

**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 June 30, 2022

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-38293

**SCPHARMACEUTICALS INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

2400 District Avenue, Suite 310  
Burlington, Massachusetts  
(Address of principal executive office)

46-5184075  
(I.R.S. Employer  
Identification No.)

01803  
(Zip Code)

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

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

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

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 August 8, 2022, the Registrant had 27,402,121 common shares, \$0.0001 par value per share, outstanding.

## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Quarterly Report") 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:

- the review and potential approval of the FUROSCIX<sup>®</sup> new drug application, or NDA, with West's proprietary on-body infusor on our current projected timelines by the U.S. Food and Drug Administration, or FDA, including any delays in 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 the potential label thereof, launch preparation, ability to interact with physicians, patient access to FUROSCIX, manufacturing and supply chain matters, including any delays related to COVID-19 in our future planned Phase 4 studies of FUROSCIX incorporating West's proprietary on-body infusor to support the pricing and access to our product candidates;
- the pricing, reimbursement or pharmacoeconomic benefit 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 supplies, components and drug product for commercialization of FUROSCIX or any other of our product candidates, including any delays related to COVID-19;
- our ability to maintain and establish collaborations;
- our ability to fund or obtain funding for our continuing operations, including the commercialization of FUROSCIX, if approved, and the development of our product candidates;
- our future 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, 2021.

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, 2021, which was filed with the Securities and Exchange Commission on March 22, 2022, 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.

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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, 2021	June 30, 2022
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 74,268	\$ 41,178
Restricted cash	182	—
Short-term investments	1,010	14,673
Prepaid expenses	2,791	1,673
Other current assets	24	331
Total current assets	78,275	57,855
Restricted cash	—	182
Property and equipment, net	69	57
Right-of-use lease assets - operating, net	410	785
Deposits and other assets	283	283
Total assets	<u>\$ 79,037</u>	<u>\$ 59,162</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 544	\$ 982
Accrued expenses	3,995	4,126
Term loan, short-term	9,805	9,851
Lease obligation - operating, short-term	476	553
Other current liabilities	26	28
Total current liabilities	14,846	15,540
Term loan, long-term	7,354	2,463
Lease obligation - operating, long-term	—	271
Other liabilities	367	431
Total liabilities	22,567	18,705
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 June 30, 2022; 27,366,707 and 27,395,146 shares issued and outstanding as of December 31, 2021 and June 30, 2022, respectively	3	3
Additional paid-in capital	246,166	247,587
Accumulated deficit	(189,698)	(207,126)
Accumulated other comprehensive loss	(1)	(7)
Total stockholders' equity	56,470	40,457
Total liabilities and stockholders' equity	<u>\$ 79,037</u>	<u>\$ 59,162</u>

*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 June 30,		Six Months Ended June 30,	
	2021	2022	2021	2022
Operating expenses:				
Research and development	\$ 3,807	\$ 5,142	\$ 7,816	\$ 9,489
General and administrative	2,649	4,279	5,381	7,172
Total operating expenses	6,456	9,421	13,197	16,661
Loss from operations	(6,456)	(9,421)	(13,197)	(16,661)
Other income	33	64	288	78
Interest income	12	107	32	120
Interest expense	(651)	(447)	(1,287)	(965)
Net loss	\$ (7,062)	\$ (9,697)	\$ (14,164)	\$ (17,428)
Net loss per share — basic and diluted	\$ (0.26)	\$ (0.35)	\$ (0.52)	\$ (0.64)
Weighted average common shares outstanding — basic and diluted	27,355,454	27,378,507	27,346,141	27,373,459
Other comprehensive loss:				
Unrealized gain (loss) on short-term investments	\$ 1	\$ (3)	\$ (1)	\$ (6)
Comprehensive loss	\$ (7,061)	\$ (9,700)	\$ (14,165)	\$ (17,434)

