million for the nine months ended September 30, 2019. The decrease of $1.1 million was primarily attributable to lower interest rates on our financial instruments.

Interest expense. Interest expense was $1.9 million for the nine months ended September 30, 2020, compared to $1.1 million for the nine months ended September 30, 2019. The increase was due to the restructuring of the term loan in September 2019 with Solar Capital Ltd. and Silicon Valley Bank, which increased the principal from $10.0 million to $20.0 million.

LIQUIDITY AND CAPITAL RESOURCES

Overview

We have funded our operations from inception through September 30, 2020 primarily through the sale of shares of our common stock and, prior to that, through the private placement of our preferred stock and the incurrence of debt. As of September 30, 2020, we had received net cash proceeds of $92.7 million from our initial public offering, $56.7 million from sales of our preferred stock, net cash proceeds of $18.8 million from borrowings under our term loan, net cash proceeds of $13.5 million from sales of convertible notes, net cash proceeds of $50.2 million from the public offering and net cash proceeds of $14.4 million from the sale of common stock in our at-the-market offering. As of September 30, 2020, we had cash, cash equivalents and restricted cash of $44.5 million and short term investments of $70.1 million.

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

- the potential FDA approval of FUROSCIX;
- the costs and expenses of establishing our U.S. sales and marketing infrastructure;
- the degree of success we experience in commercializing FUROSCIX, if approved;
- the revenue generated by sales of FUROSCIX, if approved, and other products that may be approved;
- the pricing and reimbursement of FUROSCIX, if approved, and of other product candidates that may be approved;
- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the emergence of competing or complementary technological developments;
- the extent to which FUROSCIX, if approved, is adopted by the healthcare community;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the impact of COVID-19 on our operations; 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.

CASH FLOWS

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

(in thousands)	Nine Months Ended September 30, 2019	2020
Net cash (used in) provided by:		
Operating activities	$ (15,607)	$ (18,513)
Investing activities	-	(70,161)
Financing activities	9,691	60,328
Net decrease in cash, cash equivalents and restricted cash	$ (5,916)	$ (28,346)

Net Cash Used in Operating Activities

During the nine months ended September 30, 2020, net cash used in operating activities was $18.5 million, consisting primarily of a net loss of $24.4 million. This was offset by non-cash charges of $2.6 million and an increase in net operating liabilities of $3.3 million. The non-cash charges primarily consisted of depreciation, amortization related to our right of use leased assets, stock-based compensation expense, non-cash interest expense related to amortization of debt discount associated with the 2019 Loan Agreement, accretion of discount on investments and the fair value adjustment to the derivative liability.

During the nine months ended September 30, 2019, net cash used in operating activities was $15.6 million, consisting primarily of a net loss of $22.2 million. This was offset by non-cash charges of $1.5 million and an increase in net operating liabilities of $5.0 million. The non-cash charges primarily consisted of depreciation, amortization related to our right of use leased assets, stock-based compensation expense and non-cash interest expense related to amortization of debt discount associated with the 2017 Loan Agreement. The increase in net operating liabilities related to accrued expenses for device and pharmaceutical development costs and materials as well as the amortization of prepaid insurance.

Net Cash Used in Investing Activities

During the nine months ended September 30, 2020, net cash used by investing activities was $70.2 million, consisting of purchases of short term investments.

There was no cash from investing activities during the nine months ended September 30, 2019.

Net Cash Provided by Financing Activities

During the nine months ended September 30, 2020, net cash provided by financing activities was $60.3 million, consisting primarily of net proceeds of $50.2 million from the public offering, net proceeds of $10.4 million from the at-the-market offering and stock option exercises. The proceeds were offset by the $0.8 million Exit Fee associated with the 2019 Loan Agreement and tax obligations on the settlement of restricted stock units.

During the nine months ended September 30, 2019, net cash provided by financing activities was $9.7 million, consisting primarily of net proceeds from the 2019 Loan Agreement, net proceeds from sales made pursuant to the ATM Agreement, and stock option exercises.

OFF-BALANCE SHEET ARRANGEMENTS

We currently have no off-balance sheet arrangements.

CONTRACTUAL OBLIGATIONS

There were no material changes in our commitments under contractual obligations, as disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 24, 2020.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these 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. Our critical accounting policies are more fully described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 24, 2020.

JOBS ACT ACCOUNTING ELECTION

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

Item 3. 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 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 September 30, 2020, our aggregate outstanding indebtedness was $20.0 million, which bears interest at the rate at the higher of (i) LIBOR plus 7.95% or (ii) 10.18%. Due to the short-term duration and variable rate of our indebtedness, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our debt instruments.

Item 4. Controls and Procedures.

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation of our disclosure controls and procedures as September 30, 2020, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

There were no changes in our internal control over financial reporting during the nine months ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. 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 1A. Risk Factors

Our business involves material and other risks, some of which are summarized and described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the condensed financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

Risks Related to our Product Candidates

Risks Related to Approval and Commercialization of our Product Candidates

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

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

We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA, or in any foreign jurisdiction until we receive the requisite approvals from such jurisdiction. We resubmitted our NDA for FUROSCIX with the FDA on June 30, 2020. The resubmission was a response to a CRL from the FDA with respect to our NDA submitted in August 2017, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required device modifications necessary to advance FUROSCIX using the existing technology, we decided to transition to our next generation device, which is being developed through a partnership with West Pharmaceutical Services, Inc., or West, using its proprietary, wearable, SmartDose drug delivery system. On July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a PDUFA target action date of December 30, 2020 for completion of its review of the NDA.

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

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

- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;

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

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

If we are not able to obtain required regulatory approvals, we will not be able to commercialize FUROSCIX, and our ability to generate revenue will be materially impaired. There is no assurance that, if approved, 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 regulatory authorities outside the United States. Failure to obtain marketing approval for FUROSCIX will prevent us from commercializing it.

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

The FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example, the FDA has already delayed our timeline to commercialization of FUROSCIX by issuing a CRL in June 2018 with respect to our NDA for FUROSCIX. We resubmitted our NDA for FUROSCIX with the FDA on June 30, 2020 and on July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a PDUFA target action date of December 30, 2020 for completion of its review of the NDA. Moreover, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, the FDA may not be able to continue its current pace and review timelines could be extended. In addition, the FDA:

- could determine that we cannot rely on the Section 505(b)(2) regulatory pathway for FUROSCIX;
- could determine that the information provided by us was inadequate, contained clinical deficiencies or otherwise failed to demonstrate the safety and effectiveness of FUROSCIX or any of our product candidates for any indication;
- could determine that additional clinical, human factors or other studies are required to evaluate FUROSCIX incorporating the next generation SmartDose drug delivery system;

- may not find the data from bioequivalence studies and/or clinical trials sufficient to obtain marketing approval in the United States, including any findings that the clinical and other benefits of our product candidates outweigh their safety risks;
- may disagree with our trial design or our interpretation of data from preclinical studies, bioequivalence studies and/or clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our trials;
- may determine that there are unacceptable risks associated with the device component of FUROSCIX or that there are deficiencies with the information submitted to demonstrate the safety, effectiveness and reliability of the device component;
- may determine that we have identified the wrong listed drug or drugs or that approval of our Section 505(b)(2) application for FUROSCIX or any of our other product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously-approved drugs with the same conditions of approval as FUROSCIX (e.g., subcutaneous injection);
- may delay the timing of routine or pre-approval inspections due to COVID-19, which could impact the approval process, or identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for the manufacturing of our product candidates;
- may approve our product candidates for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials;
- may change its approval policies or adopt new regulations; or
- may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

To date, most patients who have been evaluated in studies of our product candidates have been treated with versions of our product candidates incorporating the sc2Wear Infusor. As of February 2019, we have discontinued use of the sc2Wear Infusor in our product candidates and have pivoted to incorporate the next generation SmartDose drug delivery system. We resubmitted our NDA for FUROSCIX with the FDA on June 30, 2020. The resubmission was a response to a CRL from the FDA with respect to our NDA submitted in August 2017, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required device modifications necessary to advance FUROSCIX using the existing technology, we decided to transition to our next generation device, which is being developed through a partnership with West, using its proprietary, wearable, SmartDose drug delivery system. On July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a PDUFA target action date of December 30, 2020 for completion of its review of the NDA. If we are required to conduct additional testing or additional clinical studies, it could adversely affect the commercial viability of our product candidates and may adversely affect our ability to generate revenue, as a result of which our business, prospects, financial condition and results of operations may suffer.

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

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

We have supported and continue to support investigator sponsored clinical trials evaluating novel approaches utilizing FUROSCIX to manage patients with worsening heart failure who display reduced responsiveness to oral diuretics and do not require

hospitalization. We do not control the design or administration of investigator-sponsored trials, and the investigator-sponsored trials could, depending on the actions of such third parties, jeopardize the validity of the clinical data generated, identify significant concerns with respect to FUROSCIX that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities.

