

REFINITIV

DELTA REPORT

10-Q

SEEL - SEELOS THERAPEUTICS, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS 1810

CHANGES	297
DELETIONS	771
ADDITIONS	742

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **September 30, 2023** **March 31, 2024**

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 **000-22245**

SEELOS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada

87-0449967

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

300 Park Avenue, 2nd Floor, New York, NY 10022

(Address of Principal Executive Offices) (Zip Code)

(646) 293-2100

(Registrant's telephone number, including area code)

(Former name, former address, and former fiscal year, if changed since last report)

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	SEEL	The Nasdaq Stock Market LLC

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: As of **November 06, 2023** May 8, 2024, **161,379,805** **17,384,638** shares of the common stock, par value \$0.001, of the registrant were outstanding.

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PART I.

ITEM 1. FINANCIAL STATEMENTS

Seelos Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Assets				
Current assets				
Cash	\$ 2,584	\$ 15,533	\$ 524	\$ 2,996
Grant receivable	221	—	968	763
Prepaid expenses and other current assets	3,383	7,141	2,058	1,644
Total current assets	6,188	22,674	3,550	5,403
Operating lease right-of-use asset	30	72	62	15
Total assets	\$ 6,218	\$ 22,746	\$ 3,612	\$ 5,418
Liabilities and stockholders' equity				
Current liabilities				
Accounts payable	\$ 9,320	\$ 3,626	\$ 15,268	\$ 16,403
Accrued expenses	6,340	7,282	4,524	2,516
Licenses payable	—	2,195	—	—
Short-term portion of convertible notes payable, at fair value	15,573	11,865	13,075	14,213

Warrant liabilities, at fair value	4,063	132	3,787	5,781
Operating lease liability	31	58	62	15
Total current liabilities	35,327	25,158	36,716	38,928
Convertible notes payable, at fair value	1,303	8,184		
Operating lease liability, long-term	—	15		
Total liabilities	36,630	33,357	36,716	38,928
Commitments and contingencies (note 12)				
Stockholders' equity (deficit)				
Preferred stock, \$0.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of September 30, 2023 and December 31, 2022	—	—	—	—
Common stock, \$0.001 par value, 480,000,000 and 240,000,000 shares authorized, 159,502,724 and 107,168,256 issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	159	107		
Preferred stock, \$0.001 par value, 10,000,000 shares authorized, no shares issued or outstanding as of March 31, 2024 and December 31, 2023	—	—	—	—
Common stock, \$0.001 par value, 400,000,000 and 16,000,000 shares authorized, 15,256,268 and 9,794,594 issued and outstanding as of March 31, 2024 and December 31, 2023, respectively (note 1)	15	10		
Additional paid-in-capital	216,602	204,026	222,171	219,106
Accumulated deficit	(247,173)	(214,744)	(255,290)	(252,626)
Total stockholders' equity (deficit)	(30,412)	(10,611)	(33,104)	(33,510)
Total liabilities and stockholders' equity (deficit)	\$ 6,218	\$ 22,746	\$ 3,612	\$ 5,418

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

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Seelos Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
For the Three Months Ended March 31, 2024 and Nine Months Ended September 30, 2023 and 2022
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023		2022		2024	
	Revenue	Operating expense	Loss from operations	Other income (expense)	Net income (loss) and comprehensive income (loss)	Net loss and comprehensive loss
Grant revenue	\$ 406	\$ —	\$ 1,550	\$ —	\$ 579	\$ 808
Total revenue	406	—	1,550	—	579	808
Operating expense						
Research and development	10,022	14,750	24,199	43,115	3,525	5,668
General and administrative	2,987	2,660	9,839	9,544	3,109	4,072
Total operating expense	13,009	17,410	34,038	52,659	6,634	9,740
Loss from operations	(12,603)	(17,410)	(32,488)	(52,659)	(6,055)	(8,932)
Other income (expense)						
Interest income	36	36	186	81	10	67
Interest expense	(42)	(2)	(56)	(14)	(23)	(7)
Change in fair value of convertible notes	(799)	(2,137)	(1,349)	(2,477)	(203)	66
Loss on extinguishment of debt	(3,631)	—	(9,151)	—	(1,493)	(13)
Loss on issuance of common stock and warrants	—	—	(4,301)	—	—	(4,301)
Change in fair value of warrant liabilities	27,537	(91)	14,730	192	5,100	(311)
Total other income (expense)	23,101	(2,194)	59	(2,218)	3,391	(4,499)
Net income (loss) and comprehensive income (loss)	\$ 10,498	\$ (19,604)	\$ (32,429)	\$ (54,877)		
Total income (loss) per share basic	\$ 0.08	\$ (0.18)	\$ (0.26)	\$ (0.52)		
Total loss per share-diluted	\$ (0.12)	\$ (0.18)	\$ (0.26)	\$ (0.52)		
Weighted-average common shares outstanding used for basic	135,330,494	106,689,924	126,672,513	106,100,413		
Weighted-average common shares outstanding used for diluted	148,138,721	106,689,924	126,672,513	106,100,413		
Net loss and comprehensive loss					\$ (2,664)	\$ (13,431)
Total loss per share basic (note 1)					\$ (0.20)	\$ (3.58)
Total loss per share-diluted (note 1)					\$ (0.20)	\$ (3.58)
Weighted-average common shares outstanding used for basic (note 1)					13,007,556	3,751,468
Weighted-average common shares outstanding used for diluted (note 1)					13,007,556	3,751,468

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

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Seelos Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)
For the Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023
 (In thousands, except share data)
 (Unaudited)

	Common Stock		Capital	Accumulated Deficit	Stockholders' Equity	Total
	(Shares)	(Amount)				
Balance as of June 30, 2023	124,188,236	\$ 124	\$ 210,367	\$ (257,671)	\$ (47,180)	
Stock-based compensation expense	—	—	974	—	974	
Issuance of common stock, warrant exercise	19,331,819	19	1,981	—	2,000	
Issuance of common stock for payment of convertible notes payable and interest	925,192	1	961	—	962	
Issuance of common stock and warrants, net of issuance costs	15,000,000	15	2,283	—	2,298	
Issuance of common stock, ESPP	57,477	—	36	—	36	
Net income	—	—	—	10,498	10,498	
Balance as of September 30, 2023	159,502,724	\$ 159	\$ 216,602	\$ (247,173)	\$ (30,412)	

	Common Stock		Capital	Accumulated Deficit	Stockholders' Equity	Total
	(Shares)	(Amount)				
Balance as of June 30, 2022	106,190,773	\$ 106	\$ 202,604	\$ (176,483)	\$ 26,227	
Stock-based compensation expense	—	—	973	—	973	
Issuance of common stock for prepaid services	100,000	—	107	—	107	
Issuance of common stock for license acquired	500,000	—	—	—	—	
Issuance of common stock in at-the-market offering, net of issuance costs	350,000	1	151	—	152	
Issuance of common stock, ESPP	27,483	—	24	—	24	
Net loss	—	—	—	(19,604)	(19,604)	
Balance as of September 30, 2022	107,168,256	\$ 107	\$ 203,859	\$ (196,087)	\$ 7,879	

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

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Seelos Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)
For the Nine Months Ended September 30, 2023 and 2022
(In thousands, except share data)
(Unaudited)

	Additional					Total Stockholders' Equity
	Common Stock		Paid-In	Accumulated		
	(Shares)	(Amount)	Capital	Deficit		
Balance as of December 31, 2023	9,794,594	\$ 10	\$ 219,106	\$ (252,626)	\$ (33,510)	
Stock-based compensation expense	—	—	955	—	955	
Issuance of common stock for payment of convertible notes payable and interest	2,054,082	2	1,518	—	1,520	
Issuance of common stock and warrants, net of issuance costs	3,404,256	3	588	—	591	
Issuance of common stock, ESPP	3,336	—	4	—	4	
Net income	—	—	—	(2,664)	(2,664)	
Balance as of March 31, 2024	15,256,268	\$ 15	\$ 222,171	\$ (255,290)	\$ (33,104)	

	Additional					Total Stockholders' Equity
	Common Stock		Paid-In	Accumulated		
	(Shares)	(Amount)	Capital	Deficit		
Balance as of December 31, 2022	107,168,256	\$ 107	\$ 204,026	\$ (214,744)	\$ (10,611)	
Stock-based compensation expense	—	—	3,024	—	3,024	
Issuance of common stock for prepaid services	250,000	—	190	—	190	
Repurchase and retirement of common stock	(1,000,000)	(1)	1	—	—	
Issuance of common stock and warrants	27,059,298	27	2,283	—	2,310	
Issuance of common stock, warrants exercised	19,331,819	19	1,981	—	2,000	
Issuance of common stock, convertible note amendment consideration	1,000,000	1	1,009	—	1,010	
Issuance of common stock for payment of convertible notes payable and interest	5,468,461	6	3,923	—	3,929	
Issuance of common stock in at-the-market offering, net of issuance costs	75,768	—	68	—	68	
Issuance of common stock, ESPP	149,122	—	97	—	97	
Net loss	—	—	—	(32,429)	(32,429)	
Balance as of September 30, 2023	159,502,724	\$ 159	\$ 216,602	\$ (247,173)	\$ (30,412)	

Additional	Total	Additional	Total

	Common Stock				Paid-In	Accumulated	Stockholders'	Common Stock				Paid-In	Accumulated	Stockholders'
	(Shares)	(Amount)	Capital	Deficit	Equity	(Shares)	(Amount)	Capital	Deficit	Equity				
Balance as of December 31, 2021	105,500,445	\$ 105	\$198,428	\$(141,210)	\$ 57,323									
Balance as of December 31, 2022														
(note 1)														
Stock-based compensation expense	—	—	4,166	—	4,166	—	—	—	—	1,062	—	—	1,062	—
Issuance of common stock, options exercised	6,250	—	8	—	8									
Issuance of common stock for prepaid services	200,000	—	167	—	167	8,334	—	190	—	190	—	—	190	—
Issuance of common stock for license acquired	1,000,000	1	840	—	841									
Repurchase and retirement of common stock						(33,334)	—	—	—	—	—	—	—	—
Issuance of common stock, net of issuance costs						401,978	—	12	—	12	—	—	12	—
Issuance of common stock for payment of convertible notes payable						105,538	—	1,991	—	1,991	—	—	1,991	—

Issuance of common stock in at-the-market offering, net of issuance costs	350,000	1	151	—	152	2,527	—	68	—	68
Issuance of common stock, ESPP	111,561	—	99	—	99	3,056	—	61	—	61
Net loss	—	—	—	(54,877)	(54,877)	—	—	—	(13,431)	(13,431)
Balance as of September 30, 2022	107,168,256	\$ 107	\$203,859	\$(196,087)	\$ 7,879					
Balance as of March 31, 2023						4,060,370	\$ 4	\$207,513	\$(228,175)	\$ (20,658)