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 CAPITAL	ACCUMULATED DEFICIT	OTHER COMPREHENSIVE INCOME	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
<b>At December 31, 2021</b>	27,366,707	\$ 3	\$ 246,166	\$ (189,698)	\$ (1)	\$ 56,470
Net loss	—	—	—	(7,731)	—	(7,731)
Issuance of common stock upon exercise	—	—	—	—	—	—
of stock options	4,781	—	21	—	—	21
Stock-based compensation	—	—	636	—	—	636
Unrealized loss on short-term investments	—	—	—	—	(3)	(3)
<b>At March 31, 2022</b>	27,371,488	3	246,823	(197,429)	(4)	49,393
Net loss	—	—	—	(9,697)	—	(9,697)
Issuance of common stock through employee stock purchase plan	23,658	—	84	—	—	84
Stock-based compensation	—	—	680	—	—	680
Unrealized loss on short-term investments	—	—	—	—	(3)	(3)
<b>At June 30, 2022</b>	27,395,146	\$ 3	\$ 247,587	\$ (207,126)	\$ (7)	\$ 40,457
<b>At December 31, 2020</b>	27,325,959	\$ 3	\$ 243,830	\$ (161,664)	\$ 1	\$ 82,170
Net loss	—	—	—	(7,102)	—	(7,102)
Issuance of common stock upon exercise	—	—	—	—	—	—
of stock options	2,500	—	9	—	—	9
Vesting of restricted stock	26,994	—	(81)	—	—	(81)
Stock-based compensation	—	—	521	—	—	521
Unrealized loss on short-term investments	—	—	—	—	(2)	(2)
<b>At March 31, 2021</b>	27,355,453	3	244,279	(168,766)	(1)	75,515
Net loss	—	—	—	(7,062)	—	(7,062)
Issuance of common stock upon exercise	—	—	—	—	—	—
of stock options	1	—	—	—	—	—
Stock-based compensation	—	—	589	—	—	589
Unrealized gain on short-term investments	—	—	—	—	1	1
<b>At June 30, 2021</b>	27,355,454	\$ 3	\$ 244,868	\$ (175,828)	\$ —	\$ 69,043

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

SCPHERMACEUTICALS INC.

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

	Six Months Ended June 30,	
	2021	2022
<b>Cash flows from operating activities</b>		
Net loss	\$ (14,164)	\$ (17,428)
Adjustments to reconcile net loss to cash used in operating activities		
Depreciation expense	16	18
Amortization expense - right-of-use leased assets - operating	199	212
Accretion of discount on investments	115	(24)
Stock-based compensation	1,110	1,316
Non-cash interest expense	263	218
Changes in operating assets and liabilities		
Prepaid expenses and other assets	143	809
Accounts payable, accrued expenses and other liabilities	(2,568)	335
Net cash used in operating activities	<u>(14,886)</u>	<u>(14,544)</u>
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	—	(6)
Maturities of short-term investments	26,100	7,000
Purchases of short-term investments	(7,992)	(20,645)
Net cash provided by (used in) investing activities	<u>18,108</u>	<u>(13,651)</u>
<b>Cash flows from financing activities</b>		
Principal payments on term loan	—	(5,000)
Proceeds from employee stock purchase plan	—	84
Proceeds from the exercise of vested stock options	9	21
Settlements of restricted stock units for tax withholding obligations	(81)	—
Net cash used in financing activities	<u>(72)</u>	<u>(4,895)</u>
<b>Net increase (decrease) in cash, cash equivalents and restricted cash</b>	3,150	(33,090)
Cash, cash equivalents and restricted cash at beginning of period	72,001	74,450
Cash, cash equivalents and restricted cash at end of period	<u>\$ 75,151</u>	<u>\$ 41,360</u>
<b>Supplemental cash flow information</b>		
Interest paid	\$ 1,114	\$ 794
Taxes paid	\$ 125	\$ 114

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



## Notes to 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, 2021 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 22, 2022. The Company has determined that it operates in one segment.

The accompanying condensed consolidated balance sheet as of June 30, 2022, the condensed consolidated statements of operations and comprehensive loss and stockholders' equity for the three and six months ended June 30, 2021 and 2022 and condensed consolidated statements of cash flows for the six months ended June 30, 2021 and 2022 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 six months ended June 30, 2022 are not necessarily indicative of the results expected for the full year ending December 31, 2022.

**Liquidity**

As of June 30, 2022, the Company had an accumulated deficit of approximately \$207.1 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 June 30, 2022, the Company had cash, cash equivalents, restricted cash, and short-term investments of \$56.0 million. The Company's existing cash, cash equivalents, restricted cash and short-term investments 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. Additionally, the Company expects to have access to funds pursuant to an at-the-market offering program with Cowen and Company, LLC (Note 9), or could otherwise seek additional funding through a combination of public or private equity offerings or debt financing if it believes additional resources are needed. Additional financing may not be available on a timely basis on terms acceptable to the Company, or at all.