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

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

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

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

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

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

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

Because our product candidates are designed to be self-administered subcutaneously by patients, they are drug-device combination products that require coordination within the FDA and similar foreign regulatory agencies for review of their device and

drug components. Although the FDA and similar foreign regulatory agencies have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. For example, we resubmitted our NDA for FUROSCIX with the FDA on June 30, 2020. The resubmission was a response to a CRL from the FDA with respect to our NDA submitted in August 2017, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required device modifications necessary to advance FUROSCIX using the existing technology, we decided to transition to our next generation device, which is being developed through a partnership with West, using its proprietary, wearable, SmartDose drug delivery system. On July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a PDUFA target action date of December 30, 2020 for completion of its review of the NDA. Further, we cannot assure you that the FDA will not require device modifications with respect to this next generation device following its review of any regulatory submission that we make. Any such findings could further delay regulatory approval for FUROSCIX or any of our other product candidates that incorporate our next generation device.

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

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

Risks Related to Clinical Development

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

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

- difficulties obtaining regulatory approval to commence a clinical trial or complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial;
- delays in reaching or failing to reach agreement on acceptable terms with prospective contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure of our third-party contractors, such as CROs and CMOs, or our investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner;
- insufficient or inadequate supply or quality of a product candidate or other materials necessary to conduct our clinical trials;
- difficulties obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;
- the FDA requiring alterations to any of our study designs, our nonclinical strategy or our manufacturing plans;

- challenges recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including size and nature of subject population, proximity of subjects to clinical sites, eligibility criteria for the trial, nature of trial protocol, the availability of approved effective treatments for the relevant disease and competition from other clinical trial

  programs for similar indications;

- difficulties maintaining contact with subjects after treatment, which results in incomplete data;

- receipt by a competitor of marketing approval for a product targeting an indication that our product targets, such that we are not "first to market" with our product candidate;

- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines; and

- varying interpretations of data by the FDA and similar foreign regulatory agencies.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;

- unforeseen safety issues, including serious adverse events associated with a product candidate, or lack of effectiveness; and

- lack of adequate funding to continue the clinical trial.

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

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

Additionally, several of our past and planned and ongoing clinical trials utilize an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Our product candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our product candidates or following

approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

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

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

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

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

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

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;

- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to motivate key employees of any acquired businesses.

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

Risks Related to Acceptance, Sales, Marketing and Competition

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

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

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

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

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

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

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

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

We are in the process of establishing sufficient infrastructure for the sales, marketing or distribution of FUROSCIX, if approved, and for our other product candidates, and the cost of establishing and maintaining such an organization may exceed the benefits of doing so. In order to market FUROSCIX, if approved by the FDA, we must continue to build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services.

We are in the early stages of establishing a sales force to promote FUROSCIX to hospital networks, healthcare providers and third-party payers in the United States, if we obtain FDA approval. There are significant expenses and risks involved with establishing our own sales and marketing capabilities, including our ability to hire, retain and appropriately incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could delay any product launch, which would adversely impact the commercialization of FUROSCIX. For example, if we recruit any sales representatives or establish marketing capabilities prior to the commercial launch of FUROSCIX and the commercial launch is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We cannot be sure that we will be able to hire a sufficient number of sales representatives or that they will be effective at promoting FUROSCIX. In addition, we will need to commit significant additional management and other resources to establish and grow our sales organization. We may not be able to achieve the necessary development and growth in a cost-effective manner or realize a

positive return on our investment. We will also have to compete with other companies to recruit, hire, train and retain sales and marketing personnel.

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

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians 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 our product candidates, if approved.

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

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

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

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

Risks Related to the COVID-19 Pandemic

COVID-19 may materially and adversely affect our business and our financial results, including the pending approval of FUROSCIX and our intended commercial launch of FUROSCIX, if approved.

The ongoing and developing 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 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 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. Similarly, the FDA may not be able to conduct any required inspection prior to the PDUFA target action date due to restrictions on travel and public health concerns related to COVID-19. As of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, the FDA may not be able to continue its current pace and review timelines could be extended. Any delay in the inspection could negatively impact our ability to obtain regulatory approval for and to commercialize our product candidates, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including encouraging all employees to work remotely. Strict protocols have been established for any employee working in the office. We have already suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, 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 threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

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

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 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.

As of June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain this pace and delays or setbacks are possible in the future. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, the FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. We have received a General Advice Letter from the FDA indicating that West's facility in Scottsdale, Arizona will need to undergo a routine pre-approval inspection. While we are actively working with the FDA to address this inspection prior to the PDUFA target action date, we cannot guarantee that the FDA will be able to complete the inspection or take other necessary actions with respect to our NDA by the PDUFA target action date of December 30, 2020, which could result in the FDA issuing us a complete response letter or deferring action on our NDA if an in-person inspection is required and cannot be completed timely. A delay in the review of our NDA could have a material impact on our results of operations.

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, if it is approved.

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

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

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

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

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

For example, in our Phase 3 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 the sc2Wear Infusor, likely due to user errors. As a result, the study did not meet its specified primary endpoints. If we are not successful in promoting the proper use of FUROSCIX, if approved, by patients, healthcare professionals and caregivers, we may not be able to achieve market acceptance or effectively commercialize FUROSCIX.

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

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

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 $22.2 million and $24.4 million for the nine months ended September 30, 2019 and 2020, respectively. In addition, our accumulated deficit as of September 30, 2020 was $153.9 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and absent the realization of sufficient revenues from product sales, if any, of our current or future product candidates, if approved, we may never attain profitability in the future. We have devoted substantially all of our financial resources and efforts to date to research and development, including preclinical studies and our clinical trials, and preparation for commercialization of our lead product candidate, FUROSCIX, if approved. On July 27, 2020, the FDA accepted our NDA resubmission for our lead product candidate, FUROSCIX and set a Prescription Drug User Fee Act, or PDUFA, target action date of December 30, 2020 for the completion of its review of the NDA.

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

- continue pursuing regulatory approval of FUROSCIX incorporating the SmartDose drug delivery system;
- continue to build our sales, marketing, distribution and other commercial infrastructure and manufacture commercial inventory in anticipation of the potential regulatory approval of FUROSCIX;
- initiate and continue research, preclinical and clinical development efforts for FUROSCIX and any additional or future product candidates;
- seek to identify additional product candidates;
- seek regulatory and marketing approvals for other product candidates that successfully complete clinical trials;
- manufacture larger quantities of product candidates for clinical development and, potentially, commercialization;
- maintain, expand and protect our intellectual property portfolio;
- hire and retain additional personnel, such as clinical, quality control, commercial, 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 unless and until we are able to obtain marketing approval for, and successfully commercialize, FUROSCIX or any other product candidates that we may develop. Successful commercialization will require achievement of key milestones, including completing clinical trials of our product candidates that are under clinical development, obtaining marketing approval for our product candidates, manufacturing, marketing and selling those products for which we, or any of our future collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payers. Because of the uncertainties and risks associated with these activities, we are unable to accurately predict the timing and amount of revenues, and if or when we might achieve profitability. We and any future collaborators may never succeed in these activities and, even if we or any future collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We have 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 resubmitted our NDA for FUROSCIX with the FDA on June 30, 2020. The resubmission was a response to a CRL from the FDA with respect to our NDA submitted in August 2017, which indicated that, among other things, certain device modifications to our infusor were required. Based on our interactions with the FDA, which required device modifications necessary to advance the development of FUROSCIX using the existing technology, we decided to transition to our next generation device, which is being developed through a partnership with West, using its proprietary, wearable, SmartDose drug delivery system. On July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a PDUFA target action date of December 30, 2020 for completion of its review of the NDA. There can be no assurance that FUROSCIX will be approved by the FDA. We have not yet demonstrated an ability to obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

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

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

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

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from FUROSCIX, and we do not know when, or if, we will generate any revenue.

There can be no guarantee that the FDA will approve FUROSCIX in a timely fashion, if at all. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and begin to sell, FUROSCIX. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

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

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

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. We resubmitted our NDA for FUROSCIX to the FDA on June 30, 2020. On July 23, 2020, the FDA accepted the resubmission of our NDA and assigned a PDUFA target action date of December 30, 2020 for completion of its review of the NDA. In addition, if

FUROSCIX or any of our other product candidates are approved, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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

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

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

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

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

Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under our secured credit facility could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under our secured credit facility as a result of an event of default, we may not have sufficient funds

or may be unable to arrange for additional financing to repay our indebtedness while still pursuing our current business strategy. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

Risks Related to Government Regulation

Risks Related to Ongoing Regulatory Obligations

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

Successful sales of FUROSCIX and any other product candidates that receive regulatory approval depend on the availability of adequate coverage and reimbursement 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 other product candidates that we attempt to commercialize will depend significantly on access to third-party payers' drug formularies, or lists of medications for which third-party payers provide coverage. 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, the principal decisions about reimbursement for new medications are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS 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. However, no uniform policy for coverage and reimbursement of products exists among third-party payers. 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 or other applicable regulatory authorities approve generic products that compete with any of our product candidates, the sales of our product candidates, if approved, could be adversely affected.

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

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

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

For NDAs submitted under section 505(b)(2), the patent certification and related provisions of the Hatch-Waxman Act apply. Accordingly, if we rely for approval on the safety or effectiveness information for a previously approved drug, referred to as a listed drug, we will be required to include patent certifications in our 505(b)(2) application regarding any patents covering the listed drug. If there are patents listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for the listed drug, and we seek to obtain approval prior to the expiration of one or more of those patents, we will be required to submit a Paragraph IV certification indicating our belief that the relevant patents are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of our 505(b)(2) application. Otherwise, our 505(b)(2) application cannot be approved by the FDA until the expiration of any patents listed in the Orange Book for the listed drug. In connection with our NDA for FUROSCIX that we resubmitted to the FDA in July 2020, we certified that there were no unexpired patents for furosemide contained in the Orange Book.