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

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Seelos Therapeutics, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
For the Nine Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023
(In thousands)
(Unaudited)

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Cash flows from operating activities				
Net loss	\$ (32,429)	\$ (54,877)	\$ (2,664)	\$ (13,431)
Adjustments to reconcile net loss to net cash used in operating activities				
Stock-based compensation expense	3,024	4,166	955	1,062
Change in fair value of warrant liability	(14,730)	(192)	(5,100)	311
Change in fair value of convertible notes payable	1,349	2,477	203	(66)

Research and development expense - license amendment	—	841		
Loss on issuance of common stock and warrants	4,301	—	—	4,301
Amortization of right-of-use asset	42	—	15	14
Net loss on extinguishment of debt	9,151	—	1,493	13
Changes in operating assets and liabilities				
Grant receivable	(221)	—	(205)	(793)
Prepaid expenses and other current assets	3,948	(5,103)	(414)	(1,399)
Accounts payable	5,693	4,259	(1,135)	2,337
Accrued expenses	(1,087)	289	2,225	(1,684)
Derivative liability	—	(1,174)		
Lease liability	(42)	—	(15)	(13)
Licenses payable	(1,000)	800	—	(1,000)
Net cash used in operating activities	(22,001)	(48,514)	(4,642)	(10,348)
Cash flows (used in) provided by financing activities				
Payment on convertible notes	(5,487)	—	(1,314)	(1,286)
Proceeds from issuance of common stock and warrants	15,569	—	3,480	11,226
Proceeds from issuance of common stock in at-the-market offering	68	457	—	68
Payment of deferred offering costs	—	(273)		
Payment for repurchase of common stock	(1,195)	—	—	(1,195)
Proceeds from exercise of options	—	8		
Proceeds from sales of common stock under ESPP	97	99	4	61
Net cash (used in) provided by financing activities	9,052	291		
Net (decrease) increase in cash	(12,949)	(48,223)		
Net cash provided by (used in) financing activities			2,170	8,874
Net decrease in cash			(2,472)	(1,474)
Cash, beginning of period	15,533	78,734	2,996	15,533
Cash, end of period	\$ 2,584	\$ 30,511	\$ 524	\$ 14,059
Supplemental disclosure of cash flow information:				
Cash paid for interest	\$ 316	\$ 11	\$ 180	\$ 114
Cash paid for income taxes	\$ —	\$ —	\$ —	\$ —
Non-cash investing and financing activities:				
Fair value of warrants issued	\$ 17,415	\$ —	\$ 3,106	\$ 15,515
Fair value of warrants issued in extinguishment of convertible notes	\$ 3,247	\$ —		
Increase in principal in extinguishment of convertible notes	\$ 4,882	\$ —		
Issuance of common stock for license payable	\$ —	\$ 840		
Right-of-use asset obtained in exchange for operating lease liabilities			\$ 62	\$ —
Deferred offering costs, accrued but not paid	\$ 145	\$ 32	\$ 217	\$ —
Issuance of common stock for cashless exercise	\$ 2,000	\$ —		
Issuance of common stock for modification of convertible debt	\$ 1,010	\$ —		
Issuance of common stock for principal payments on convertible notes	\$ 3,498	\$ —	\$ 1,374	\$ 1,833
Issuance of common stock for interest payments on convertible notes	\$ 431	\$ —	\$ 146	\$ 157

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Seelos Therapeutics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Description of Business

Seelos Therapeutics, Inc. (together with its subsidiaries, the "Company") is a clinical-stage biopharmaceutical company focused on achieving efficient development of products that address significant unmet needs in Central Nervous System ("CNS") disorders and other rare disorders. The Company's lead programs are SLS-002 for the potential treatment of acute suicidal ideation and behavior in patients with major depressive disorder ("ASIB in MDD") and SLS-005 for the potential treatment of Amyotrophic Lateral Sclerosis ("ALS") and Spinocerebellar Ataxia ("SCA"). SLS-005 for the potential treatment of Sanfilippo Syndrome currently requires additional natural history data, which is being considered. Additionally, the Company is developing several preclinical programs, most of which have well-defined mechanisms of action, including: SLS-004, SLS-006 and SLS-007 for the potential treatment of Parkinson's Disease ("PD"). On March 29, 2023, the Company announced that it plans to focus the majority of its resources on the Phase II study of SLS-002 for ASIB in MDD and the fully enrolled Phase II/III study of SLS-005 in ALS. The Company further announced that it has temporarily paused additional enrollment of patients in the SLS-005-302 study in SCA. Patients already enrolled will continue in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. The Company also announced that it is pausing all non-essential preclinical work. Further, on April 29, 2024, the Company announced a strategic focus on mental health initiatives related to, among other things, its ketamine expertise with SLS-002 in suicidality. Additionally, on April 30, 2024, the Company announced a reduction in its workforce that affected approximately 33% of its current employees (the "RIF"), along with a reduction in working hours and related compensation for all of its remaining employees.

Reverse Stock Split

On November 27, 2023, the Company filed a Certificate of Change with the Secretary of State of the State of Nevada to (i) effect a 1-for-30 reverse stock split (the "Reverse Stock Split") of its issued and outstanding shares of common stock, effective at 12:01 a.m. Eastern Time, on November 28, 2023, and (ii) decrease the number of total authorized shares of the Company's common stock from 480,000,000 shares to 16,000,000 shares. The Company's common stock begin trading on a Reverse Stock Split-adjusted basis on the Nasdaq Capital Market at the opening of the market on November 28, 2023. Unless specifically provided otherwise herein, the share and per share information in this Quarterly Report on Form 10-Q gives effect to the Reverse Stock Split.

2. Liquidity and Going Concern

The accompanying condensed consolidated unaudited financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal

course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

The Company has generated limited revenues, has incurred operating losses since inception, and expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of **September 30, 2023** **March 31, 2024**, the Company had **\$2.6 million** **\$0.5 million** in cash and an accumulated deficit of **\$247.2 million** **\$255.3 million**. The Company has historically funded its operations through the issuance of convertible notes (see Note 9), the sale of common stock and warrants (see Note 6) and exercises of warrants (see Note 10).

On September 21, 2023, the Company entered into a Securities Purchase Agreement (the "September 2023 Securities Purchase Agreement") with certain purchasers identified on the signature pages thereto (the "Purchasers"), pursuant to which, on September 25, 2023, the Company issued and sold 15,000,000 shares (the "Shares") of its common stock and accompanying common stock warrants to purchase up to 10,010,010 shares of common stock (the "September 2023 Warrants") in a registered direct offering (the "September 2023 RDO"). The Shares and the September 2023 Warrants were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-251356) filed with the Securities and Exchange Commission (the "SEC") on December 15, 2020, as amended by Amendment No. 1 thereto filed with the SEC on December 22, 2020 and declared effective on December 23, 2020 (as amended, the "Registration Statement"). The exercise price of the September 2023 Warrants was \$0.325 per share, subject to adjustment as provided therein, and the September 2023 Warrants were immediately exercisable upon issuance and were to expire on the date that is five years following the original issuance date. In addition, the September 2023 Warrants contained an alternative "cashless exercise" provision whereby a September 2023 Warrant could be exchanged cashlessly for shares of common stock at the rate of 0.999 of a share of common stock per full share otherwise issuable upon a cash exercise. The combined purchase price for one Share and accompanying September 2023 Warrant to purchase shares of common stock was \$0.30. The aggregate net proceeds from the September 2023 RDO, after deducting the fees payable to financial advisors and other estimated offering expenses, were approximately \$4.1 million (see Note 6). The fair value of the September 2023 Warrants upon issuance was \$1.9 million and such amount was included within warrant liabilities, at fair value on the condensed consolidated balance sheets. On September 26, 2023 and September 27, 2023, the holders of the September 2023 Warrants elected to cashlessly exchange their September 2023 Warrants in full for an aggregate issuance of 2,222,222 and 7,777,778 shares of common stock, respectively, and, thereafter, no September 2023 Warrants remain outstanding. As a result of the exercise of the September 2023 Warrants, the Company recognized a \$100,000 expense within change in fair value of warrant liabilities on the condensed consolidated statement of operations.

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On **March 10, 2023** **January 26, 2024**, the Company entered into a **Securities Purchase Agreement** **securities purchase agreement** (the "March 2023" "January 2024 Securities Purchase Agreement") with a life sciences-focused investment fund **certain institutional investors** (the "Investor" "January Investors"), pursuant to which, on **March 14, 2023** **January 30, 2024**, the Company issued and sold **an aggregate of 12,059,298** **3,404,256** shares of common stock, pre-funded warrants exercisable for an aggregate of **9,340,702** shares of common stock (the "March 2023 Pre-Funded Warrants" "January Shares") and accompanying common warrants exercisable for an aggregate of **26,750,000** shares of common stock in a registered direct offering (the "March 2023" "January 2024 RDO"), resulting in total net proceeds of **\$10.4 million**, after deducting financial advisor fees. In a concurrent

private placement (the "January 2024 Private Placement" and other offering expenses (see Note 6). On May 19, 2023 together with the January 2024 RDO, the "January 2024 Offering"), the Company entered into Amendment No. 1 also agreed to issue and sell to the March 2023 Securities Purchase Agreement (the "2023 Purchase Agreement Amendment"), pursuant to which the Investor agreed to, among other things, waive certain restrictions on issuing and registering shares of January Investors unregistered common stock contained within the March 2023 Securities Purchase Agreement to permit the Company to make the May Through September Payments (as defined below) in a combination of cash and shares of common stock as contemplated in the 2021 Note Amendment (as defined below). In consideration for entering into the 2023 Purchase Agreement Amendment, on May 19, 2023, the Company issued to the Investor warrants to purchase up to an aggregate of 4,000,000 shares of common stock. The fair value of these warrants upon issuance was \$3.2 million and such amount is included within loss on extinguishment of debt on the condensed consolidated statement of operations. On July 3, 2023 and September 19, 2023, the holders of the March 2023 Pre-Funded Warrants exercised their March 2023 Warrants on a cashless basis for an issuance of an aggregate of 2,719,999 and 6,611,820 3,404,256 shares of common stock respectively, (the "January 2024 Common Warrants"). The combined purchase price for one January Share and thereafter, no March 2023 Pre-Funded Warrants remain outstanding.