**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 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 June 30, 2022, the Company classified \$182,000 as restricted cash related to a letter of credit issued as a security deposit in connection with the Company's lease of its corporate office facilities (Note 11). Cash, cash equivalents and restricted cash consists of the following (in thousands):

	December 31, 2021	June 30, 2022
Cash and cash equivalents	\$ 74,268	\$ 41,178
Restricted cash	182	182
Cash, cash equivalents and restricted cash	\$ 74,450	\$ 41,360

### **Concentration of Credit Risk**

Financial instruments that subject the Company to credit risk primarily consist of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. The Company's short-term investments consist of United States Treasury 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 June 30, 2022, the Company had no such accruals.

As part of the Tax Cuts and Jobs Act of 2017 (TCJA), beginning with the Company’s fiscal year ending December 31, 2022, the Company is required to capitalize research and development expenses, as defined under section 174 of the Internal Revenue Code of 1986, as amended. For expenses that are incurred for research and development in the United States, the amounts will be amortized over 5 years, and expenses that are incurred for research and experimentation outside the United States will be amortized over 15 years. The Company already capitalizes its research and development expenses for income tax purposes as it is a start-up company, so there is no material impact forecasted for this change in legislation in 2022.

### 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 June 30,		Six Months Ended June 30,	
	2021	2022	2021	2022
Net loss	\$ (7,062)	\$ (9,697)	\$ (14,164)	\$ (17,428)
Weighted-average shares used in computing net loss per share	27,355,454	27,378,507	27,346,141	27,373,459
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.35)	\$ (0.52)	\$ (0.64)

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 June 30,		Six Months Ended June 30,	
	2021	2022	2021	2022
Stock options to purchase common stock	2,677,368	3,771,435	2,677,368	3,771,435
Unvested restricted stock units	42,250	42,250	42,250	42,250
Total	2,719,618	3,813,685	2,719,618	3,813,685

### 4. Investments

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

A summary of the Company’s available-for-sale classified investments as of December 31, 2021 and June 30, 2022 consisted of the following (in thousands):

	At December 31, 2021			
	Cost Basis	Accumulated Unrealized Gains	Accumulated Unrealized Losses	Fair Value
<b>Investments - Current:</b>				
Corporate debt securities	\$ 1,011	\$ -	\$ (1)	\$ 1,010
Total	\$ 1,011	\$ -	\$ (1)	\$ 1,010

At June 30, 2022

<b>Investments - Current:</b>	Cost Basis	Accumulated Unrealized Gains	Accumulated Unrealized Losses	Fair Value
United States Treasury securities	\$ 9,992	\$ -	\$ (6)	\$ 9,986
Corporate debt securities	1,801	-	(1)	1,800
Commercial paper	2,887	-	-	2,887
<b>Total</b>	<b>\$ 14,680</b>	<b>\$ -</b>	<b>\$ (7)</b>	<b>\$ 14,673</b>

The amortized cost and fair value of the Company's available-for-sale investments, by contract maturity, as of June 30, 2022 consisted of the following (in thousands):

	Amortized Cost	Fair Value
Due in one year or less	\$ 14,680	\$ 14,673
<b>Total</b>	<b>\$ 14,680</b>	<b>\$ 14,673</b>

## 5. Property and Equipment

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

	ESTIMATED USEFUL LIFE	December 31, 2021	June 30, 2022
Office equipment	5 years	\$ 10	\$ 6
Office furniture	7 years	126	126
Computer equipment	3 years	8	8
Leasehold improvements	Life of lease	95	95
		239	235
Less: Accumulated depreciation		(170)	(178)
<b>Property and equipment, net</b>		<b>\$ 69</b>	<b>\$ 57</b>

Depreciation expense for the three months ended June 30, 2021 and June 30, 2022 was \$8,000 and \$9,000, respectively.

Depreciation expense for the six months ended June 30, 2021 and June 30, 2022 was \$16,000 and \$18,000, respectively.