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

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

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

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

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

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

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

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

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or FCPA, prohibits 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.

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

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

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

On March 27, 2020, President Trump signed into law the CARES Act in response to the U.S. COVID-19 pandemic. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances the FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of any approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we obtain any product approvals and experience shortages in the supply of our marketed products, our results could be materially impacted.

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

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

- refusal to permit the import or export of products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

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.

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. We are responsible for training our marketing and sales force against promoting our product candidates for off-label use, but healthcare providers may use our products 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. Although our policy is to refrain from statements that could be considered off-label promotion of our products or false or misleading claims, 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 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 FUROSCIX, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

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

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for 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 remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In December 2018, CMS published a new final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of $12 billion in "risk corridor" funding. On December 14, 2018, a Texas United States District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur on November 10, 2020. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030, unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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 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. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance (over a period of time) to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a plan to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. The HHS has solicited feedback on some of these measures and has implemented others under its existing authority.

On July 24, 2020 and September 13, 2020, President Trump announced five executive orders related to prescription drug pricing that collectively attempt to implement several of the administration's proposals, including, among other items, a policy that would impose "most favored nation" pricing for prescription drugs reimbursed by Medicare Parts B and D and a directive for HHS to finalize the rulemaking process on modifying the federal AKS safe harbors to address pharmaceutical manufacturer rebates provided to health plans and pharmacy benefit managers. The probability of success of these newly announced policies and their impact on the U.S. prescription drug marketplace is unknown. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have indicated that they will continue to seek new legislative and/or administrative measures to control drug costs.

We may face competition in the United States for our product candidates, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the FDA issued a final guidance document on October 1, 2020 outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The market implications of the final guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

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

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:

- *Anti-Kickback Statute.* The federal AKS prohibits, among other things, individuals or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation or arranging of the purchase, lease or order of, any good, facility, item or service, for which

  payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors to the AKS protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or ordering of products may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person can be found guilty of violating the federal AKS without actual knowledge of the statute or specific intent to violate it. Violations may result in significant civil, criminal and administrative fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the federal FCA or federal Civil Monetary Penalties Law.

- *False Claims Laws.* The federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of products for unapproved, and thus non-reimbursable, uses.

- *HIPAA.* The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or 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 (i.e., 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, fictitious, or fraudulent statements, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal AKS, a person does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Additionally, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, imposes obligations on covered healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform services on their behalf that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. Such obligations include mandatory contractual terms and physical, technical and administrative safeguards, with respect to maintaining the privacy and security of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions.

- *Transparency Requirements.* The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, medical devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or transfers of value made to physicians (defined to include doctors of medicine or osteopathy, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as information regarding ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners.

- *Analogous State and Foreign Laws.* Analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to our business practices, including but not limited to, research,

  distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payers, and are generally broad and are enforced by many different federal and state agencies as well as through private actions. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. In some cases, state laws require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing information, while other state and local laws require registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. 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. 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.

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 applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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, including but not limited to, building out appropriate compliance program policies and procedures, processes and systems to promote ethical and compliant conduct. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

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

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or

breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

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

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

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

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

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

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

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

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 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 product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;

- patent applications may not result in any patents being issued;

- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;

- our competitors, many of whom have substantially greater resources and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our potential product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and

- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates in such countries.

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

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

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

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

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

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

identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or patent applications, in our licensed patents or patent applications or in third-party patents.

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

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

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent(s) will not: (a) be sufficient to protect our technology, (b) provide us with a basis for commercially viable products or (c) provide us with any competitive advantages;
- 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, 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 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 (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

As is the case with other 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 and patents. In these adversarial actions, the USPTO reviews patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and uses a lower burden of proof than used in litigation in U.S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U.S. patent invalidated in a USPTO post-grant review or *inter partes* review proceeding than invalidated in litigation in a U.S. federal court. If any of our or our licensors’ patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we or our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent rights to us.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

In addition to the protection afforded by patents, we also rely on trade secret protection for certain aspects of our intellectual property. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Any party with whom we have executed such an agreement may breach that agreement and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating such trade secrets. Further, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

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

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

Risks Related to 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 FDA's Orange Book for the listed drug; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. We can avoid certifying to a method-of-use patent if we do not seek approval of the patented condition of use. If we certify to the FDA that a patent is invalid or not infringed, or a Paragraph IV certification, a notice of the Paragraph IV certification must also be sent to the patent owner and NDA holder shortly after our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us asserting infringement of the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our 505(b)(2) application until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our application will not be subject to the 30-month stay. However, even if the third party does not sue within the 45-day time limit, thereby invoking the 30-month stay, it may still challenge our right to market our product upon FDA approval; therefore, some risk of an infringement suit remains even after the expiry of the 45-day limit.

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

Filing, prosecuting, enforcing and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our product candidates.

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

compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

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

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

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates, including interference and post-grant proceedings before the USPTO. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the 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 product candidates in any jurisdiction. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be accused of infringing. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Accordingly, third parties may assert infringement claims against us based on intellectual property rights that exist now or arise in the future. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use or manufacture. The scope of protection afforded by a patent is subject to interpretation by the courts, and the interpretation is not always uniform. If we

were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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

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

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

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

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

whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks.

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

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

Risks Related to Our Reliance on Third Parties

Risks Related to Third Party Performance

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

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

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

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

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

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

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. 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 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 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 lead product candidate, FUROSCIX, is a drug-device combination product that will be regulated under the drug regulations of the FDA based on its primary mode of action as a drug. Third-party manufacturers may not be able to comply with the regulatory requirements, known as current good manufacturing practice, or cGMP, applicable to drug-device combination products, including applicable provisions of the FDA's drug cGMP regulations, device cGMP requirements embodied in the QSR or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and QSRs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and QSR requirements. Any failure to comply with cGMP or QSR requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval.

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

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

In order to produce sufficient quantities to meet the demand for any additional clinical trials and subsequent commercialization of FUROSCIX or any of our other product candidates in our pipeline or that we may develop, our third-party manufacturers will be required to increase their production and automate and otherwise optimize their manufacturing processes while maintaining the quality of the product. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are

not able to automate and otherwise optimize their manufacturing process to increase the product yield for the next generation SmartDose drug delivery system and other components of our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining quality, then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate revenues and have a material adverse impact on our business and results of operations.

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

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

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

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

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

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

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

Risks Related to 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 September 30, 2020, we had 26 full-time employees. Our focus on the development of FUROSCIX has required us to optimize cash utilization and to manage and operate our business in a lean manner. We cannot assure you that we will be able to hire and/or retain adequate staffing levels to commercialize FUROSCIX or run our operations and/or to accomplish all of the objectives that we otherwise would seek to accomplish.

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

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

Our industry has experienced a high rate of turnover of management personnel in recent years. Any of our personnel may terminate their employment at will. If we lose one or more of our executive officers or other key employees, our ability to implement our business strategy successfully could be seriously harmed. Departed personnel have sought to compete with us historically and may

continue to do so in the future. Furthermore, replacing executive officers or other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain marketing approval of and commercialize products successfully.

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

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

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

We will need to transition from a company with a development focus to a company capable of supporting commercial activities. We are in the process of building our sales force and preparing for the launch of FUROSCIX, if approved. Since FUROSCIX, if approved, will be 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 product candidates.

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

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

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

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

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

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

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

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

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

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:

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

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

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

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

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

Based upon shares outstanding as of September 30, 2020, 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 64.6% 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 an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years following our completed initial public offering. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the consolidated financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may choose to take advantage of some, but not all, of the available exemptions. We will continue to take advantage of these reduced reporting requirements for as long as we remain an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

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

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

We are subject to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, and the related rules of the SEC that generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an "emerging growth company" or, if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing of our internal controls, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to timely file accurate

quarterly and annual reports with the SEC under the Securities Exchange Act of 1934, or the Exchange Act, as amended. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences.

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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None**.**

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
10.1*#	Supply Agreement, dated August 15, 2020, by and between West Pharmaceutical Services, Inc. and the Company.
31.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

\# Portions of this exhibit (indicated by asterisks) were omitted in accordance with the rules of the Securities and Exchange Commission.

† This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, 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 Securities Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SCPHARMACEUTICALS INC.

Date: November 16, 2020

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

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (the "Agreement") dated August 15, 2020 (the "Effective Date"), is between West Pharmaceutical Services, Inc., a Pennsylvania corporation with an address at 530 Herman O. West Drive, Exton, Pennsylvania 19341 on behalf of itself and its Affiliates ("West"), and scPharmaceuticals Inc., a Delaware corporation with an address at 2400 District Avenue, Suite 310, Burlington, MA 01803 ("Customer").

Customer desires to purchase from West, and West desires to sell to Customer, the items listed on Exhibit A hereto (the "Product") on the terms and subject to the conditions set forth below.