On May 12, 2022, the Company entered into an Open Market Sale Agreementsm (the "Sale Agreement") with Jefferies LLC, as sales agent (the "Agent"), pursuant accompanying January 2024 Common Warrant to which the Company may offer and sell shares purchase one share for each share of its common stock from time to time through the Agent (the "ATM Offering"). purchased was \$1.175. The Company also filed a prospectus supplement, dated May 12, 2022, with the SEC in connection with the ATM Offering (the "Prospectus Supplement") under the Company's existing Registration Statement. Pursuant to the Prospectus Supplement, the Company may offer and sell shares having January 2024 Common Warrants have an aggregate offering exercise price of up to \$50.0 million. Under \$1.05 per share of common stock, are exercisable immediately upon issuance and expire five years following the terms initial date of the Sale Agreement, the Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sale Agreement. exercise. The Company also reimburses the Agent for certain expenses incurred in connection with the Sale Agreement exercise price and agreed to provide indemnification and contribution to the Agent with respect to certain liabilities, including liabilities under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended. During the nine months ended September 30, 2023, the Company sold an aggregate of 75,768 shares under the Sale Agreement, receiving net proceeds of \$68,000. However, the Company agreed in the March 2023 Securities Purchase Agreement that it would not, subject to certain exceptions (including in relation to the satisfaction of the May Through September Payments), effect or enter into an agreement to effect any issuance number of shares of common stock or common stock equivalents involving a variable rate transaction, which includesissuable upon the Sale Agreement, until exercise of the earlier of: (a) such time as no investor holds any warrants issued January 2024 Common Warrants will be subject to adjustment in the March 2023 RDO, and (b) the three year anniversary (or, event of any stock dividend, stock split, reverse stock split, recapitalization, reorganization or similar transaction, as described in the case January 2024 Common Warrants. If at any time after the six month anniversary of an at-the-market offering, the one year anniversary) of the earlier of: (i) the date of public announcement by issuance, a registration statement covering the Company issuance of the full readout of the Phase II data with respect to SLS-002 in acute suicidal ideation and behavior in patients with major depressive disorder, and (ii) the date on which the VWAP (as defined in the warrants issued in the March 2023 RDO) of the Company's common stock is at or above \$2.00 (subject to adjustment for reverse and forward share splits, recapitalizations and similar transactions following the date hereof) for three consecutive trading days (the trading day following the earlier of (i) and (ii), the "Trigger Date"). The Trigger Date was September 21, 2023. Additionally, the Company agreed in the September 2023 Securities Purchase Agreement that, until March 25, 2024, the Company will not effect or enter into an agreement to effect any issuance of shares of common stock or common stock equivalents involving an at-the-market offering or variable rate transaction, which includesissuable upon exercise of the Sale Agreement. January 2024 Common Warrants is not available for the issuance, then the holders may exercise the January 2024 Common Warrants by means of a "cashless exercise."

On November 21, 2022 April 30, 2024, the Company received a written notice (the "Bid Notice") from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for its the Company's common stock had

closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company was provided an initial period of 180 calendar days, or until May 22, 2023, to regain compliance. On May 23, 2023, Nasdaq provided a notice to the Company that the Company has not regained compliance with Rule 5550(a)(2) and was not eligible for a second 180 calendar day compliance period as the Company does not comply with the minimum \$5,000,000 stockholder's equity requirement for initial listing on the Nasdaq Capital Market. The Company timely submitted a hearing request before the Nasdaq Hearings Panel, and also provided the Nasdaq Hearings Panel with a plan to regain compliance, which plan included a commitment and intent to conduct a reverse stock split of the Company's common stock to regain compliance with Rule 5550(a)(2) (the "Compliance Plan"). On June 26, 2023, the Company received a letter from Nasdaq granting the Company a temporary exception until October 31, 2023 to regain compliance with Rule 5550(a)(2) by evidencing a closing bid price of \$1.00 or more per share for a minimum of ten consecutive trading sessions. On July 24, 2023, the Company received a letter from Nasdaq notifying the Company that it regained compliance with Rule 5550(a)(2), as required by the Nasdaq Hearings Panel and the Compliance Plan. This letter further noted that the Nasdaq Hearings Panel determined to continue the listing of the Company's common stock.

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On November 1, 2023, the Company received an additional written notice from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for its common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market under Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an initial period of 180 calendar days, or until April 29, 2024 October 28, 2024, to regain compliance. The Bid Notice states that the Nasdaq staff will provide written confirmation that the Company has achieved compliance with Rule 5550(a)(2) if at any time before April 29, 2024 October 28, 2024, the bid price of the Company's common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. In addition, on

If the Company does not regain compliance with Rule 5550(a)(2) by October 28, 2024, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of its intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities will be subject to delisting.

On November 2, 2023, the Company received an additional written notice (the "Initial Notice") from Nasdaq indicating that, for the last thirty-two consecutive business days, the market value of the Company's listed securities has been below the minimum requirement of \$35 million for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2) ("Rule 5550(b)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company has been provided a period of 180 calendar days, or until April 30, 2024, to regain compliance. The Initial Notice stated that the Nasdaq staff will provide written notification that the Company has achieved compliance with Rule 5550(b)(2) if at any time before April 30, 2024, the market value of the Company's common stock closes at \$35 million or more for a minimum of ten consecutive business days. The

On May 1, 2024, the Company ~~intends~~ received written notice (the "Delist Notice" and, together with the Bid Notice and Initial Notice, the "Notices") from Nasdaq indicating that, based upon the Company's continued non-compliance with Rule 5550(b)(2), the Nasdaq staff has determined to monitor the bid price of its common stock and consider available options if delist the Company's common stock ~~does not trade at a level likely to result in the Company regaining compliance with~~ from the Nasdaq Capital Market's minimum bid price rule market effective May 10, 2024 unless the Company timely requests an appeal of this determination before the Nasdaq Hearings Panel (the "Panel") by ~~April 29, 2024, or~~ May 8, 2024. The Company timely requested a hearing before the minimum market value Panel, which had the effect of staying the suspension of the Company's common stock pending the Panel's final written decision. During the pendency of any requested hearing before the Panel, the Company's common stock will remain listed ~~securities~~ rule by April 30, 2024, which may include, among other options, effectuating and trading on Nasdaq.

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The Company is diligently working to evidence compliance with all applicable requirements for continued listing on the Nasdaq Capital Market and expects to submit a ~~reverse stock split~~. There plan to that effect to the Panel as part of the hearing process; however, there can be no ~~assurances~~ assurance the Panel will grant any request for continued listing or that the Company will be able to regain compliance with Nasdaq's minimum bid price rule or Nasdaq's minimum market value the applicable listing criteria within the period of ~~listed securities~~ rule or time that the Company will otherwise be in compliance with the other listing standards for the Nasdaq Capital Market. If the Company does not regain compliance with Rule 5550(a)(2) by April 29, 2024, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, granted by the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the deficiency during the second compliance period, which may include, if necessary, implementing a reverse stock split. However, if it appears to the Nasdaq staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible, Nasdaq would notify the Company that its securities will be subject to delisting. Additionally, if the Company does not regain compliance with Rule 5550(b)(2) by April 30, 2024, the Company will receive written notification that its securities are subject to delisting. In the event the Company receives any such notification, the Company may appeal the Nasdaq staff's determination to delist its securities, but there can be no assurances that the Nasdaq staff would grant any request for continued listing. ~~Panel~~.

Pursuant to the ~~Registration Statement~~, Company's shelf registration statement on Form S-3 (File No. 333-276119) filed with the SEC on December 18, 2023 and declared effective on December 27, 2023 (the "Registration Statement"), the Company may offer from time to time any combination of debt securities, common and preferred stock, ~~warrants, units and~~ ~~warrants~~ rights. As of ~~September 30, 2023~~ March 31, 2024, the Company had ~~approximately \$59.4 million~~ \$246.0 million available under the Registration Statement (inclusive of the \$49.5 million that remained allocated to sales of shares pursuant to the Sale Agreement as of such date). ~~Statement~~. The Company also has the ability to raise funds through other means, such as through the filing of a registration statement on Form S-1 or in private placements. The rules and regulations of the SEC or any other regulatory agencies may restrict the Company's ability to conduct certain types of financing activities or may affect the timing of and amounts it can raise by undertaking such activities.

The Company evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern within one year beyond the ~~date of~~ filing of this Quarterly Report on Form 10-Q.

Based on such evaluation and the Company's current plans (including the ongoing clinical programs for SLS-002, SLS-005 and other product candidates), which are subject to change, management believes that the Company's existing cash and cash equivalents as of **September 30, 2023** **March 31, 2024** are not sufficient to satisfy its operating cash needs for at least one year and that there is substantial doubt about its ability to continue as a going concern for within one year beyond the year after the date of filing of this Quarterly Report on Form 10-Q.

The Company's future liquidity and capital funding requirements will depend on numerous factors, including:

- its ability to raise additional funds to finance its operations;
- its ability to maintain compliance with the listing requirements of the Nasdaq Capital Market;
- the outcome, costs and timing of clinical trial results for the Company's current or future product candidates;
- potential litigation expenses;
- the emergence and effect of competing or complementary products or product candidates;
- its ability to maintain, expand and defend the scope of its intellectual property portfolio, including the amount and timing of any payments the Company may be required to make, or that it may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

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- its ability to retain its current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing, or other arrangements that it has or may establish;
- the trading price of its common stock; and
- its ability to increase the number of authorized shares as may be required to facilitate future financing events.

The Company may raise substantial additional funds, and if it does so, it may do so through one or more of the following: issuance of additional debt or equity and/or the completion of a licensing or other commercial transaction for one or more of the Company's product candidates. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected. This could affect future development and business activities and potential future clinical studies and/or other future ventures. Failure to obtain additional equity or debt financing will have a material, adverse impact on the Company's business operations. There can be no assurance that the Company will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or convertible debt financings will likely have a dilutive effect on the holdings of the Company's existing stockholders.

3. Significant Accounting Policies

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto as of and for the year ended **December 31, 2022** **December 31, 2023**, included in the Company's Annual Report on Form 10-K (the "Annual Report") filed with the SEC on **March 10, 2023** **March 6, 2024**. The accompanying financial statements have been prepared by the Company in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial

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information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. In the opinion of management, the accompanying unaudited condensed consolidated financial statements for the periods presented reflect all adjustments, consisting of only normal, recurring adjustments, necessary to fairly state the Company's financial position, results of operations and cash flows. The December 31, 2022 December 31, 2023 condensed consolidated balance sheet was derived from audited financial statements, but it does not include all U.S. GAAP disclosures. The unaudited condensed consolidated financial statements for the interim periods are not necessarily indicative of results for the full year. The preparation of these unaudited condensed consolidated financial statements requires the Company to make estimates and judgments that affect the amounts reported in the financial statements and the accompanying notes. The Company's actual results may differ from these estimates under different assumptions or conditions.