## 6. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2021	June 30, 2022
Contract research and development	\$ 2,350	\$ 2,162
Employee compensation and related costs	1,152	1,412
Consulting and professional service fees	265	386
Interest	154	106
Financing related costs	60	60
State taxes	5	—
Other	9	—
<b>Total accrued expenses</b>	<b>\$ 3,995</b>	<b>\$ 4,126</b>

## 7. Fair Value of Financial Instruments

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

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

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

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

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

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

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

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

	As of June 30, 2022			
	TOTAL	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Assets:</b>				
Cash equivalents	\$ 39,381	\$ 38,381	\$ 1,000	\$ —
Total cash equivalents	39,381	38,381	1,000	—
United States Treasury securities	9,986	9,986	—	—
Corporate debt securities	1,800	—	1,800	—
Commercial paper	2,887	—	2,887	—
Investments	14,673	9,986	4,687	—
Total	\$ 54,054	\$ 48,367	\$ 5,687	\$ —

## 8. Term Loan

In May 2017, the Company entered into a loan and security agreement (the "2017 Loan Agreement"), with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank (together, the "Lenders"), for \$10.0 million.

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 2019 Loan Agreement extends the term of the credit facility until September 17, 2023. 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 was an interest-only period until September 30, 2021. The rate at June 30, 2022 was 10.18%. Pursuant to the 2019 Loan Agreement, the Company provided a first priority security interest in substantially all of the Company's assets, including intellectual property, subject to certain exceptions.

The Company entered into 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 paid the Exit Fee during 2020 in conjunction with the Company's public offering, which was deemed to be an exit event pursuant to the Exit Agreement.

As of June 30, 2022, unpaid borrowings under the 2019 Loan Agreement totaled \$12.5 million. For the three and six months ended June 30, 2022, the Company recorded \$74,000 and \$155,000, respectively, related to the amortization of debt discount associated with the 2019 Loan Agreement. For the three and six months ended June 30, 2021, the Company recorded \$95,000 and \$182,000, respectively, 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 six months ended June 30, 2022, the Company recorded \$29,000 and \$63,000, respectively, related to the amortization of the final payment fee associated with the 2019 Loan Agreement. For the three and six months ended June 30, 2021, the Company recorded \$41,000 and \$81,000, respectively, 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):

	June 30, 2022
Face value	\$ 12,500
Less: discount	(186)
Total	\$ 12,314
Less: current portion	(9,851)
Long-term portion	\$ 2,463

As of June 30, 2022, future principal payments due under the 2019 Loan Agreement are as follows (in thousands):

Year ended:	
December 31, 2022	\$ 5,000
December 31, 2023	7,500
Total	\$ 12,500

## 9. Stockholders' Equity

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

On March 23, 2021, the Company entered into a Sales Agreement (the "2021 ATM Agreement") with Cowen and Company, LLC ("Cowen") with respect to an at-the-market offering program under which the Company could offer and sell shares of its common stock (the "2021 ATM Shares"), having an aggregate offering price of up to \$50.0 million through Cowen as its sales agent. The Company agreed to pay Cowen a commission up to 3.0% of the gross sales proceeds of such 2021 ATM Shares. As of June 30, 2022, the Company had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

## 10. 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 effective upon the completion of the Company's initial public offering and no further options will be granted under the 2014 Stock Plan. At June 30, 2022, there were 598,619 options outstanding under the 2014 Stock Plan.

As of June 30, 2022, there were 6,143,876 shares of the Company's common stock authorized for issuance under the 2017 Stock Plan, including 359,652 options that have been forfeited from the 2014 Stock Plan.

At June 30, 2022, there were 2,899,006 options available for issuance under the 2017 Stock Plan, 3,172,816 options outstanding and 42,250 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:

	Six Months Ended June 30,	
	2021	2022
Risk-free interest rate	0.50% - 0.88%	1.67% - 3.58%
Expected dividend yield	0%	0%
Expected life	5.5-6.7 years	5.5-6.7 years
Expected volatility	72%-74%	70%-73%
Weighted-average grant date fair value	\$ 4.26	\$ 2.97

The following table summarizes information about stock option activity during the six months ended June 30, 2022 (in thousands, except share and per share data):

	NUMBER OF SHARES	WEIGHTED- AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM	AGGREGATE INTRINSIC VALUE
Outstanding, December 31, 2021	2,662,752	\$ 6.28		
Granted	1,138,469	4.63		
Exercised	(4,781)	4.42		
Forfeited	(25,005)	6.58		
Outstanding, June 30, 2022	3,771,435	\$ 5.79	7.79	\$ 1,097
Vested and exercisable, June 30, 2022	1,782,180	\$ 6.17	6.35	\$ 739
Vested and expected to vest, June 30, 2022	3,090,150	\$ 5.85	7.51	\$ 978