Accordingly, the parties hereto, intending to be legally bound, agree as follows:

1. Definitions. As used herein, the following terms will have the following meanings:

   a. "Affiliate" has the meaning set forth in Section 2(f).

   b. "Agreement" has the meaning set forth in the Preamble.

   c. "Applicable Laws" means all relevant federal, state, local, and foreign laws, statutes, rules, regulations, and ordinances and industry standards and guidelines as in effect on the Effective Date or adopted thereafter and which are applicable to a party's activities hereunder, including, without limitation, all applicable cGMPs together with amendments thereto.

   d. "cGMP" means the current good manufacturing practices, including the regulations promulgated by the FDA under the U.S. Federal Food, Drug, and Cosmetic Act, 21 C.F.R. Part 820, as amended from time to time.

   e. "Claims" has the meaning set forth in Section 15(a).

   f. "Combination Product" means a product comprised of the Customer Drug Product plus the Product.

   g. "Confidential Information" has the meaning set forth in Section 22(a).

   h. "Customer" has the meaning set forth in the Preamble.

   i. "Customer Drug Product" means Customer's proprietary formulation of the drug product Furosemide.

   j. "Effective Date" has the meaning set forth in in the Preamble.

   k. "Facility" means West's manufacturing plant located at Scottsdale, AZ or any other manufacturing plant mutually agreed to by the parties to be used by West to manufacture the Product.

   l. "FDA" means the U.S. Food and Drug Administration or any successor entity thereto.

   m. "Force Majeure" has the meaning set forth in Section 12.

   n. "Indemnitee" has the meaning set forth in Section 15(a).

o. “Indemnitor” has the meaning set forth in Section 15(a).

p. “Initial Term” has the meaning set forth in Section 3.

q. “Latent Defect” means a defect that causes a Product to fail to conform to the Product Warranty, which is not discoverable upon the inspection which (a) Customer would have been expected to carry out in its ordinary course of business upon delivery of such Product or (b) Customer is required to conduct, as mutually agreed to by the parties in writing, but in each case that is discovered at a later time.

r. “Losses” has the meaning set forth in Section 15(a).

s. “"MPP” has the meaning set forth in Section 2(d).

t. “Nonconforming Product” means Product that does not conform to the Product Warranty.

u. “"Partners” has the meaning set forth in Section 22(j).

v. “Principals” has the meaning set forth in Section 16.

w. “Product” has the meaning set forth in the recitals.

x. “Production Capacity” has the meaning set forth in Section 2(d).

y. “Product Specifications” means specifications specifically agreed to by West and Customer contained or referred to in specification document number 19559012.

z. “Product Warranty” has the meaning set forth in Section 14(c).

aa. “Purchase Requirement” has the meaning set forth in Section 2(b).

bb. “Quality Agreement” has the meaning set forth in Section 2(g).

cc. “Records” has the meaning set forth in Section 17(a).

dd. “Renewal Term” has the meaning set forth in Section 3.

ee. “"Representatives” has the meaning set forth in Section 22(b).

ff. “Term” has the meaning set forth in Section 3.

gg. “U.S.” means the United States of America.

hh. “West” has the meaning set forth in the Preamble.

2. Commitment to Sell and Purchase Product.

a. Supply of Product. During the Term of this Agreement, West will manufacture the Product in accordance with the terms and conditions of this Agreement, the Quality Agreement and the Product Specifications and in compliance with Applicable Laws, and Customer will purchase from West such Product, subject to the terms and conditions of this Agreement. The geographic territory of this Agreement (including for the sake of clarity Customer’s distribution, sale, or transfer for subsequent resale of the Combination Product) is limited to the U.S. unless the parties mutually agree via an amendment to this Agreement to expand the geographic territory.

b. Requirements. West will sell to Customer, and Customer will purchase from West, one hundred percent (100%) of Customer’s U.S. requirements of the Product for use in delivering the Customer Drug Product (the “Purchase Requirement”) in accordance with the terms and subject to the conditions of this Agreement, including the Exhibits hereto. For clarity,

nothing is this Agreement will restrict Customer from manufacturing products and/or purchasing products from third parties for use with the Customer Drug Product that perform the same or substantially the same function as the Product.

c. Facility. West will manufacture the Product at its Scottsdale, AZ manufacturing plant. Customer will permit West to manufacture Product at other West manufacturing plant(s), subject to such other manufacturing plant(s)' satisfying the quality and regulatory obligations imposed herein. In the event that West unilaterally determines that it is necessary to manufacture Product at other manufacturing plant(s), West will qualify such other manufacturing plant(s) at its sole cost and expense. Customer will cooperate with West in good faith to qualify such other manufacturing plant(s).

d. Commercial Capacity. Customer acknowledges that as of the Effective Date, the maximum annual production capacity for the Product available to Customer is [***] ("Maximum Annual Production Capacity"), available on a non-dedicated basis reserved only by issuance of a purchase order for the initial six (6) months, a firm purchase order for the seventh (7th) month, and seventeen (17) months non-binding forecast (the "MPP"), (the "Production Capacity"). Additional terms and conditions for expanded commercial scale capacity are set forth Exhibit B attached hereto and incorporated herein by reference.

e. Intentionally Omitted.

f. Affiliates. Customer's Affiliates may participate in this Agreement upon written notification to West of their agreement to be bound by the terms and conditions hereof as though they were a party hereto, and the term "Customer" will be deemed to include those of its Affiliates that provide the foregoing written notification to West. Customer will be jointly and severally liable for its Affiliates hereunder. The term "Affiliate", with respect to the parties hereto, means any corporation or business entity fifty percent (50%) or more of the voting stock or voting equity interests of which are owned directly or indirectly by such party, or any corporation or business entity which directly or indirectly owns fifty percent (50%) or more of the voting stock or voting equity interests of such party.

g. Quality Agreement. The parties entered into that certain Quality Agreement dated effective as of December 19, 2019 setting out the responsibilities of the parties with respect to quality assurance of the Product manufactured and supplied by West pursuant to this Agreement (the "Quality Agreement"). The Quality Agreement is hereby incorporated by reference into this Agreement.

3. Term. This Agreement will commence on the Effective Date and, unless terminated earlier as provided herein, will continue in effect until the fifth (5th) anniversary thereof (the "Initial Term"); the Initial Term will automatically extend by successive one (1) year periods (each a "Renewal Term" and together with the Initial Term, the "Term") thereafter at West's then-current rates unless either party provides notice to the contrary to the other party not less than nine (9) months prior to the end of the then-current Term.

4. Preferred Supplier. During the Term of this Agreement Customer will designate West as Customer's "Preferred Supplier" for the type of products covered by this Agreement. As such, West will consider in good faith any requests from Customer (but will not have the obligation) to: (a) participate in Customer's development projects that involve the Product or other products; (b) quote on proposals for Customer's purchase of other products; and (c) quote on proposals for Customer's purchase of

other items sold by West that are not listed on Exhibit A. For clarity, nothing in the foregoing imposes upon Customer an obligation to enter into any discussions or agreements with West with respect to any development projects, whether or not related to the Product, or for the purchase of additional quantities of the Product or other items sold by West.

5. Forecasts and Purchase Orders.

   a. Firm orders for Product shall be placed by Customer in writing. All orders shall specify the Product and quantities ordered (which shall be in whole batch size quantities), delivery and shipping instructions, requested delivery dates, and such other information as West may reasonably request in order to allow West to fill the order.

   b. To facilitate timely delivery of Product, West and Customer shall cooperate fully in estimating and scheduling the first order of commercial quantities of Product to be placed by Customer. In the first six (6) months following the regulatory approval for the commercial sale of the Combination Product in the U.S., West and Customer will work together to reasonably mitigate any unforeseen demands during the launch period of the Combination Product; thereafter, Customer will need to abide by the six (6) month firm window. Customer shall deliver to West a Master Production Plan on or before the 15th day of each calendar month (or the Friday prior in the event the 15th falls on a weekend or holiday) during the Term that covers the following twenty-four (24) month period, includes a non-cancellable purchase order for the initial six (6) months, a firm purchase order for the seventh (7th) month, and seventeen (17) months non-binding forecast (the "MPP"). Customer may also provide an optional "upside forecast" to support West's rough cut capacity analysis in month eight (8) onward to support raw material procurement and capacity planning. [***].

   c. Each MPP and accompanying binding purchase order shall be deemed to be automatically accepted unless West notifies Customer of its rejection of the same within ten (10) business days of receipt. West shall not unreasonably reject a MPP if it is less than or equal to the prorated portion of the Maximum Annual Production Capacity and West shall not unreasonably reject a binding purchase order from Customer if the quantities of Product is less than or equal to the binding portion of the MPP and consistent with then-current lead times and minimum and maximum monthly ordering quantities. If the quantities indicated outside the binding period of the MPP are greater than the MPP, West will use commercially reasonable efforts to accommodate the supply of Product ordered by Customer. Once accepted by West, Purchase Orders are binding on both parties and may not be cancelled or modified unless mutually agreed upon by the parties or as specified in Section 11. The MPP shall be updated to reflect the acknowledged delivery dates.

   d. Failure to Supply. In the event West fails to deliver the quantities of Product specified in any binding purchase order by the delivery date set forth therein for any two (2) consecutive calendar months with a combined unit shortage greater than [***]. West will provide daily updates on progress and status of the corrective action if so required by the Customer until the required supply has been fulfilled.

   e. The parties agree to meet (in person or by telephone) on a reasonable ad hoc basis upon the request of either party to review and discuss the forecasting, ordering and shipping procedures implemented pursuant to this Agreement.