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 disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The most significant estimates in the Company's financial statements relate to the valuation of warrants, valuation of convertible notes payable, and the valuation of stock options. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Fair Value Measurements

The Company follows the accounting guidance in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 820, Fair Value Measurements and Disclosures ("ASC 820"), for its fair value measurements of financial assets and liabilities measured at fair value on a recurring basis. Under this accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

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The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Fair Value Option

As permitted under FASB ASC Topic 825, Financial Instruments ("ASC 825"), the Company elected the fair value option to account for its November 2021 and December 2021 convertible notes (collectively, the "2021 Convertible Notes"). In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded in the Condensed Consolidated Statement of Operations and Comprehensive Loss. As a result of applying the fair value option, direct costs and fees related to the convertible notes were expensed as incurred and were not deferred.

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Grant Revenue

Revenue from grants is recognized as the qualifying expenses related to the contracts are incurred, provided that there is reasonable assurance of recoverability. Revenue recognized upon incurring qualifying expenses in advance of receipt of funding is recorded as grant receivable, in the Consolidated Balance Sheet.

Research and Development

Research and development costs are expensed as incurred and include milestone and upfront payments for license arrangements, the cost of employee compensation and related expenses, as well as expenses for third parties who conduct research and development on the Company's behalf, pursuant to development and consulting agreements in place.

Stock-based Compensation

The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant-date fair value of the awards and forfeitures rates. The Company accounts for forfeitures as they occur. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent

management's best estimates and involve inherent uncertainties and the application of management's judgment. All stock-based compensation costs are recorded in general and administrative or research and development costs in the statements of operations based upon the underlying individual's role at the Company.

Performance share awards are initially valued based on the Company's closing stock price on the date of grant. The number of performance share awards that vest will be determined based on the achievement of specified performance milestones by the end of the performance period. Compensation expense for performance awards is recognized over the service period and will vary based on remeasurement during the performance period. If achievement of the performance milestone is not probable of achievement during the performance period, compensation expense is reversed.

Income (Loss) Per Common Share

Basic income (loss) per share is computed by dividing net income (loss) applicable to common stockholders by the weighted average number of shares of common stock outstanding during each period. Diluted loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, warrants, performance-based restricted stock unit awards and stock options that would result in the issuance of incremental shares of common stock. For warrants that are liability-classified, during periods when the impact is dilutive, the Company assumes share settlement of the instruments as of the beginning of the reporting period and adjusts the numerator to remove the change in fair value of the warrant liability and adjusts the denominator to include the dilutive shares calculated using the treasury stock method.

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The following table sets forth the computation of basic and diluted income (loss) per share (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net income (loss) attributable to common stockholders - basic	\$ 10,498	\$ (19,604)	\$ (32,429)	\$ (54,877)
Less: change in fair value of warrant liabilities	(27,637)	—	—	—
Net income (loss) attributable to common stockholders - diluted	\$ (17,139)	\$ (19,604)	\$ (32,429)	\$ (54,877)
Denominator:				
Weighted average common shares outstanding- basic	135,330,494	106,689,924	126,672,513	106,100,413
Effect of dilutive securities	12,808,227	—	—	—
Weighted average common shares outstanding - diluted	148,138,721	106,689,924	126,672,513	106,100,413
Net income (loss) per share attributable to common stockholders - basic	\$ 0.08	\$ (0.18)	\$ (0.26)	\$ (0.52)
Net income (loss) per share attributable to common stockholders - diluted	\$ (0.12)	\$ (0.18)	\$ (0.26)	\$ (0.52)

The following potentially dilutive securities outstanding for the three and nine months ended **September 30, 2023** **March 31, 2024** and **2022** **2023** have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive (in thousands):

	Three Months		Nine Months		Three Months Ended	
	Ended September 30,		Ended September 30,		March 31,	
	2023	2022	2023	2022	2024	2023
Outstanding stock options	15,342	10,400	15,342	10,400	789	511
Outstanding warrants	1,222	2,545	32,274	2,545	8,667	975
Convertible debt	2,806	3,704	2,806	3,704	72	97
	19,370	16,649	50,422	16,649	9,528	1,582

Amounts in the table reflect the common stock equivalents of the noted instruments.

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Recent Accounting Pronouncements

In August 2020, the FASB issued Accounting Standards Update ("ASU") No. 2020-06: Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU 2020-06"). This standard simplifies the accounting for convertible debt instruments by removing the separation models for convertible debt with a cash conversion feature, as well as convertible instruments with a beneficial conversion feature. As a result, entities will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce non-cash interest expense for entities that have issued a convertible instrument that was within the scope of those models before the adoption of ASU 2020-06. Additionally, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share and precludes the use of the treasury stock method for certain debt instruments. The provisions of ASU 2020-06 are applicable for the Company beginning after January 1, 2024, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020, and an entity should adopt the provisions at the beginning of its annual fiscal year. The Company has decided to early adopt the provisions of ASU 2020-06 as of January 1, 2023, and the Company does not expect the adoption of ASU 2020-06 to have an impact on its consolidated financial statements and related disclosures.

In June 2022, the FASB issued ASU No. 2022-03: ASC Subtopic 820 - Value Measurement of Equity Securities Subject to Contractual Sale Restrictions ("ASU 2022-03"). ASU 2022-03 amends ASC 820 to clarify that a contractual sales restriction is not considered in measuring an equity security at fair value and to introduce new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. ASU 2022-03 applies to both holders and issuers of equity and equity-linked securities measured at fair value. The amendments in ASU 2022-03 are effective for the Company for fiscal years beginning after December 15, 2023, and the interim periods within those fiscal years. Early adoption is permitted for both interim and annual

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financial statements that have not yet been issued or made available for issuance. The Company is evaluating the impact of this pronouncement on its consolidated financial statements and related disclosures.

4. Fair Value Measurement

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values. There were no transfers between fair value measurement levels during the three and nine months ended **September 30, 2023** **March 31, 2024**.

The Company's financial assets and liabilities measured at fair value at **September 30, 2023** **March 31, 2024** and **December 31, 2022** **December 31, 2023** are as follows (in thousands):

	Fair Value Measurements as of September 30, 2023				Fair Value Measurements as of March 31, 2024			
	(Level 1)	(Level 2)	(Level 3)	Total	(Level 1)	(Level 2)	(Level 3)	Total
	Assets:				Liabilities:			
Cash	\$ 2,584	\$ —	\$ —	\$ 2,584	\$ 524	\$ —	\$ —	\$ 524
Liabilities:								
Convertible notes payable, at fair value	\$ —	\$ —	\$ 16,876	\$ 16,876	\$ —	\$ —	\$ 13,075	\$ 13,075
Warrant liabilities, at fair value	—	—	4,063	4,063	—	—	3,787	3,787
	\$ —	\$ —	\$ 20,939	\$ 20,939	\$ —	\$ —	\$ 16,862	\$ 16,862

	Fair Value Measurements as of December 31, 2022				Fair Value Measurements as of December 31, 2023			
	(Level 1)	(Level 2)	(Level 3)	Total	(Level 1)	(Level 2)	(Level 3)	Total
	Assets:				Liabilities:			
Cash	\$ 15,533	\$ —	\$ —	\$ 15,533	\$ 2,996	\$ —	\$ —	\$ 2,996
Liabilities:								
Convertible notes payable, at fair value	\$ —	\$ —	\$ 20,049	\$ 20,049	\$ —	\$ —	\$ 14,213	\$ 14,213
Warrant liabilities, at fair value	—	—	132	132	—	—	5,781	5,781
	\$ —	\$ —	\$ 20,181	\$ 20,181	\$ —	\$ —	\$ 19,994	\$ 19,994

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The fair value of the Company's money market funds is based on quoted active market prices for the funds and is determined using the market approach.

The Company measures the 2021 Convertible Notes and warrant liabilities at fair value based on significant inputs not observable in the market, which causes them to be classified as a Level 3 measurement within the fair value hierarchy. These valuations use assumptions and estimates the Company believes would be made by a market participant in making the same valuation. The Company assesses these assumptions and estimates on an on-going basis as additional data impacting the assumptions and estimates are obtained. Changes in the fair value of the **convertible notes payable** **2021 Convertible Notes** and warrant liabilities related to updated assumptions and estimates are recognized within the **Condensed Consolidated Statements of Operations and Comprehensive Loss**.

The fair value of the 2021 Convertible Notes and warrant liabilities may change significantly as additional data is obtained, impacting the Company's assumptions regarding probabilities of outcomes used to estimate the fair value of the liabilities. The estimates of fair value may not be indicative of the amounts that could be realized in a current market exchange. Accordingly, the use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts, and such changes could materially impact the Company's results of operations in future periods.

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2021 Convertible Notes

The 2021 Convertible Notes are valued using a Monte Carlo simulation model. The following assumptions were used in determining the fair value of the 2021 Convertible Notes as of **September 30, 2023** **March 31, 2024** and **December 31, 2022** **December 31, 2023**:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Risk-free interest rate	5.41 %	4.24 %	5.28 %	4.89 %
Volatility	125 %	105 %	125 %	125 %
Dividend yield	— %	— %	— %	— %
Contractual term (years)	1.1	1.9	0.7	0.9
Stock price	\$ 0.18	\$ 0.68	\$ 0.59	\$ 1.39

Warrant Liabilities

The common stock warrant liabilities are recorded at fair value using the Black-Scholes option pricing model.