The following table summarizes information about RSU activity during the six months ended June 30, 2022:

	RSUs	AVERAGE GRANT DATE FAIR VALUE (IN DOLLARS PER SHARE)
Outstanding, December 31, 2021	42,250	\$ 3.25
Granted	—	—
Vested	—	—
Forfeited	—	—
RSUs outstanding at June 30, 2022	42,250	\$ 3.25

Unrecognized compensation expense related to unvested options as of June 30, 2022 was \$4.1 million and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 2.5 years. Unrecognized compensation expense related to unvested RSUs as of June 30, 2022 was \$11,000 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 3 months.

### **Employee Stock Purchase Plan**

In October 2017, the board of directors approved the 2017 Employee Stock Purchase Plan ("the ESPP") which became effective in November 2017, upon the closing of the Company's IPO. As part of the ESPP, eligible employees may acquire an ownership



interest in the Company by purchasing common stock, at a discount, through payroll deductions. Eligible employees who elected to participate were able to participate in the ESPP beginning September 1, 2021.

During the six months ended June 30, 2022, 23,658 shares of common stock were issued under the ESPP. As of June 30, 2022, there were 1,164,971 shares of common stock available for issuance under the ESPP.

The Company recorded stock-based compensation expense in the following expense categories of its accompanying condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2021 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2022	2021	2022
Research and development	\$ 233	\$ 265	\$ 459	\$ 519
General and administrative	356	415	651	797
<b>Total</b>	<b>\$ 589</b>	<b>\$ 680</b>	<b>\$ 1,110</b>	<b>\$ 1,316</b>

## 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 2025 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 June 30, 2022 (in thousands):

Year ended:	
December 31, 2022	\$ 286
December 31, 2023	596
December 31, 2024	9
December 31, 2025	1
Total minimum lease payments	892
Less imputed interest	(68)
<b>Total</b>	<b>\$ 824</b>

	Six Months Ended June 30,	
	2021	2022
<b>Lease cost:</b>		
Operating lease cost	\$ 244	\$ 250
Short-term lease cost	-	18
Sublease income	(26)	(26)
<b>Total lease cost</b>	<b>\$ 218</b>	<b>\$ 242</b>
<b>Other information</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ 262	\$ 264
Operating cash flows from operating leases	\$ (28)	\$ (26)
Weighted-average remaining lease term - operating leases	1.4 years	1.4 years
Weighted-average discount rate - operating leases	10.1 %	10.1 %

**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.

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

*The following discussion and analysis of our financial condition and 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, 2021 (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 22, 2022. 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 April 8, 2022. The resubmission was accepted on May 13, 2022 and we were assigned a Prescription Drug User Fee Act, or PDUFA, target action date of October 8, 2022.

This resubmission was in response to a Complete Response Letter, or CRL, we received on December 3, 2020 in response to an NDA we submitted on July 23, 2020. In the CRL, the FDA raised questions related to testing, labeling and features of the combination product unrelated to the drug constituent. The FDA also indicated that they needed to conduct pre-approval inspections at certain of our third-party manufacturing facilities. No clinical deficiencies were noted. On January 28, 2021, we had a Type A meeting with the FDA to discuss the issues described in the CRL and steps required for the resubmission of the NDA for FUROSCIX. On June 2, 2021, we had a Type C meeting with the FDA regarding the requirements for resubmission of the FUROSCIX NDA. Based on guidance we received during the meeting and subsequently contained within the meeting minutes, we conducted the required bench testing for West's proprietary on-body infusor. We anticipate the FDA will still need to conduct pre-approval inspections at certain of our third-party manufacturing facilities. If the NDA is approved, we plan to launch in the fourth quarter of 2022.