6. Raw Materials.

a. Safety Stock. West will procure and maintain for the manufacturing of the Product a safety stock of raw materials and other components required to be used by West for the manufacture of the Product and as necessary to satisfy the Master Production Plan and applicable binding purchase orders for the Product and avoid supply shortages. In addition, West will procure strategic supply for any raw materials that have a lead-time in excess of the binding period for a raw material that may be reasonably expected to be in short supply based on industry trends within the 24 month forecasted quantity. West will be responsible for the costs and expenses associated with such safety stock.

b. Allocation of Raw Materials.

i. In the event that West's supply of raw materials or other components supplied by third parties necessary for the manufacture of the Product is disrupted or adversely affected during the term of this Agreement, such that any such raw materials or components are in short supply for a period of at least thirty (30) days, then West will allocate that portion of the available quantity of such raw materials or components to Customer as Customer's consumption of such raw materials or components related to West's aggregate use of such raw material or components during the calendar quarter immediately preceding the occurrence of the event giving rise to the short supply, except to the extent in West's reasonable judgment a different allocation of raw materials or components is required to avoid serious harm or injury to patients.

ii. In the event the disruption in the supply of raw materials or components is reasonably expected to continue for an indefinite period, the parties will jointly consider their available options including the selection of an alternate supplier of the raw material or component, the identification of suitable alternate raw material or component and the acquisition of sufficient quantities of the raw material or component to enable the continued manufacture of the Product for a reasonable period.

iii. West has a formal business continuity plan detailing West's plans, procedures and designated resources for timely response to and recovery from potential information technology, civil, natural, and physical disasters that could reasonably be expected to disrupt West's performance of the manufacturing of the Product, and covering potential disruption that might arise in connection with the COVID-19 pandemic ("Business Continuity Plan"). Without limiting the foregoing, the Business Continuity Plan identifies the necessary steps that West will take to mitigate potential risks and threats to its ability to manufacture and supply products to its customers. The Business Continuity Plan contains site level procedures for maintaining and restoring critical business operations to acceptable functionality in the unlikely event of a severe disruption in normal operations. West will evaluate and update the Business Continuity Plan on a yearly basis, and upon request, West will make a summary of such Business Continuity Plans available to Customer or its designated representative (subject to the execution of a written confidentiality agreement between West and such designated representative) for review. West will consider in good faith any reasonable comments that Customer may have with respect to the Business Continuity Plans. During the Term of this Agreement, West will promptly notify Customer in writing of any potential disruption to the manufacturing and supply of the Product.

7. Invoices; Payment Terms.

   a. West will invoice Customer at the time of shipment to Customer of the Product. Customer will pay all invoices for undisputed payments within thirty (30) days from the date of invoice unless otherwise stated or agreed in writing by West. All invoice and payments under this Agreement will be in U.S. Dollars. [***] on any unpaid undisputed amounts not paid on the applicable due date. In the event Customer disputes an invoice in good faith, Customer shall (i) provide to West within the payment terms a written statement setting forth, in reasonable detail, the specific nature of the dispute, and (ii) pay the undisputed portion of such invoice within the applicable invoice terms for payment. The parties shall attempt to resolve any such invoice dispute in good faith as soon as possible.

   b. Pro rata payments will become due as partial shipments are made, including multiple shipments on a single order. If shipments are delayed by Customer for any reason, West may elect to invoice Customer for the Product prior to shipment and will store the Product either on or off-site; such storage will be at Customer's risk and expense as provided in Section 10 hereof.

   c. For Product shipped from West locations in Brazil, Israel and the United States, Product prices do not include shipping pallets, which are separately chargeable by West. Customer will select the size and type of shipping pallet to be used in the shipping of each order shipped from those locations; provided, in the absence of any specific instruction from Customer, West will select a size and type of shipping pallet it reasonably deems appropriate.

8. Delivery; Risk of Loss. West will deliver the Product within plus or minus five (+/-5) days of the date of delivery set forth in the applicable purchase order. Unless otherwise agreed in the applicable purchase order, all sales are EXW (INCOTERM 2020) point of manufacture. Title to the Product will pass to Customer upon Customer's designated common carrier taking possession of the shipment. Delivery of ten percent (10%) more or less than the quantity of the Product specified will constitute fulfillment of the purchase order, and in each case the difference will be paid for or allowed at the current price. Customer and West may agree to allow West to make delivery in installments, which will be separately invoiced at the time of shipment and paid for by Customer within thirty (30) days of invoice date, without regard to subsequent deliveries.

9. Non-conforming Products.

   a. Incoming Visual Examination. Customer will verify that the shipment upon its arrival at the specified destination is intact, that there is no obvious shortage, loss or damage, and that the shipment does not contain any Nonconforming Product apparent under reasonable visual examination of the incoming shipping cartons or pallets. Customer will notify West within ten (10) days of (i) receipt of shipment, if the shipment is not intact, has obvious shortage, loss or damage, or contains any Nonconforming Product; or (ii) within thirty (30) days of discovery of a Latent Defect, but in any event within the Product shelf-life. For orders for which risk of loss transfers at West's facility based on the applicable INCOTERMS, claims for loss or damage to Product in transit by common carrier must be made to the carrier and not to West.

   b. Product Testing. If Customer and West are unable to agree as to whether certain the Product is Nonconforming Product, the parties will cooperate to have the Product in dispute analyzed by an independent testing laboratory of recognized repute selected by Customer and approved by West, which approval will not be unreasonably withheld,

conditioned or delayed. The results of such laboratory testing will be final and binding on the parties as to whether such Product is a Nonconforming Product. If the alleged Nonconforming Product is determined to meet the Product Warranty, then Customer will bear the cost of the independent laboratory testing and pay for the Product in accordance with this Agreement. If the Product is determined not to have met the Product Warranty, then West will bear the cost of laboratory testing and Customer will be entitled to avail itself of the remedies provided in Section 9(c).

c. Remedies of Buyer. Provided a claim is made within the timeframes specified in Section 9(a), at Customer's option: [***].

d. Recalls. In the event any regulatory authority issues in the U.S., or Customer voluntarily undertakes, a recall of the Product, Customer will promptly notify West, and West will provide reasonable assistance to Customer in conducting such recall, including providing Customer with all reasonably pertinent records and information. [***].

10. Storage. West will store the Product in accordance with the applicable Product Specifications. If West is not able to ship the Product to Customer within thirty (30) days after notification has been made to Customer that they are ready for shipping due to Customer's failure to give shipping instructions or for any other reason within Customer's control, or if Customer otherwise refuses to accept delivery of the Product upon its arrival at the location specified in Customer's order, then West may store the Product in accordance with the applicable Product Specifications or Customer's written instructions in a warehouse or upon West's premises, and Customer will promptly pay all handling, transportation and storage expenses at the prevailing commercial rates following West's submission of invoices for such amounts. Risk of loss to such Product will pass to Customer upon their transfer into storage.

11. Changes to Submitted Orders. For all orders that have been accepted by West, reduction in the quantity of Products ordered, cancellation or suspension of deliveries, order increases, expedited delivery and all other changes are not allowed except with West's consent and may be subject to Customer's payment of West's fees (including, without limitation, the Idle Capacity Fee) for permitted order changes, in accordance with West's Order Cancellation Policy.

12. Force Majeure. Neither party hereto will be held liable to the other party for any loss or damage or be in breach of this Agreement for its delay or inability to perform its obligations hereunder to the extent such delay or failure results from causes beyond its reasonable control that are not reasonably foreseeable or avoidable, including without limitation embargoes, war, fires, earthquakes, floods, strikes, pandemics or government actions ("Force Majeure"). Should any Force Majeure events occur, the affected party will give prompt notice to the other party of such cause, and will take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible. If a Force Majeure event persists for more than thirty (30) calendar days, the parties shall work together for a mutually agreed upon corrective action. However, the nonaffected party may terminate this Agreement upon thirty (30) days' written notice to the other party if the adverse effects of a Force Majeure event on the other party's performance persists for more than ninety (90) calendar days. Notwithstanding the foregoing, disruptions or other adverse effects attributable in whole or in part to COVID-19 disease or the SARS-CoV-2 virus, including any subtypes or strains thereof, including without limitation (a) the failure of a party's suppliers to provide products or materials, (b) labor shortages, (c) government action, (d) reduction in customer demand or (e) any related Force Majeure events, will be deemed to be a Force Majeure event for the purpose of this Section, subject to West's obligations under Section 6(b)(iii).