The following assumptions were used in determining the fair value of the warrant liabilities valued using the Black-Scholes option pricing model as of **September 30, 2023** **March 31, 2024** and **December 31, 2022** **December 31, 2023**:

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Risk-free interest rate	4.60% - 5.56 %	4.71 %	4.23% - 4.26 %	3.85% - 5.60 %
Volatility	121.0% - 125.0 %	91.90 %	125% - 129 %	123% - 127 %
Dividend yield	— %	— %	— %	— %
Expected term (years)	0.32 - 5.14	1.07	4.46 - 4.83	0.07 - 4.91
Weighted-average fair value	\$ 0.03 - 0.13	\$ 0.44	\$ 0.44	\$ 1.10

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The following table is a reconciliation for the common stock warrant liabilities and convertible notes measured at fair value using Level 3 unobservable inputs (in thousands):

	Warrant liabilities		Convertible notes, at fair value		Convertible notes, at fair value	
Balance as of December 31, 2021	\$ 424	\$ 1,174	\$ 18,920			
Settlement of derivative liability	—	(1,174)	—			
Principal payment of convertible notes, at fair value	—	—	(1,888)			
Issuance of derivative liability	—	—	—			
Change in fair value measurement of derivative liability	—	—	—			
Change in fair value measurement of convertible notes	—	—	3,017			
Change in fair value measurement of warrant liability	(292)	—	—			
Balance as of December 31, 2022	\$ 132	\$ —	\$ 20,049	\$ 132	\$ 20,049	
Principal payment of convertible notes, at fair value	—	—	(8,672)	—	(11,695)	
Interest payment of convertible notes, at fair value	—	—	(745)	—	(1,085)	
Issuance of convertible note	—	—	4,882	—	4,882	
Loss on extinguishment of debt	—	—	13	—	13	
Change in fair value measurement of convertible notes	—	—	1,349	—	2,049	
Fair value of warrants issued	20,661	—	—	25,644	—	
Warrant exercised	(2,000)	—	—	(2,000)	—	
Change in fair value measurement of warrant liability	(14,730)	—	—	(17,995)	—	

Balance as of September 30, 2023	\$ 4,063	\$ —	\$ 16,876	
Balance as of December 31, 2023			\$ 5,781	\$ 14,213
Principal payment of convertible notes, at fair value			—	(2,549)
Interest payment of convertible notes, at fair value			—	(285)
Loss on extinguishment of debt			—	1,493
Change in fair value measurement of convertible notes			—	203
Fair value of warrants issued			3,106	—
Change in fair value measurement of warrant liability			(5,100)	—
Balance as of March 31, 2024			\$ 3,787	\$ 13,075

For the three and nine months ended **September 30, 2023** **March 31, 2024**, and the year ended **December 31, 2022** **December 31, 2023**, the changes in fair value of the convertible notes and warrant liability primarily resulted from the volatility of the Company's common stock and the change in risk-free interest rates.

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5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets are comprised of the following (in thousands):

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Prepaid insurance	\$ 249	\$ 104	\$ 626	\$ 51
Prepaid clinical costs	3,081	6,837	1,317	1,516
Other	53	200	115	77
Prepaid expenses and other current assets	\$ 3,383	\$ 7,141	\$ 2,058	\$ 1,644

6. Common Stock Offerings

March 2023 Registered Direct Offering

On March 10, 2023, the Company entered into **the March a Securities Purchase Agreement** (the "March 2023 Securities Purchase Agreement", **Agreement**"), with a life-sciences focused investment fund (the "March Investor"), pursuant to which the Company issued and sold an aggregate of **12,059,298** **401,977** shares of common stock, pre-funded warrants exercisable for an aggregate of **9,340,702** **311,357** shares of common stock (the "March 2023 Pre-Funded Warrants") and accompanying common stock

warrants exercisable for an aggregate of **26,750,000** 891,667 shares of common stock ("March 2023 Common Warrants" and together with the March 2023 Pre-Funded Warrants, the "March 2023 Warrants") in the March a registered direct offering (the "March 2023 RDO, RDO"), resulting in total net proceeds of \$10.4 million, after deducting financial advisor fees and other offering expenses. The securities were offered by the Company pursuant to the Company's previous shelf registration statement on Form S-3 (File No. 333-251356) filed with the Securities and Exchange Commission (the "SEC") on December 15, 2020, as amended by Amendment No. 1 thereto filed with the SEC on December 22, 2020 and declared effective on December 23, 2020 (as amended, the "Prior Registration Statement, Statement").

The March 2023 Pre-Funded Warrants were exercisable immediately upon issuance and had an exercise price of **\$0.001** \$0.03 per share of common stock. During the quarter ended September 30, 2023, all of the Pre-Funded Warrants were exercised in full on a cashless basis, and no March 2023 Pre-Funded Warrants remain outstanding. The March 2023 Common Warrants have an exercise price of **\$0.60** \$18.00 per share of common stock, became exercisable on September 11, 2023, and will expire on September 10, 2028 September 14, 2028.

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The combined purchase price for one share and one accompanying March 2023 Common Warrant to purchase 1.25 shares of common stock in the March 2023 RDO was **\$0.525** \$15.75 and the combined purchase price for one March 2023 Pre-Funded Warrant and one accompanying March 2023 Common Warrant to purchase 1.25 shares of common stock in the March 2023 RDO was **\$0.524** \$15.72. The closing of the March 2023 RDO occurred on March 14, 2023.

On May 19, 2023, the Company entered into Amendment No. 1 to the March 2023 Securities Purchase Agreement Amendment (the "2023 Purchase Agreement Amendment") pursuant to which the March Investor agreed to, among other things, waive certain restrictions on issuing and registering shares of common stock contained within the 2023 Securities Purchase Agreement to permit the Company to make the May Through September Payments (as defined below) in a combination of cash and shares of common stock as contemplated in the 2021 Note Amendment No. 3 (as defined below). In consideration for entering into the 2023 Purchase Agreement Amendment, on May 19, 2023, the Company issued to the March Investor warrants to purchase up to an aggregate of **4,000,000** 133,334 shares of common stock (the "May 2023 Warrants"). The exercise price of the May 2023 Warrants is **\$1.06** \$31.80 per share, subject to adjustment as provided therein, and the May 2023 Warrants will be became exercisable beginning on November 19, 2023 and will expire on November 20, 2028. The fair value of these warrants the May 2023 Warrants upon issuance was \$3.2 million and such amount is included within loss on extinguishment of debt on the condensed consolidated statement of operations, operations and comprehensive loss.

September 2023 Registered Direct Offering

On September 21, 2023, The Company entered into the September a Securities Purchase Agreement (the "September 2023 Securities Purchase Agreement") with certain Purchasers, purchasers identified on the signature pages thereto (the "September Investors"), pursuant to which the Company agreed to issue and sell **15,000,000** 500,000 shares (the "Shares" "September 2023 Shares") of its common stock and accompanying common stock warrants to purchase up to **10,010,010** 333,667 shares of common stock (the "September 2023 Warrants") in a registered direct offering (the "September 2023 RDO"). The September 2023 Shares and the September 2023 Warrants were offered by the Company pursuant to its Prior Registration Statement.

The exercise price of the September 2023 Warrants was \$0.325 \$9.75 per share, subject to adjustment as provided therein, and the September 2023 Warrants were immediately exercisable upon issuance and expire on the date that is five years following the original issuance date. In addition, the September 2023 Warrants contained an alternative "cashless exercise" provision whereby a September 2023 Warrant could be exchanged cashlessly for shares of common stock at the rate of 0.999 of a share of common stock per full share otherwise issuable upon a cash exercise. The fair value of the September 2023 Warrants upon issuance was \$1.9 million and such amount was included within warrant liabilities, at fair value on the condensed consolidated balance sheets. On September 26, 2023 and September 27, 2023, the holders of the September 2023 Warrants elected to cashlessly exchange their September 2023 Warrants in full for an aggregate issuance of 2,222,222 74,075 and 7,777,778 259,260 shares of common stock, respectively, and, thereafter, no

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September 2023 Warrants remain outstanding. As a result of the exercise of the September 2023 Warrants the Company recognized a \$100,000 \$0.1 million expense within change in fair value of warrant liabilities on the condensed consolidated statement of operations. operations and comprehensive loss.

December 2023 Underwritten Public Offering

On November 28, 2023, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Titan Partners Group, LLC, a division of American Capital Partners, LLC ("Titan"), pursuant to which, on December 1, 2023, the Company sold, in an underwritten public offering (the "December 2023 Offering") (i) 1,781,934 shares of its common stock, (ii) pre-funded warrants to purchase 2,422,612 shares of common stock (the "December 2023 Pre-Funded Warrants") and (iii) accompanying warrants to purchase up to 4,204,546 shares of common stock (the "December 2023 Common Warrants" and, together with the December 2023 Pre-Funded Warrants, the "December 2023 Warrants"). The combined public offering price for each share of common stock and accompanying December 2023 Common Warrant to purchase one share of common stock was \$1.32 and the combined public offering price for each share of common stock subject to a December 2023 Pre-Funded Warrant and accompanying December 2023 Common Warrant to purchase one share of common stock was \$1.319. The net proceeds to the Company were approximately \$5 million, after deducting the underwriting discounts and commissions and other estimated offering expenses payable by us. The December 2023 Pre-Funded Warrants were exercised in full during the year ended December 31, 2023.

The per share exercise price for the December 2023 Common Warrants is \$1.32, subject to adjustment as provided therein. The December 2023 Common Warrants were exercisable immediately and expire on December 1, 2028. Each holder of a December 2023 Common Warrant does not have the right to exercise any portion of its December 2023 Common Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of the number of shares of the common stock outstanding immediately after giving effect to such exercise (the "Common Warrant Beneficial Ownership Limitation"); provided, however, that upon 61 days' prior notice to the Company, the holder may increase the Common Warrant

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Beneficial Ownership Limitation, but not to above 9.99%. The exercise price and number of shares of common stock issuable upon the exercise of the December 2023 Common Warrants is subject to adjustment in the event of any stock dividend, stock split, reverse stock split, recapitalization, reorganization or similar transaction, as described in the December 2023 Common Warrants. If a registration statement covering the issuance of the shares of common stock issuable upon exercise of the December 2023 Common Warrants is not available for the issuance, then the holders may exercise the Common Warrants by means of a "cashless exercise."

January 2024 Registered Direct Offering

On January 26, 2024, the Company entered into a securities purchase agreement (the "January 2024 Securities Purchase Agreement") with certain institutional investors identified on the signature pages thereto (the "January Purchasers"), pursuant to which, on January 30, 2024, the Company issued and sold 3,404,256 shares (the "January 2024 Shares") of its common stock in a registered direct offering (the "January 2024 RDO"). In a concurrent private placement (the "January 2024 Private Placement" and together with the January 2024 RDO, the "January 2024 Offering"), the Company also agreed to issue and sell to the January Purchasers unregistered common warrants to purchase up to 3,404,256 shares of Common Stock (the "January 2024 Common Warrants"). The combined purchase price for one January 2024 Share and accompanying January 2024 Common Warrant to purchase one share for each share of common stock purchased was \$1.175.