We completed enrollment in the AT HOME-HF Pilot study, a Phase 2, multicenter, randomized, proof-of-concept study in heart failure patients with worsening signs and symptoms of congestion requiring augmentation in diuretic therapy outside of an acute care setting. The objective of this pilot study was to evaluate prospective endpoints that could inform the design and sample size of a clinical trial that could be used to seek expansion of the indication for FUROSCIX to include a reduction of hospitalizations for heart failure or inclusion in treatment guidelines. The primary endpoint was a 30-day hierarchical composite of cardiovascular death, heart failure hospitalizations, emergency department visits for heart failure and % change of NT-proBNP at day seven from baseline, utilizing the Finkelstein-Schoenfeld win ratio. The Finkelstein-Schoenfeld win ratio is a statistical method used to compare composite outcomes for every pair in a clinical trial from the treatment and control group. Pre-defined secondary endpoints were evaluated from baseline across the 30-day study period and included the number of days alive and heart failure event free, global assessment via visual analog scale, composite clinical congestion score, 5- and 7-point Likert dyspnea scores, health-related quality of life measured by the Kansas City Cardiomyopathy Questionnaire, or KCCQ-12, serum creatinine, weight, six-minute walk test and ReDS® (Remote Dielectric Sensing) lung fluid measurement. The study compared FUROSCIX to a "treatment as usual" approach, was descriptive only and did not include a powered statistical hypothesis test. The study enrolled 51 subjects, of which 34 received FUROSCIX and 17 received "treatment as usual".

On July 12, 2022, we announced top-line results from the AT HOME-HF Phase 2 Pilot study demonstrating a positive trend in the Finkelstein-Schoenfeld win ratio in the FUROSCIX group compared to the "treatment as usual" group across multiple analysis populations. Subjects randomized to FUROSCIX had a 37% reduction in the risk of a heart failure hospitalization relative to patients randomized to "treatment as usual" at day 30. All pre-defined secondary endpoints measuring symptoms of congestion, quality of life and functional status favored the FUROSCIX group and included a two kilogram greater weight loss at day three and a 12-point increase in the KCCQ-12 summary score at day 7 and day 30. There were 11 subjects that experienced 21 adverse events during the 30-day study period that were determined by the investigator to be related to FUROSCIX. The most common related adverse event was infusion site pain that was mild in severity. There was one serious adverse event (dehydration) that was assessed by the investigator as possibly related to FUROSCIX, which resolved. During the 30-day study period, there was

one death (sudden cardiac death) in the FUROSCIX group which occurred on study day 30 and was assessed by the investigator to be not related to FUROSCIX.

We have funded our operations from inception through June 30, 2022 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 June 30, 2022, we had an accumulated deficit of \$207.1 million. We expect to continue to incur net losses for the foreseeable future as we develop the infrastructure to commercialize our products, if approved, in the United States, including building our sales and marketing organization, continuing research and development efforts, engaging in scale-up manufacturing and seeking regulatory approval for new product candidates and enhancements. We will need additional funding to pay expenses related to our operating activities, including selling, general and administrative expenses and research and development expenses. Adequate funding may not be available to us on acceptable terms, or at all. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations or financial condition.

## **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. In May 2022, we expanded the opening of our offices to accommodate a hybrid work environment for our employees with access to our facilities five days a week. The health of our employees remains a top priority and we are continuing to monitor the impact of COVID-19, including the pace of vaccinations, the emergence of new and more contagious strains of the virus and government regulations.

To date, the third parties that perform our manufacturing, assembly, packaging and testing of our products have experienced delays relating to supply chain logistics but have generally remained operational. The extent of the impact of the evolving COVID-19 pandemic on the timing of the FDA’s review of the FUROSCIX NDA or the ability to timely enroll patients in our upcoming clinical trials 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, the impact of new strains of the virus, the effectiveness and availability of vaccines and other actions that may be taken by governmental authorities. Such developments may also impact the ability of the FDA to inspect facilities required for approval of our NDA, the business of our suppliers, service providers or customers, and other items identified under “Risk Factors” in our Annual Report on Form 10-K, all of which are uncertain and cannot be predicted. An extended period of global supply chain and economic disruption may continue to impact us and could materially affect our business, results of operations, access to sources of liquidity and financial condition.

## **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;
- cost of pre-approval pharmaceutical batch manufacturing; and
- cost of facilities and supplies used for internal research and development and clinical activities.

We expense R&D costs as incurred. Given the emphasis to date on our 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 West’s proprietary on-body infusor;
- 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 West's proprietary on-body infusor, 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 June 30, 2021 and 2022**

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2022 (in thousands):

	Three Months Ended June 30,		Increase (Decrease)
	2021	2022	
Operating expenses:			
Research and development	\$ 3,807	\$ 5,142	\$ 1,335
General and administrative	2,649	4,279	1,630
Total operating expenses	6,456	9,421	2,965
Loss from operations	(6,456)	(9,421)	2,965
Other income	33	64	31
Interest income	12	107	95
Interest expense	(651)	(447)	(204)
Net loss	\$ (7,062)	\$ (9,697)	\$ 2,635

*Research and development expenses.* R&D expenses were \$5.1 million for the three months ended June 30, 2022, compared to \$3.8 million for the three months ended June 30, 2021. The increase of \$1.3 million was primarily attributable to a \$1.2 million increase in pharmaceutical development costs and supplies and a \$0.4 million increase in employee-related costs. The increase was offset by a \$0.3 million decrease in regulatory consulting costs.