13. Intentionally omitted.

14. Representations, Warranties, Remedies and Limitations of Liability.

a. Mutual Representations. Each party hereto represents and warrants that as of the Effective Date: it is, and will remain, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization; it has the authority to enter into this Agreement; the execution and delivery of this Agreement has been authorized by all requisite corporate action; this Agreement is and will remain a valid and binding obligation of the executing party, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors; the individual executing this Agreement on behalf of such party is authorized to do so; there is no action, suit or proceeding, at law or in equity, before or by any court or governmental authority, pending or, to the best of such party's knowledge, threatened against it, wherein an unfavorable decision, ruling or filing would materially adversely affect its performance of its obligations hereunder or the other transactions contemplated hereby, or which, in any way, would adversely affect the enforceability of this Agreement, or any other agreement or instrument entered into by it in connection with the transactions contemplated hereby; and, during the Term it will comply with all Applicable Laws and regulations regarding its obligations arising under this Agreement, including but not limited to compliance with the U.S. Federal Food, Drug, and Cosmetic Act .

b. West Representations and Warranties. West represents and warrants that as of the Effective Date: West holds all necessary permits, approvals, consents and licenses necessary to enable the performance of the manufacturing services at the Facility; the Facility is, and will remain during the Term of this Agreement, in compliance with Applicable Laws; and, the Product and the use of West's intellectual property to manufacture the Product under this Agreement will not infringe the intellectual property rights of any third party and West will promptly notify Customer in writing should it become aware of any claims asserting such infringement; provided, however, that the parties acknowledge and agree that certain registration activities will need to occur following the regulatory approval for the commercial sale of the Combination Product in the U.S. (i.e., the addition of the approved Combination Product to West's licenses).

c. Product Warranty. West represents and warrants that all Product delivered to Customer will: (ii) on the date of shipment to Customer meet the Product Specifications; (ii) be manufactured and delivered in accordance with the Quality Agreement and cGMPs; and (iii) not be adulterated or misbranded within the meaning of the U.S. Federal Food, Drug, and Cosmetic Act, as amended, and any regulations promulgated thereunder (the "Product Warranty"). In addition, West represents and warrants that all Product delivered to Customer will, on the date of shipment to Customer, be free and clear of any lien or encumbrance levied as a result of West's actions or inactions.

d. Disclaimer of Representations and Warranties. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES, AND EACH PARTY EXPRESSLY DISCLAIMS, ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE OR NON-INFRINGEMENT. THE REPRESENTATIONS AND WARRANTIES IN THIS AGREEMENT RUN SOLELY TO THE PARTIES HERETO.

e. Customer Responsibility. Customer acknowledges and agrees that all Products are sold only on the basis that it is the sole responsibility and duty of Customer to assure that the Products are fit for the uses and purposes for which Customer intends to use them, and are compatible with Customer's particular product and its processing and packaging methods. Except to the extent of any obligations expressly imposed on West pursuant to this Agreement, Customer assumes all risks whatsoever as to the result of the use of the Products, whether used singly or in combination with other goods or substances.

f. Limitations of Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, CONSEQUENTIAL OR INDIRECT DAMAGES, LOST PROFITS OR REVENUES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (INCLUDING, WITHOUT LIMITATION, NEGLIGENCE OR DELAYED PERFORMANCE OR DELIVERY). THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. NOTWITHSTANDING THE FOREGOING, THIS SECTION 14(F) WILL NOT APPLY TO ANY CLAIMS OR DAMAGES RESULTING FROM A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OR A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 15 OR ITS DUTY OF CONFIDENTIALITY AND NON-USE IMPOSED UNDER SECTION 22 OR CUSTOMER'S PAYMENT OBLIGATIONS HEREUNDER. [***].

15. Indemnification.

a. [***].

b. Each Indemnitee agrees to give the Indemnitor prompt written notice of any Claim; provided, however, that the failure to provide such prompt notice will not eliminate the Indemnitor's obligation to indemnify the Indemnitee under this Section 15 except (and to the extent) the Indemnitor has been prejudiced by such failure. The Indemnitor will have sole control of the defense and settlement of such claim; provided; however, that the Indemnitor will not enter into a settlement or otherwise compromises such claim in any manner which requires the Indemnitee to admit fault without the Indemnitee's prior written consent, such consent not to be unreasonably withheld, delayed or conditioned. The Indemnitee will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist therein. The Indemnitee will provide the Indemnitor with such information and assistance as the Indemnitor may reasonably request, at the expense of the Indemnitor. The Indemnitor's obligation under this Section is conditional upon the Indemnitee's agreement that, if the use of the Confidential Information becomes, or in the Indemnitor's opinion is likely to become, the subject of an infringement claim, then the Indemnitee will permit the Indemnitor, at the Indemnitor's expense, either to procure the right for the Indemnitee to continue to use such items or to replace or modify them so that they become non-infringing. This is the sole indemnification arising under this Agreement, and Customer's sole remedy and West's sole liability relating to infringement of third party intellectual property rights resulting from the Product or the use of West's intellectual property to manufacture the Product under this Agreement.

16. Certification Regarding Debarment. Each party certifies, to the best of its knowledge and belief, that it and its Principals, Affiliates, subcontractors, employees or any other person performing obligations under this Agreement: (a) have not been debarred and are not presently debarred, suspended, proposed for debarment pursuant to Section 306 of the U.S. Federal Food, Drug, and

Cosmetic Act, 21 U.S.C. § 335a, or declared ineligible for the award of contracts by any federal agency; (b) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)); (c) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (d) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. "Principals", for the purposes of this certification, means officers, directors, owners, partners, and persons having primary management or supervisory responsibilities within a business entity (e.g., general manager, plant manager, head of a subsidiary, division, or business segment, and similar positions). Each party will provide immediate written notice to the other party if, at any time prior to the execution of or during the term of this Agreement, it learns that such party, its Principals, Affiliates, or subcontractors, employees or any person used to perform obligations under this Agreement, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending. The certification in this provision is a material representation of fact upon which reliance was placed when entering into this Agreement. Notwithstanding any provision to the contrary in this Agreement, if it is later determined that either party knowingly rendered an erroneous certification or such certification becomes erroneous by reason of changed circumstances, the other party may terminate this Agreement immediately upon written notice to such party.

17. Records; Audit Rights; Regulatory Inspections.

    a. Records. For eight (8) years from Product manufacture, or for such longer period as may be required by Applicable Laws, West will maintain true, complete and accurate records, reports and all other information relating the manufacture of the Product, including all information required to be maintained by Applicable Laws (the "Records").

    b. Customer Audits. No more than once per calendar year (except in the case of "for cause" audits), upon reasonable advance notice and during normal working hours, Customer or its designee may audit (i) the Facility and West's quality systems and manufacturing operations at the Facility to the extent related to the manufacture of the Product and (ii) the Records, in each case to verify that West is manufacturing the Product in accordance with this Agreement. The parties will mutually agree on the date, time, scope, duration, and number of auditors in advance of any audit. "For cause" audits to investigate deviations will be scheduled on an expedited basis. Customer will not be entitled to audit financial records (except to the extent needed to verify shipping quantities and invoices) or personnel records, nor any portion of the Facility that is solely dedicated to either the manufacture of Products or the performance of services for third parties. Confidential Information observed during an audit is subject to the confidentiality obligations in Section 22; provided, however, that West reserves the right to require the execution of a confidentiality and nondisclosure agreement prior to the audit activity that specifically relates to such audit. Each party is liable for its own costs and expenses related to the conduct of an audit pursuant to this section 17(b).

18. Price and Price Adjustments. [***].

    a. [***].

    b. [***].

19. Cost Savings. [***].

20. Intentionally Omitted.

21. Intellectual Property.

a. All specifications, Product Specifications, drawings, design, data, information, ideas, methods, patterns, and/or inventions made, conceived, developed, or acquired by West in connection with procuring and/or executing Customer's purchase order will vest in and inure to West's sole benefit notwithstanding any charges therefor which may have been or may be imposed by West.

b. This Agreement does not contemplate or include a license to or transfer of ownership of any of either party's intellectual property to the other party.

c. Customer agrees to include the following notice regarding trademarks on any printed materials and webpages created after the Effective Date of this Agreement and as soon as reasonably practicable thereafter which shows the exterior of the Product: "The exterior configuration of this drug delivery device is a trademark of West Pharma. Services IL, Ltd., a subsidiary of West Pharmaceutical Services, Inc., and is used with permission."