The January 2024 Common Warrants have an exercise price of \$1.05 per share of common stock, are exercisable immediately upon issuance and expire five years following the initial date of exercise. The exercise price and number of shares of common stock issuable upon the exercise of the January 2024 Common Warrants will be subject to adjustment in the event of any stock dividend, stock split, reverse stock split, recapitalization, reorganization, or similar transaction, as described in the January 2024 Common Warrants. If at any time after the six-month anniversary of the date of issuance, a registration statement covering the issuance of the shares of common stock issuable upon exercise of the January 2024 Common Warrants is not available for the issuance, then the holders may exercise the Common Warrants by means of a "cashless exercise." The fair value of the January 2024 Common Warrants upon issuance was \$3.1 million and such amount was included within warrant liabilities, at fair value on the condensed consolidated balance sheets.

The January 2024 Common Warrants are not and will not be listed for trading on any national securities exchange or other nationally recognized trading system.

On January 26, 2024, the Company also entered into a placement agent agreement (the "Placement Agent Agreement") with A.G.P./Alliance Global Partners (the "Placement Agent"), pursuant to which the Placement Agent acted as placement agent for the January 2024 Offering and the Company agreed to pay the Placement Agent a fee equal to 7% of the aggregate gross proceeds received by the Company from the sale of the securities in the January 2024 Offering. The Placement Agent Agreement includes indemnity and other customary provisions for transactions of this nature. The Company also agreed to reimburse the Placement Agent for up to \$50,000 for the Placement Agent's legal fees and expenses and non-accountable expenses in an amount not to exceed \$15,000.

7. License Agreements

Specific information pertaining to each of the Company's significant license agreements is discussed in its audited financial statements included in the Annual Reports on Form 10-K for the years ended **December 31, 2022** **December 31, 2023** and **2021**, 2022, including their nature and purpose, the significant rights and obligations of the parties, and specific accounting policy

elections. The following represents There have been no updates for during the three and nine months ended September 30, 2023 March 31, 2024, if applicable, to the Company's significant license agreements: agreements.

Acquisition of Assets from Phoenixus AG f/k/a Vyera Pharmaceuticals, AG and Turing Pharmaceuticals AG ("Vyera")

On April 8, 2022, Seelos Corporation ("STI"), a wholly-owned subsidiary of the Company, and Vyera, entered into an amendment (the "Amendment") to the Asset Purchase Agreement by and between STI and Vyera, dated March 6, 2018 (as amended by a first amendment thereto entered into on May 18, 2018, a second amendment thereto entered into on December 31, 2018, a third amendment thereto entered into on October 15, 2019 and a fourth amendment thereto entered into on February 15, 2021, the "Vyera Purchase Agreement"). Pursuant to the Vyera Purchase Agreement, STI acquired the assets and liabilities of Vyera related to a product candidate currently referred to as SLS-002 (intranasal ketamine) (the "Vyera Assets") and agreed, among other things, to make certain development and commercialization milestone payments and royalty payments related to the Vyera Assets (the "Milestone and Royalty Payment Obligations") and further agreed that in the event that the Company sold, directly or indirectly, all or substantially all of the Vyera Assets to a third party, then the Company would pay Vyera an amount equal to 4% of the net proceeds actually received by the Company as an upfront payment in such sale (the "Change of Control Payment Obligation").

Pursuant to the Vyera Purchase Agreement, as amended by the Amendment, STI agreed to (i) make a cash payment to Vyera in the aggregate amount of \$4.0 million on or before April 8, 2022 (the "Cash Payment"); (ii) issue to Vyera on or before April 11, 2022, 500,000 shares of the Company's common stock (the "Initial Shares"); (iii) issue to Vyera on or before July 11, 2022, an additional 500,000 shares of the Company's common stock (as adjusted for stock splits, stock dividends, combinations, recapitalizations and the like) (the "July 2022 Shares"); and (iv) issue to Vyera on or before January 11, 2023, an additional number of shares of the Company's common stock equal to \$1.0 million divided by the volume weighted average closing price of the Company's common stock for the ten consecutive trading days ending on the fifth trading day prior to the applicable date of issuance of the shares of the Company's common stock (the "January 2023 Shares"), and together with the Cash Payment, the Initial Shares and the July 2022 Shares, the "Final Payments"). In consideration for the Final Payments, all of STI's contingent payment obligations under the Vyera Purchase Agreement, including the Milestone and Royalty Payment Obligations and the Change of Control Payment Obligation, as well as all commercialization covenants of STI under the Vyera Purchase Agreement, will terminate in full upon the date that all of the Final Payments have been made.

On December 22, 2022, the Company entered into a Share Repurchase Agreement (the "Repurchase Agreement") with Vyera, pursuant to which the Company agreed to repurchase the Initial Shares and the July 2022 Shares previously issued to Vyera for an aggregate purchase price of \$1.2 million in January 2023.

The Company paid the \$4.0 million Cash Payment and issued the Initial Shares to Vyera in April 2022. The Company issued the July 2022 Shares to Vyera in July 2022, and subsequently agreed to repurchase the Initial Shares and the July 2022 Shares in January 2023 pursuant to the Repurchase Agreement on December 22, 2022. The Company recognized \$5.8 million in research and development expense during the nine months ended September 30, 2022 related to the Amendment, which consisted of the initial cash payment of \$4.0 million and \$0.8 million for the Initial Shares and the July 2022 Shares, which were measured at their grant-date fair value. The Company also recognized a liability of \$1.0 million related to the January 2023 Shares within accrued licenses payable. The Company recognized a liability of \$1.2 million related to the Repurchase Agreement, as well as \$0.5 million in research and development expense for the premium paid for the repurchased shares.

On January 3, 2023, the Company paid \$1.2 million in cash to Vyera under the Repurchase Agreement to repurchase the Initial Shares and the July 2022 Shares.

On January 10, 2023, STI entered into Amendment No. 6 to the Vyera Purchase Agreement ("Amendment No. 6") with Vyera, pursuant to which, STI agreed to make two cash payments to Vyera of \$500,000 each on January 31, 2023 and February 28, 2023, in

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lieu of issuing the January 2023 Shares to Vyera. The Company paid the \$500,000 cash payments on each of January 31, 2023 and February 28, 2023 in satisfaction of all Final Payments under the Vyera Purchase Agreement.

Acquisition of License from Stuart Weg, MD

On August 29, 2019, the Company entered into an amended and restated exclusive license agreement with Stuart Weg, M.D. (the "Weg License Agreement"), pursuant to which the Company was granted an exclusive worldwide license to certain intellectual property and regulatory materials related to SLS-002. Under the terms of the Weg License Agreement, the Company paid an upfront license fee of \$75,000 upon execution of the agreement. The Company agreed to pay additional consideration to Dr. Weg as follows: (i) \$0.1 million on January 2, 2020, (ii) \$0.125 million on January 2, 2021, and (iii) in the event the FDA has not approved a New Drug Application for a product containing ketamine in any dosage on or before December 31, 2021, \$0.2 million on January 2, 2022. The Company paid the required \$0.1 million on January 2, 2020, \$0.125 million on January 2, 2021 and \$0.2 million on January 2, 2022.

The remaining potential regulatory and commercial milestones are not yet considered probable, and no other milestone payments have been accrued as of September 30, 2023.

8. Accrued Expenses

Accrued expenses are comprised of the following (in thousands):

	September 30,	December 31,	March 31,	December 31,
	2023	2022	2024	2023
Professional fees	\$ 195	\$ 278	\$ 345	\$ 250
Personnel related	1,121	1,288	381	56
Outside research and development services	4,909	5,627	3,245	2,152
Insurance	72	—	482	—
Other	43	89	71	58
Accrued expenses, net	<u>\$ 6,340</u>	<u>\$ 7,282</u>	<u>\$ 4,524</u>	<u>\$ 2,516</u>

9. Debt

Convertible Notes

November 2021 and December 2021 Convertible Notes and Private Placement

On November 23, 2021, the Company entered into a Securities Purchase Agreement (the "2021 Lind Securities Purchase Agreement") with Lind Global Asset Management V, LLC ("Lind") pursuant to which, among other things, on November 23, 2021 (the "Closing Date"), the Company issued and sold to Lind, in a private placement transaction (the "Private November 2021 Private Placement"), in exchange for the payment by Lind of \$20.0 million, (i) a convertible promissory note (as amended from time to time,

the (the "2021 Note") in an initial aggregate principal amount of \$22.0 million (the "Principal Amount"), which will bear bore no interest until the first anniversary of the issuance of the 2021 Note and will thereafter bear bore interest at a rate of 5% per annum until October 1, 2023 when the 2021 Note began to bear interest at an annual rate of 12% per annum, and is set to mature on November 23, 2024 (the "Maturity Date"), and (ii) 534,759 17,826 shares of Company common stock.

Commencing August 23, 2022, and from time to time and before the Maturity Date, Lind has the option to convert any portion of the then-outstanding Principal Amount of the 2021 Note into shares of common stock Common Stock at a price per share of \$6.00, \$180.00, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions (the "Conversion Price"). Commencing August 23, 2022, the Company has the right to prepay, in whole or in part (exercisable by the Company at any time or from time to time prior to the Maturity Date), up to the full remaining Principal Amount of the 2021 Note with no penalty; however, if the Company exercises such prepayment right, Lind will have the option to convert up to thirty-three and one-third percent (33 1/3%) of the amount that the Company elects to prepay at the Conversion Price. However, pursuant to the 2023 Securities Purchase Agreement Amendment, the Company agreed that, until September 21, 2023, except for the May Through September Payments (as defined below) made by the Company to Lind under the 2021 Note, all other payments under the 2021 Note would be made in cash.

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Subject to certain exceptions, the Company will be required to direct proceeds from any subsequent debt financings (including subordinated debt, convertible debt or mandatorily redeemable preferred stock but other than purchase money debt or capital lease obligations or other indebtedness incurred in the ordinary course of business) to repay the 2021 Note, Notes, unless waived by Lind in advance.

Beginning on November 23, 2022, the 2021 Note amortizes in twenty-four monthly installments equal to the quotient of (i) the then-outstanding Principal Amount of the 2021 Note, divided by (ii) the number of months remaining until the Maturity Date. All amortization payments shall be payable, at the Company's sole option, in cash, shares of common stock Common Stock or a combination of both. In addition, commencing on the last business day of the first month following November 23, 2022, the Company will pay, on a monthly basis, all interest that has accrued and remains unpaid on the then-outstanding Principal Amount of the 2021 Note. Any Effective May 1, 2024, any portion of an amortization payment or interest payment that is paid in shares of common stock Common Stock shall be priced at 90% 85% of the average of the five lowest daily volume weighted average prices of the common stock Common Stock during the 20 trading days prior to the date of issuance of the shares. If, after the first amortization payment, the Company elects to make any amortization payments in cash, the Company shall pay a 5% premium on each cash payment. However, pursuant to the 2023 Securities Purchase Agreement Amendment, the Company agreed that, until September 21, 2023, except for the May Through September Payments made by the Company to Lind under the 2021 Note, all other payments under the 2021 Note would be made in cash. In conjunction with the 2021 Lind Securities Purchase Agreement and the 2021 Note, on the Closing Date, the Company and Lind entered into a security agreement, which

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provides Lind with a first priority lien on the Company's assets and properties. During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, the Company issued **5,468,461** **2,054,083** shares to Lind to satisfy interest and principal payments due under the 2021 Note.