*General and administrative expenses.* G&A expenses were \$4.3 million for the three months ended June 30, 2022, compared to \$2.6 million for the three months ended June 30, 2021. The increase of \$1.6 million was primarily attributable to a \$1.2 million increase in employee-related costs, a \$0.5 million increase in commercial preparation costs, and a \$0.1 million increase in public company costs. The increase was offset by a \$0.2 million decrease in consulting and professional service costs.

*Other income.* Other income was \$64,000 for the three months ended June 30, 2022, compared to \$33,000 for the three months ended June 30, 2021. The increase in income of \$31,000 was primarily attributable to income from a rental arrangement.

*Interest income.* Interest income was \$107,000 for the three months ended June 30, 2022, compared to \$12,000 for the three months ended June 30, 2021. The increase of \$95,000 was primarily attributable to higher interest rates on and balances in our financial instruments.

*Interest expense.* Interest expense was \$447,000 for the three months ended June 30, 2022 compared to \$651,000 for the three months ended June 30, 2021. The decrease of \$204,000 was due to lower term loan balances as a result of principal payments

payable pursuant to our \$20.0 million term loan with SLR Investment Corp. (f/k/a Solar Capital Ltd.) and Silicon Valley Bank, entered into in September 2019 (the "2019 Loan Agreement"), which commenced October 1, 2021.

### Comparison of Six Months Ended June 30, 2021 and June 30, 2022

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2022 (in thousands):

	Six Months Ended June 30,		Increase (Decrease)
	2021	2022	
Operating expenses:			
Research and development	\$ 7,816	\$ 9,489	\$ 1,673
General and administrative	5,381	7,172	1,791
Total operating expenses	13,197	16,661	3,464
Loss from operations	(13,197)	(16,661)	3,464
Other income	288	78	(210)
Interest income	32	120	88
Interest expense	(1,287)	(965)	(322)
Net loss	\$ (14,164)	\$ (17,428)	\$ 3,264

**Research and development expenses.** R&D expenses were \$9.5 million for the six months ended June 30, 2022, compared to \$7.8 million for the six months ended June 30, 2021. The increase of \$1.7 million was primarily attributable to a \$0.9 million increase in pharmaceutical development and supplies, a \$0.5 million increase in employee-related costs, a \$0.2 million increase in patent related costs, a \$0.1 million increase in clinical study costs, and a \$0.1 million increase in device development consulting. The increase was offset by a \$0.1 million decrease in regulatory consulting costs.

**General and administrative expenses.** G&A expenses were \$7.2 million for the six months ended June 30, 2022, compared to \$5.4 million for the six months ended June 30, 2021. The increase of \$1.8 million was primarily attributable to a \$1.3 million increase in employee-related costs and a \$0.5 million increase in commercial preparation costs.

**Other income.** Other income was \$78,000 for the six months ended June 30, 2022, compared to \$288,000 for the six months ended June 30, 2021. The decrease in income of \$210,000 was primarily attributable to the recovery of fees associated with a post-employment matter in the six months ended June 30, 2021.

**Interest income.** Interest income was \$120,000 for the six months ended June 30, 2022, compared to \$32,000 for the six months ended June 30, 2021. The increase of \$88,000 was primarily attributable to higher interest rates on and balances in our financial instruments.

**Interest expense.** Interest expense was \$1.0 million for the six months ended June 30, 2022 compared to \$1.3 million for the six months ended June 30, 2021. The decrease of \$0.3 million was due to lower term loan balances as a result of principal payments payable pursuant to our 2019 Loan Agreement, which commenced October 1, 2021.