22. Confidentiality Obligations.

a. As used in this Agreement, the term "Confidential Information" means any and all information (including but not limited to trade secrets, customer business associations, transactions, financial arrangements and technical or commercial affairs of the disclosing party, specifications, know-how, materials, data, reports and other communications relating to the supply of Products) which are disclosed or provided by one party to the other in connection with this Agreement, whether in oral, written, or in any electronic or other tangible form and whether furnished before, on or after the Effective Date. Confidential Information includes, without limitation, all portions of analyses, studies and other documents containing any of the foregoing, and the existence of this Agreement and its terms.

b. Each party will keep all of the other party's Confidential Information confidential and will not use such Confidential Information in any way except in connection with the performance of its obligations or exercise of its rights under this Agreement. Without the prior written consent of the other party, neither party will analyze, have analyzed, or otherwise attempt to determine the composition or structure of any samples, nor disclose any of the other party's Confidential Information to any third party; provided, however, that each party may disclose the other party's Confidential Information to its Affiliates and to its and its Affiliates' directors, officers, employees, agents, subcontractors, consultants, auditors, lenders or other representatives ("Representatives") who have a need-to-know and are bound by written obligations of confidentiality and non-use at least as restrictive as those set forth in this Agreement. Each party will be liable to the other party for breach by its Representatives of the obligations of confidentiality and non-use of this Section 22.

c. All written disclosures of information considered to be Confidential Information by the disclosing party will bear the notation "Confidential". All non-written disclosures of Confidential Information must be confirmed by the disclosing party as being confidential at the time of disclosure or in writing within thirty (30) days following the non-written disclosure. The written confirmation will identify the particular Confidential Information, state that it is considered confidential. Notwithstanding the requirements of this Section

22(c), the failure to label or identify any information as Confidential Information will not change the confidential status of such information if a reasonable person would know that such information was confidential or proprietary to the disclosing party.

d. Each party will ensure that the other party's Confidential Information is not used or disclosed in any manner except as permitted by this Agreement.

e. All Confidential Information will remain the property of the disclosing party, except for analyses, studies, or other documents prepared for the recipient which contain, reflect or are based upon, in whole or in part, any Confidential Information furnished by the disclosing party. Upon the written request of the disclosing party: (i) all tangible Confidential Information (including all copies thereof), except analyses, studies, and other documents prepared for the benefit of the recipient, will be promptly returned to the disclosing party or destroyed by the recipient; (ii) to the extent any analyses, studies, and other documents prepared for the benefit of the recipient (including all copies thereof) contain, reflect or are based upon Confidential Information, such analyses, studies, and other documents will be destroyed.

f. The obligations of confidentiality and non-use set forth in this Section will not apply to any portion of the Confidential Information which:

    i. legitimately and through no other breach of any confidentiality obligation is or becomes available to the general public other than through the act or default of the recipient or its agents;

    ii. is obtained by the recipient from a third party who is rightfully in possession of the Confidential Information and does not violate any obligation of confidentiality or non-use by disclosing such Confidential Information on a non-confidential basis;

    iii. is in the recipient's possession and is not subject to any confidentiality obligation prior to disclosure by the disclosing party; or

    iv. is independently developed by the recipient without use of or access to the Confidential Information.

g. If the recipient of Confidential Information is required by any governmental authority, court order or a court of competent jurisdiction or by Applicable Laws, including for any legal process (such as deposition, interrogatories, requests for information, documents or admissions, subpoenas, or the like), to disclose any Confidential Information, the recipient may disclose the disclosing party's Confidential Information, provided it notifies the disclosing party in advance of any such disclosure as promptly as practicable. The disclosing party may seek an appropriate protective order and/or waive the recipient's obligation to comply with this Agreement. The recipient will fully cooperate with all efforts to obtain any such order and take all reasonable and lawful actions to avoid or minimize the degree of such disclosure and to have the disclosed Confidential Information treated as confidential. Any such disclosure, however, will not relieve the recipient of its obligations contained herein.

h. Specific aspects or details of Confidential Information will not be considered available to the general public, in the public domain, or in the prior possession of the recipient merely because it is embraced by more general information available to the general public or in the prior possession of the recipient.

i. The parties recognize and acknowledge the competitive value and confidential nature of the other's Confidential Information and the irreparable damage that could result if Confidential Information is used or disclosed in violation of this Agreement. Either party may unilaterally institute appropriate proceedings to enforce its rights hereunder. The parties acknowledge and agree that money damages would be an insufficient remedy for any violation of the confidentiality obligations under this Section 22 and, accordingly, either party will be entitled, in addition to any monetary damages, to seek specific performance and injunctive relief as remedies. These remedies will not be exclusive but will be in addition to all other remedies available at law or in equity.

j. Notwithstanding anything in this Agreement, Customer may disclose the existence and terms of this Agreement to its actual or prospective investors, lenders, acquirers, collaborators, licensors, (sub) licensees or strategic partners, and their respective accountants, financial advisors and other professional representatives, ("Partners") in each case, who have a need to know such Confidential Information and are bound by customary obligations of confidentiality; provided that, if any such Partner is a competitor or customer of West, Customer agrees to limit its disclosure to a redacted version of this Agreement that does not contain any financial terms, and Customer shall not disclose the unredacted version of this Agreement to such Partner that is a competitor or customer of West without West's prior written consent. West will have the opportunity to review the redacted version of this Agreement in advance of any such disclosure, and Customer shall consider in good faith any additional redactions reasonably suggested by West. Customer will be liable to West for breach by such Partners of the obligations of confidentiality and non-use of this Section 22.

k. Except to the extent required by Applicable Laws and as otherwise provided in this Section 22, neither party will make any public statements or releases concerning this Agreement or the transactions contemplated by this Agreement without obtaining the prior written consent of the other party, which consent will not be unreasonably withheld or delayed. For any public statements or releases that include the mention of a party's trademark, both parties agree to include a statement attributing ownership of that trademark to the appropriate party. In the event that one Party reasonably concludes that disclosure of this Agreement is required by Applicable Laws (including the disclosure requirements of the United States Securities and Exchange Commission) and the other Party would prefer not to make such disclosure, the Party seeking disclosure shall (i) provide reasonable advance notice to the other Party of the intended disclosure and the content of such disclosure; and (ii) prepare a redacted version of this Agreement and permit the other Party reasonable advance notice and the opportunity to comment on any such redacted Agreement; and (iii) file the redacted Agreement in accordance with the rules and regulations of the United States Securities and Exchange Commission. Prior to the filing, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith (A) consider incorporating such comments and (B) use reasonable efforts to incorporate such comments or limit disclosure to the extent reasonably requested by the other Party. Customer shall, whether or not requested by West, redact for any financial terms and such other additional terms, in each case in accordance with the disclosure requirements of the United States Securities and Exchange Commission, and will disclose only the minimum amount of West information that is required by Applicable Laws to be disclosed.

l. The obligations of this Section 22 will survive for a period of ten (10) years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Section 22 will continue for so long as such information remains a trade secret under Applicable Laws.

23. Quarterly Business Review Meetings. Customer and West will participate in business review meetings during the Term on a periodic (but no less than quarterly) basis at a mutually agreed time and location. The agenda for these meetings will be jointly determined, but are expected to address the current and anticipated business drivers affecting each party including, without limitation, new products and new business opportunities.

24. Default and Termination.

a. Either party has the right to terminate this Agreement upon material breach by the other party upon thirty (30) days' notice (fifteen (15) days with respect to payment obligations) if such breach is not cured within such 30-day period (fifteen (15) days with respect to payment obligations). Such notice will specify in reasonable detail the material breach and the basis upon which this Agreement is to be terminated. If by its nature such breach cannot be cured within such thirty (30) day period (fifteen (15) days with respect to payment obligations) and the breaching party is proceeding diligently to effect a cure of such breach, then this Agreement may not be terminated for an additional thirty (30) days (fifteen (15) days with respect to payment obligations) or until such time as the breaching party ceases to effect a cure, whichever is shorter. In addition to the foregoing, West shall have the right to delay shipment of product immediately upon such failure to pay if the Customer does not pay all delinquent amounts within five (5) business days of written notice ("Warning Period").

b. This Agreement may be terminated by either party on immediate written notice in the event that the other party becomes insolvent, bankrupt, makes an assignment for the benefit of creditors, or otherwise becomes subject to a plan of reorganization.

Prior to commercial launch, this Agreement may be terminated by Customer upon written notice to West if (i) Customer receives from FDA notice of FDA's refusal to approve Customer's application for approval to market the Customer Drug- Device Combination Product or (ii) a complete response letter indicating that Customer's application for approval to market the Customer Drug-Device Combination Product cannot be approved without one or more additional clinical trials being performed, in either case within ninety (90) days of receipt of FDA communication.

c. Termination or expiration of this Agreement will not affect the rights and obligations of the parties that accrued prior to the effective date of such termination or expiration. Sections 1, 7, 9, 10, 12, 14, 15, 16, 17(a), 21, 22, 24 and 25 will survive any termination or expiration of this Agreement.

25. Miscellaneous.

a. Limitation of End Usage. Notwithstanding any other provision of this Agreement, Customer acknowledges and agrees that Products will be used for packaging pharmaceutical products and not any other end usage without the prior written consent of West, which West may withhold in its sole and absolute discretion. Customer will not re-sell or further distribute Products except as they are incorporated into Customer's products as contemplated herein.

b. Conflicting Documents. Terms or conditions contained in any purchase orders, invoices, sales receipts, shipping documents, forms, billing documents or other similar documents issued by either party hereto to the other shall be without force or effect. Notwithstanding anything in the foregoing, in the event of any conflict between this Agreement and the Quality Agreement, the terms and conditions of (i) the Quality Agreement will govern with respect to all matters pertaining to quality control/quality assurance and regulatory compliance and (ii) this Agreement will govern in all other respects.

c. Assignment. Neither this Agreement nor any of the rights hereunder may be assigned by either party hereto except with the prior written consent of the other party, and any purported assignment to the contrary will be void; provided, however, that either party may assign this Agreement to (i) an Affiliate or (ii) a successor-in-interest in the event of a merger, consolidation or change of control or (iii) in connection with the transfer or sale of all, or substantially all, of the assets of such party to which this Agreement relates, but only if the successor in interest agrees in writing, in a form reasonably satisfactory to the other party, to be bound by the terms of this Agreement as if named as a party hereto. No assignment will relieve the assignor of its obligations under this Agreement. Any attempted assignment in violation of this Section 25(c) will be null and void.