On May 19, 2023, the Company entered into Amendment No. 3 (the "2021 Note Amendment" ("Amendment No. 3")) to the 2021 Note, pursuant to which the Company and Lind agreed, among other things, that: (A) effective as of May 19, 2023, the outstanding Principal Amount was increased by \$1,250,000 to \$17,750,000 and the fair value of \$1.3 million is included within loss on extinguishment of debt on the condensed consolidated statement of **operations**; **operations and comprehensive loss**; (B) the Company shall not be required to maintain any minimum balance of cash or cash equivalents with one or more financial institutions prior to September 15, 2023, and that it shall thereafter be required to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the 2021 Note or more in cash or cash equivalents with one or more financial institutions (the "Minimum Cash Condition"); (C) effective as of September 15, 2023, upon an Event of Default (as defined in the 2021 Note), Lind shall have the right to convert the then outstanding principal amount of the 2021 Note into shares of common stock at the lower of (x) the then-current conversion price (which is currently **\$6.00** **\$180.00** per share, subject to adjustment in certain circumstances as described in the 2021 Note) and (y) 85% of the average of the five lowest daily volume weighted average price of the common stock during the 20 trading days prior to the delivery by Lind of a notice of conversion; (D) all payments of accrued interest and monthly payments of the outstanding principal amount payable by the Company for the months of May, June, July, August and September 2023 (collectively, the "May Through September Payments") were to be paid by the Company to Lind in a combination of cash and shares of common stock (with such combination determined at the Company's option), and the number of shares to be issued calculated as previously provided in the 2021 Note (determined by dividing the principal amount plus interest (if any) being paid in shares by 90% of the average of the five lowest daily volume weighted average price of common stock during the 20 trading days prior to each respective payment date); provided that no less than \$600,000 of the monthly principal payments for the months of May, June, July, August and September 2023 was to be paid in cash, with the remainder paid in shares of common stock. As consideration for entering into the 2021 Note Amendment No. 3, on May 19, 2023, the Company issued to Lind **1,000,000** **33,334** shares of restricted common stock. The 2021 Note Amendment No. 3 represents a modification accounted for as an extinguishment of the debt resulting in a remeasurement event of the 2021 Note in accordance with ASC 825-10. As a result of the modification, the Company recognized a loss on extinguishment of the debt, recorded as a component of the change in fair value of convertible notes on the condensed consolidated statements of **operations**; **operations and comprehensive income**. The Company will continue to account for the 2021 Note using the fair value election. The fair value of these shares of restricted common stock upon issuance was \$1.0 million and such amount is included in loss on extinguishment of debt on the condensed consolidated statement of **operations**; **operations and comprehensive loss**.

On September 13, 2023, pursuant to an Irrevocable Waiver, Lind agreed to unilaterally, unconditionally, irrevocably and permanently waive its right to assert that any Event of Default (as defined in the 2021 Note) would be deemed to occur pursuant to the 2021 Note or that the Company breached the 2021 Note if the Company failed to satisfy the Minimum Cash Condition at any time on or after September 15, 2023 and through and including September 30, 2023 (the "Waiver Period"), in each case solely in connection with the Company's failure to satisfy the Minimum Cash Condition during the Waiver Period.

On September 21, 2023, and concurrently with the execution of the September 2023 Securities Purchase Agreement, the Company entered into a letter agreement with Lind related to the 2021 Note (the "Letter Agreement"), pursuant to which the Company and Lind agreed that, in lieu of, and in full satisfaction of, both the monthly payment that would otherwise have been due under the 2021 Note on September 23, 2023 and the interest payment that would otherwise have been due on September 29, 2023, (i) the Company would, by no later than September 29, 2023, pay to Lind cash in an aggregate amount equal to \$686,564 and (ii) Lind would have the right, at any time and from time to time, between the closing date of the September 2023 RDO and the date that is 45 days after such closing date, to convert the remaining amount of the monthly payment that would have otherwise been due on September 24, 2023 in the aggregate amount of up to \$400,000 into shares of common stock at the lower of (a) the then-current Conversion Price (as defined (which is currently \$180.00 per share, subject to adjustment in certain circumstances as described in the 2021 Note, which is currently \$6.00 per share) Note) and (b) 85% of the average of the five (5) lowest daily volume-weighted average price during the twenty (20) trading days prior to the delivery by Lind of the applicable conversion notice (the "Subsequent Conversion Right"). Pursuant to the Letter Agreement, Lind further agreed that (a) the payment date for the monthly payment under the 2021 Note that would otherwise have been due on October 23, 2023, and (b) the interest payment date for the interest payment under the 2021 Note that would otherwise have been due on October 31, 2023, shall was November 9, 2023.

On September 30, 2023, the Company and Lind entered into an Amendment No. 4 to the 2021 Note and Amendment to Letter Agreement (the "Amendment"), pursuant to which the Company and Lind agreed, among other things, that: (A) effective as of September 30, 2023, the outstanding principal amount of the 2021 Note was increased by \$3,631,528 \$3.6 million to \$16,837,084; \$16.8 million ; (B) commencing October 1, 2023, the 2021 Note will bear interest at an annual rate of 12% per annum; (C) the Company shall not be

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required to maintain any minimum balance of cash or cash equivalents with one or more financial institutions prior to March 28, 2024, and that it shall thereafter be required to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the 2021 Note or more in cash or cash equivalents with one or more financial institutions; (D) subject to certain exceptions, if the Company issues securities for cash consideration, the Company will be required utilize 25% of the net cash proceeds to repay the 2021 Note unless Lind elects not to be repaid; (E) Lind will, through March 28, 2024, forebear from exercising any right to assert or claim a Material Adverse Effect (as defined in the 2021 Note) has occurred as a result of any event, occurrence, fact, condition or change that occurred on or prior to September 30, 2023; (F) the Company shall use its reasonable best efforts to seek, at a special or annual meeting of the stockholders of the Company to be scheduled to be held no later than January 16, 2024, the stockholder approval as contemplated by Nasdaq Listing Rule 5635(d) with respect to the approval of the issuance of shares of Common Stock in excess of the limitation on the number of shares issuable under the 2021 Note as set forth in the 2021 Note and 2021 Lind Securities Purchase Agreement; and (G) subject to certain exceptions, as long as the 2021 Note remains outstanding, Lind will have the right to participate in any equity or debt financing by the Company in an amount equal to the lesser of 50% of the securities to be offered and \$5,000,000 of the securities to be offered in such financing. The Amendment provides that the number of shares issuable pursuant to the Subsequent Conversion Right was limited to an aggregate of 1,877,084 62,570 shares of Common Stock. As a result of the modification, the Company recognized a loss on extinguishment of the debt, recorded as a component of the change in fair value of convertible notes on the condensed consolidated statements of operations. The Company will continue to account for the 2021 Note using the fair value election. The

Company issued 1,877,084 62,570 shares of its common stock in connection with Lind's exercise of the Subsequent Conversion Right on October 5, 2023.

On December 2, 2021 March 27, 2024, the Company and Lind entered into two separate securities purchase agreements with certain accredited investors on substantially the same terms as an Amendment No. 5 to the 2021 Lind Securities Purchase Agreement, Note, pursuant to which the Company sold, in private placement transactions, in exchange for and Lind agreed, among other things, that: (A) effective as of March 27, 2024, the payment by the accredited investors of an aggregate of \$201,534, (i) convertible promissory notes in an aggregate outstanding principal amount of \$221,688, which did the 2021 Note was increased by \$1.5 million to \$12.9 million (the "March 2024 Principal Increase Amount"); (B) the Company shall not bear interest and mature on December 2, 2024 (the "December 2021 Notes") be required to maintain any minimum balance of cash or cash equivalents with one or more financial institutions prior to April 29, 2024, and (ii) that it shall thereafter be required to maintain an aggregate minimum balance equal to 50% of 5,388 shares of its common stock. These notes had substantially the same terms as then outstanding principal amount under the 2021 Note. On February 22, 2023 Note or more in cash or cash equivalents with one or more financial institutions; (C) the Company will not issue any shares in connection with the repayment or conversion of any portion of the March 2024 Principal Increase Amount unless the Company obtains stockholder approval as contemplated by Nasdaq Listing Rule 5635(d) (the "New Requisite Stockholder Approval") and if the Company is not able to issue shares upon repayment or conversion of any portion of the March 2024 Principal Increase Amount, then any portion of the March 2024 Principal Increase Amount that cannot be converted shall remain outstanding until repaid in cash; (D) Lind will, through April 29, 2024, forebear from exercising any right to assert or claim that a Material Adverse Effect (as defined in the Note) has occurred as a result of any event, occurrence, fact, condition or change that occurred on or prior to September 30, 2023; and (E) the Company shall use its reasonable best efforts to seek, at a special or annual meeting of the stockholders of the Company to be scheduled to be held no later than July 31, 2024, the December 2021 Notes were repaid in full, New Requisite Stockholder Approval.

During the three months ended March 31, 2024 and 2023, the Company recognized a \$203,000 loss and a \$66,000 gain on extinguishment of debt of \$13,000 during the nine months ended September 30, 2023.

During the year ended December 31, 2021, the Company received aggregate gross proceeds of \$20.2 million from the convertible note offerings. The Company elected to account for these notes under the change in fair value option. At time of issuance, the Company recorded a liability of \$19.2 million, which was determined to be the fair value at time of issuance. As of December 31, 2022 and 2021, the Company recognized a total convertible note liability of \$20.0 million and \$18.9 million, respectively. During the year ended December 31, 2022 and 2021, the Company recognized \$3.0 million loss and \$0.2 million gain, notes, respectively, on changes in fair value of convertible notes. During the three and nine months ended September 30, 2023, March 31, 2024 and 2023, the Company recognized losses of \$0.8 million \$1.5 million and \$1.3 million, respectively, on changes in fair values of convertible notes. During the three and nine months ended September 30, 2022, the Company recognized losses of \$0.1 million and \$0.3 million, respectively, on changes in fair value of convertible notes. During the three and nine months ended September 30, 2023, the Company recognized losses of \$3.6 million and \$9.1 million, \$13,000, respectively, on loss on extinguishment of debt on the condensed consolidated statement of operations, operations and comprehensive loss.