## LIQUIDITY AND CAPITAL RESOURCES

### Overview

We have funded our operations from inception through June 30, 2022 primarily through the sale of shares of our common stock, through the private placement of our preferred stock and the incurrence of debt. As of June 30, 2022, we had received net cash proceeds of \$92.7 million from our initial public offering, \$56.7 million from sales of our preferred stock, \$18.8 million from borrowings under our term loan, \$13.5 million from sales of convertible notes, \$50.2 million from our public offering in 2020 and \$14.4 million from the sale of common stock in our 2019 at-the-market offering. As of June 30, 2022, we had cash, cash equivalents and restricted cash of \$41.4 million and short-term investments of \$14.7 million.

On March 23, 2021, we entered into the 2021 ATM Agreement with Cowen to sell shares of our common stock, from time to time, with aggregate gross sales proceeds of up to \$50.0 million, through an at-the-market equity offering program under which Cowen will act as our sales agent. As of June 30, 2022, we had received no proceeds from the sale of shares of common stock pursuant to the 2021 ATM Agreement.

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 West's proprietary on-body infusor. 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. In connection with such development plans and activities, if we determine that we need additional cash resources, we would seek to access such funds either pursuant to our 2021 ATM Agreement or through a combination of public or private equity offerings or debt financings. Additionally, we continue to incur additional costs as a result of operating as a public company. Our future capital requirements will depend on many factors, including:

- the potential FDA approval of FUROSCIX incorporating West's proprietary on-body infusor;
- 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 of other product candidates 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)	Six Months Ended June 30,	
	2021	2022
Net cash (used in) provided by:		
Operating activities	\$ (14,886)	\$ (14,544)
Investing activities	18,108	(13,651)
Financing activities	(72)	(4,895)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 3,150	\$ (33,090)

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

During the six months ended June 30, 2022, net cash used in operating activities was \$14.5 million, consisting primarily of a net loss of \$17.4 million. This was offset by an increase in net operating liabilities of \$1.7 million and non-cash charges of \$1.1 million. The increase in net operating liabilities is related to accounts payable for commercial activity, recruiting and pharmaceutical development, as well as amortization of prepaid assets. 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 and accretion of discount on investments.

During the six months ended June 30, 2021, net cash used in operating activities was \$14.9 million, consisting primarily of a net loss of \$14.2 million and an increase in net operating assets of \$2.4 million. This was offset by non-cash charges of \$1.7 million, which 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 and accretion of discount on investments. The increase in net operating assets is related to accrued expenses for employee-related and device development costs.

#### ***Net Cash Provided by (Used in) Investing Activities***

During the six months ended June 30, 2022, net cash used in investing activities was \$13.7 million, consisting primarily of purchases of short-term investments, net of maturities.

During the six months ended June 30, 2021, net cash provided by investing activities was \$18.1 million, consisting of maturities of short-term investments, net of purchases.

#### ***Net Cash Used in Financing Activities***

During the six months ended June 30, 2022, net cash used in financing activities was \$4.9 million, consisting primarily of principal term loan payments, offset by purchases pursuant to our 2017 Employee Stock Purchase Plan and stock option exercises.

During the six months ended June 30, 2021, net cash used in financing activities was \$72,000, consisting primarily of tax obligations on the settlement of restricted stock units, offset by stock option exercises.

### **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, 2021, filed with the SEC on March 22, 2022.

### **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. 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, 2021, filed with the SEC on March 22, 2022.

### **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 June 30, 2022, our aggregate outstanding indebtedness was \$12.5 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.

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

#### **Item 4. Controls and Procedures.**

Our management, with the participation of our principal executive officer and 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 of June 30, 2022, 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 six months ended June 30, 2022 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**

Investing in our common stock involves a high degree of risk. Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the SEC on March 22, 2022. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K.

### **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	<a href="#">Amendment No. 1, dated April 11, 2022, to the Office Lease Agreement, dated as of June 2, 2017, by and between the Registrant and NEEP Investors Holdings LLC (incorporated by reference as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38293) filed on May 16, 2022).</a>
31.1*	<a href="#">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.</a>
32.1†	<a href="#">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.</a>
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

\* Filed herewith.

† 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.

Date: August 9, 2022

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**SCPHARMACEUTICALS INC.**

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

## Certification

I, John H. Tucker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2022 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - 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: August 9, 2022

/s/ John H. Tucker

John H. Tucker

President and Chief Executive Officer  
(Principal Executive Officer and Principal  
Financial Officer)

**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 June 30, 2022, 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: August 9, 2022

/s/ John H. Tucker

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John H. Tucker

President and Chief Executive Officer  
(Principal Executive Officer and Principal  
Financial Officer)

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