d. Notices. All notices, requests, consents, and other communications required or permitted under this Agreement will be in writing and will be hand-delivered, mailed by postage prepaid registered or certified mail, return receipt requested, or sent by a guaranteed overnight delivery service, and addressed to:

If to Customer:

scPharmaceuticals Inc.
2400 District Avenue, Suite 310
Burlington, MA 01803
Attention: John Tucker

If to West:

West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, Pennsylvania 19341
Attention: Senior Vice President of Commercial Products and Emerging Markets

with a copy to:

West Pharmaceutical Services, Inc.
530 Herman O. West Drive
Exton, Pennsylvania 19341
Attention: General Counsel

or to such other place and with such copies as either party may designate by notice to the other party in the manner prescribed above. All notices will be deemed delivered upon receipt.

e. Taxes. Each party will be responsible for all taxes imposed on it by any Applicable Laws. For the sake of clarity and without limiting the generality of the foregoing, all value added,

occupational, sales, excise, use, gross income (other than West's income tax) or other taxes associated with the sale of the Products will be paid by Customer, and all federal and state income taxes and unemployment and other employee-related taxes imposed upon West will be paid by West. Responsibility for import and export duties will be borne by West or Customer based upon the INCOTERM (2010) applicable to the associated shipment. In the event West is required to pay any tax, fee, or charge that the Customer is responsible for, Customer will reimburse West for such payment, or in lieu of such payment, Customer will provide West prior to the time the order is submitted an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.

f. Applicable Law. This Agreement will be construed and interpreted in accordance with the laws of the State of Delaware, regardless of the laws governing the principles of conflicts of laws applicable thereto. The parties agree that the provisions of the United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement, and are expressly excluded.

g. Jurisdiction. The parties hereby unconditionally and irrevocably submit to (and waive any objection on the grounds of inconvenient forum or otherwise) the jurisdiction of the courts of the State of Delaware or the United States District Court for the District of Delaware, which courts will have exclusive jurisdiction to adjudicate and determine any suit, action or proceeding regarding or relating to this Agreement. A judgment, order or decision of those courts in respect of any such claim or dispute will be conclusive and may be recognized and enforced by any courts of any state, country or other jurisdiction.

h. Severability. If any term or provision of this Agreement will for any reason be held invalid, illegal or unenforceable in any respect by a court or other body of competent jurisdiction, such invalidity, illegality or unenforceability will not affect any other term or provision hereof, and this Agreement will continue in full force and effect and will be interpreted and construed as if such term or provision, to the extent the same will have been held to be invalid, illegal or unenforceable, had never been contained herein. If any provision of this Agreement is held to be excessively broad, it will be reformed and construed by limiting and reducing it so as to be enforceable to the maximum extent permitted by law. The parties will use their commercially reasonable efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s), which, insofar as practical, implement the intent of the parties.

i. Waiver. No waiver hereunder will be effective unless signed by the party granting the waiver. Any delay or failure by either party to enforce any rights under this Agreement will not be construed as a waiver of such rights nor will a waiver by a party in one or more instances be construed as constituting a continuing waiver or as a waiver in any other instances.

j. Independent Contractor Status. The relationship of West and Customer established by this Agreement is that of independent contractors and neither party will incur any debts or make any commitments for the other party except to the extent expressly provided in this Agreement. Nothing contained in this Agreement is intended to create or will be construed as creating between West or Customer the relationship of co-partners, principal/agent, employer/employee or joint venturers with the other party or as a participant in a joint or common undertaking with the other party. Neither party will have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

k. No Third Party Beneficiaries. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons other than each party's Indemnitees pursuant to the indemnification provisions of Section 15(a).

l. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be an original but together will constitute a single Agreement. Any photocopy, facsimile or electronic reproduction of the executed Agreement will constitute an original.

m. Headings; Construction. The paragraph headings herein are for convenience only and will not affect the meaning or interpretation of this Agreement. Both parties have participated equally in the formation of this Agreement and the language of this Agreement will not be presumptively construed against either party. The words "include," "includes" and "including" when used in this Agreement are deemed to be followed by the phrase "but not limited to". The words "shall," "will" and "agrees" are imperative, and "may" is permissive.

n. Entire Agreement. This Agreement, together with the Exhibits attached hereto, the Quality Agreement and each purchase order issued under this Agreement, which are incorporated herein by reference, constitute the entire agreement between the parties concerning the subject matter contained in this Agreement and supersedes all written or oral prior agreements or understandings with respect thereto. No course of dealing, usage of trade or course of performance will be relevant to explain or supplement any of these terms and conditions. No variation or modification of any of the terms or exhibits of this Agreement or any waiver of the terms of provisions hereof will be valid unless in writing and signed by an authorized representative of each party.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized officers to execute this Agreement as of the Effective Date.

SCPHARMACEUTICALS INC.	**WEST PHARMACEUTICAL SERVICES, INC.**
By: /s/ John H. Tucker	By: /s/ Eric Green
Name: John H. Tucker	Name: Eric Green
Title: Chief Executive Officer	Title: Chief Executive Officer

EXHIBIT A
PRICING EXHIBIT

1. Product: On-body drug delivery system based on West SmartDose technology, cartridge and piston.

Part Number	Description
19559012	SMARTDOSE GEN II DEVICE
19558583	DS PISTON 10ML FR2 D21-7HW RUV 190
19550709	CARTRIDGE TUB ASSEMBLY 10ML 30 HOLE RU

2. [***].

[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

[***].

[***].

EXHIBIT B
COMMERCIAL CAPACITY [***]

1. Commercial Capacity.

   a. Capital Investment. Upon the parties' mutual written agreement, recognizing that any capacity expansion will require a lead time of approximately [***], if Customer's demand for the Product exceeds the Production Capacity, then West shall use commercially reasonable efforts to increase its commercial production capacity for the Product at a manufacturing plant selected in West's reasonable discretion to meet Customer's requirements for the Product. In exchange for West agreeing to expand capacity and the preferential pricing offered in this Agreement, Customer agrees to fund fifty percent (50%) of West's investment (which the total investment amount by the parties is estimated to be [***] as of the Effective Date) in additional equipment (the "New Production Line") to support the capacity increase, provided any such amount in excess of the aforementioned estimate has been agreed to in writing by Customer. The New Production Line shall be owned in its entirety by West, regardless of any amounts paid by Customer with respect thereto. West shall qualify such new manufacturing plant at its sole cost and expense and such new manufacturing plant shall be deemed a "Facility", subject to the terms and conditions of this Agreement, and the manufacture of any Product for Customer at such new manufacturing plant shall be subject to the terms and conditions of this Agreement.

   b. Unutilized Asset Fees. Beginning with the validation of the New Production Line, if the 6 month firm orders do not average at least [***] per month for the New Production Line, Customer shall reimburse West for expenses associated with maintaining the New Production Line (the "Unutilized Asset Fees"); provided that, West shall use commercially reasonable efforts to sell any unutilized production capacity for the New Product Line to third-party customers. The Unutilized Asset Fees consist of recurring costs and can be calculated at [***]/month for the New Production Line or [***]/month including labor expenses. West will have the option for production to remain in Scottsdale and charge the Customer [***]/month of Unutilized Asset Fees until orders of [***] for the New Production Line per month or greater are placed by the Customer. If the New Production Line has been staffed with direct labor, the Unutilized Asset Fee will be [***]/month. The Unutilized Asset Fees in any month would be reduced to the extent that the associated costs are recovered through sales to third-party customers from the New Production Line. To the extent it applies, the Unutilized Asset Fee will be charged in lieu of the Idle Capacity Fee described in (c) below.

   c. Idle Capacity Fees. Once production has commenced and orders fulfilled from the New Production Line, the June MPP and firm purchase orders provided by Customer shall create the annual volume baseline for the next calendar year. In the event that Customer does not take delivery [***], within established monthly min and max ordering quantities, West can charge the Customer an idle capacity fee equaling [***] (the "Idle Capacity Fee") times the difference between [***] (full lot quantities) of the annual volume baseline and the actual quantity delivered. The Idle Capacity Fee will be assessed and paid in the first quarter of each year following an event that triggers the Idle Capacity Fee.

d. In no event will the Unused Asset Fees exceed [***]. The Unused Asset Fee obligation will extend twenty-four (24) months beyond the validation of the New Production Line.

e. The above quantities and fees are calculated based on the assumption of the Customer committing to a capital investment of [***] into a New Production Line capable of producing [***] per year. West and the Customer may jointly agree to alter the investment amount and target capacity. As such, the above fees and quantities will be adjusted and negotiated in good faith based upon the premise of the original agreement considering the new volume and investment assumptions. As part of the agreement for the New Production Line, West and the Customer will jointly agree on initial staffing levels and target production volumes as it affects item 1(b).

Exhibit 31.1

Certification

I, John H. Tucker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2020 of SCPHARMACEUTICALS INC.;

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

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

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

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

b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: November 16, 2020

/s/ John H. Tucker
John H. Tucker
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of scPharmaceuticals Inc. (the "Company") for the period ended September 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John H. Tucker, President and Chief Executive Officer (Principal Executive Officer and Principal Financial Officer) hereby certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

1) the Report which this statement accompanies fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 16, 2020

/s/ John H. Tucker
John H. Tucker
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)