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During the nine three months ended September 30, 2023 March 31, 2024, the Company made principal payments of \$8.5 million \$2.5 million (consisting of \$3.5 million \$1.4 million of common stock and \$5.0 million \$1.1 million of cash) and interest

payments of \$0.6 million \$0.3 million (consisting of \$0.3 million \$0.1 million of common stock and \$0.3 million \$0.2 million of cash), respectively, on the convertible notes. During the year ended December 31, 2022, the Company made principal and interest payments of \$1.9 million of cash on the convertible notes. [2021 Note](#). As of December 31, 2022 and September 30, 2023 March 31, 2024, the Company recognized a total convertible note liability of \$20.1 million and \$16.9 million, respectively. \$13.1 million.

The 2021 Note contains certain restrictive covenants and event of default provisions, including a covenant requiring the Company to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the 2021 Note or more in cash and cash equivalents commencing on [March 28, 2024](#) May 31, 2024. As of [September 30, 2023](#) May 8, 2024, the outstanding principal amount of the 2021 Note was \$16.8 million \$12.6 million. Based on the Company's current operating plan and its cash balance as of September 30, 2023, the Company does not expect be able to maintain the minimum cash balance required to satisfy the minimum cash covenant if it does not raise additional financing by March 28, 2024. If the Company is unable to cure such default within fifteen days from its occurrence or otherwise obtain a waiver from Lind or amend the terms of the 2021 Note, the Company would trigger a default under the 2021 Note. If the Company is not able to comply or regain compliance with any of the covenants in, or otherwise trigger a default under, the 2021 Note, Lind could declare the 2021 Note immediately due and payable, which would require the Company to pay 120% of the outstanding principal amount of the 2021 Note and would have a material adverse effect on its liquidity, financial condition, operating results, business and prospects, and could cause the price of the Company's common stock to decline. In addition, since the borrowings under the 2021 Note are secured by a first priority lien on the Company's assets, Lind would be able to foreclose on the Company's assets if it does not cure any default or pay any amounts due and payable under the 2021 Note. In addition, upon an Event of Default (as defined in the 2021 Note), Lind shall have the right to convert the then outstanding principal amount of the 2021 Note into shares of the Company's common stock at the lower of (x) the then-current conversion price (which is currently \$6.00 \$180.00 per share, subject to adjustment in certain circumstances as described in the 2021 Note) and (y) 85% of the average of the [five lowest](#)

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daily volume weighted average price of the Company's common stock during the 20 trading days prior to the delivery by Lind of a notice of conversion.

The outstanding 2021 Note will mature on November 23, 2024.

10. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, par value \$0.001. No shares of preferred stock were outstanding as of [September 30, 2023](#) March 31, 2024 or [December 31, 2022](#) December 31, 2023.

Common Stock

The Company has authorized 480,000,000 400,000,000 and 240,000,000 16,000,000 shares of common stock as of [September 30, 2023](#) March 31, 2024 and [December 31, 2022](#) December 31, 2023, respectively. Each share of common stock is entitled to one

voting right. Common stock owners are entitled to dividends when funds are legally available and declared by the Board of Directors.

Warrants

September 2023 January 2024 Common Warrants

On **September 21, 2023** **January 26, 2024**, the Company entered into the **September 2023 January 2024** Securities Purchase Agreement pursuant to which the Company issued and sold an aggregate of **15,000,000** **3,404,256** shares of common stock in the **January 2024 RDO** and, in the concurrent **January 2024 Private Placement**, the Company also issued and sold the **January 2024 Common Warrants** exercisable for an aggregate of **3,404,256** shares of common stock. The **January 2024 Common Warrants** have an exercise price per share equal to **\$1.05**. The **January 2024 Common Warrants** were exercisable immediately and will expire on **January 26, 2029**. As of **March 31, 2024**, **January 2024 Common Warrants** to purchase **3,404,256** million shares of common stock remain outstanding at an exercise price of **\$1.05** per share.

December 2023 Warrants

On November 28, 2023, the Company entered into the Underwriting Agreement pursuant to which the Company issued and sold an aggregate of **1,781,934** shares of common stock, the **December 2023 Pre-Funded Warrants** exercisable for an aggregate of **2,422,612** shares of its common stock and the **September accompanying December 2023 Common Warrants** exercisable for an aggregate of **10,010,010** **4,204,546** shares of its common stock in the **September December 2023 RDO Offering**. The **September December 2023 Pre-Funded Warrants** were exercisable immediately upon issuance and had an exercise price per share equal to **\$0.325** **\$0.001**. The **December 2023 Common Warrants** have an exercise price per share. In addition, share equal to **\$1.32**. The **December 2023 Common Warrants** were exercisable immediately and will expire on December 1, 2028. As of March 31, 2024, the **September December 2023 Pre-Funded Warrants** contain an alternative "cashless exercise" provision whereby a **September** had been exercised in full, and **December 2023 Warrant** may be exchanged cashlessly for **Common Warrants** to purchase **4,204,546** million shares of common stock remain outstanding at a rate an exercise price of **0.999** of a share of common stock **\$1.32** per full share otherwise issuable upon a cash exercise. During the nine months ended September 30, 2023, **September 2023 Warrants** to purchase approximately **10.0** million shares of common stock were cashlessly exchanged and no **September 2023 Warrants** remain outstanding. share.

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May 2023 Warrants

On May 19, 2023, the Company entered into the 2023 Purchase Agreement Amendment, pursuant to which the **March** Investor agreed to, among other things, waive certain restrictions on issuing and registering shares of common stock contained within the **March 2023 Securities Purchase Agreement** to permit the Company to make the **May Through September Payments** in a combination of cash and shares of common stock as contemplated in **the 2021 Note Amendment**. In **Amendment No. 3**. In consideration for entering into the 2023 Purchase Agreement Amendment, on May 19, 2023, the Company issued to the **March Investor** **warrants to purchase up to the May 2023 Warrants** exercisable for an aggregate of **4,000,000** **133,334** shares of common stock (the "May 2023 Warrants"). stock. The exercise price of the May 2023 Warrants is **\$1.06** **\$31.80** per share, subject to

adjustment as provided therein, and the May 2023 Warrants will be became exercisable beginning on November 19, 2023 and will expire on November 20, 2028.

As of September 30, 2023 March 31, 2024, May 2023 Warrants to purchase 4.0 million 133,334 shares of common stock remain outstanding at an exercise price of \$1.06 per share.

March 2023 Warrants

On March 10, 2023, the Company entered into a securities purchase agreement with a life sciences-focused investment fund pursuant to which the Company issued and sold an aggregate of 12,059,298 shares of common stock, the March 2023 Pre-Funded Warrants exercisable for an aggregate of 9,340,702 shares of its common stock and the accompanying March 2023 Common Warrants exercisable for an aggregate of 26,750,000 shares of common stock in a registered direct offering. The March 2023 Pre-Funded Warrants were exercisable immediately upon issuance and had an exercise price per share equal to \$0.001. The March 2023 Common Warrants have an exercise price per share equal to \$0.60. The March 2023 Common Warrants became exercisable beginning on September 11, 2023 and will expire on September 10, 2028.

During the nine months ended September 30, 2023, March 2023 Pre-Funded Warrants to purchase approximately 9.3 million shares of common stock were exercised on a cashless basis. As of September 30, 2023, March 2023 Pre-Funded Warrants to purchase 9.3 million shares of common stock all have been exercised on a cashless basis and March 2023 Common Warrants to purchase 26.8 million shares of common stock remain outstanding at an exercise price of \$0.60 per share.

September 2020 Warrants

On September 4, 2020, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company issued and sold an aggregate of 8,865,000 shares of common stock in a registered direct offering and issued warrants to purchase up to 6,648,750 shares of common stock in a concurrent private placement (the "September 2020 Warrants"). The September 2020 Warrants are exercisable for 6,648,750 shares of common stock at an exercise price per share equal to \$0.84. The September 2020 Warrants became exercisable beginning on March 9, 2021 and will expire on March 9, 2026.

During the nine months ended September 30, 2023 and 2022, no September 2020 Warrants were exercised. As of September 30, 2023, September 2020 Warrants exercisable for 1.0 million shares of common stock remain outstanding at an exercise price of \$0.84 per share.

August 2019 Warrants

On August 23, 2019, the Company entered into a securities purchase agreement with certain institutional investors pursuant to which the Company issued and sold an aggregate of 4,475,000 shares of common stock in a registered direct offering and issued warrants to purchase up to 2,237,500 shares of common stock in a concurrent private placement (the "August 2019 Warrants"). The August 2019 Warrants were initially exercisable for 2,237,500 shares of common stock at an exercise price per share equal to \$1.78. The August 2019 Warrants became exercisable beginning on February 27, 2020 and will expire on August 28, 2023.

During the nine months ended September 30, 2023 and 2022, no August 2019 Warrants were exercised. As of September 30, 2023, August 2019 Warrants exercisable for 900,000 shares of common stock remain outstanding at an exercise price of \$1.78 \$31.80 per share.

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Series A March 2023 Warrants

On March 10, 2023, the Company entered into the March 2023 Securities Purchase Agreement, pursuant to which the Company issued and sold an aggregate of 401,977 shares of common stock, the March 2023 Pre-Funded Warrants exercisable for an aggregate of 311,357 shares of its common stock and the accompanying March 2023 Common Warrants exercisable for an aggregate of 891,667 shares of common stock in the March 2023 RDO. The March 2023 Pre-Funded Warrants were exercisable immediately upon issuance and had an exercise price per share equal to \$0.03. The March 2023 Common Warrants have an exercise price per share equal to \$18.00. The March 2023 Common Warrants became exercisable beginning on September 11, 2023 and will expire on September 14, 2028.

As of March 31, 2024, no March 2023 Pre-Funded Warrants remain outstanding and March 2023 Common Warrants to purchase 891,667 shares of common stock remain outstanding at an exercise price of \$18.00 per share.

September 2020 Warrants

On January 24, 2019 September 4, 2020, STI and the Company closed entered into a private placement securities purchase agreement with certain accredited institutional investors, pursuant to which among other things, the Company issued warrants representing the right to acquire 1,463,519 and sold an aggregate of 295,500 shares of common stock in a registered direct offering and issued unregistered warrants to purchase up to 221,625 shares of common stock in a concurrent private placement (the "Series A" September 2020 Warrants"). The Series A September 2020 Warrants were initially are exercisable for 1,463,519 33,625 shares of common stock at an exercise price per share equal to \$4.15, which was adjusted several times pursuant to the terms thereof to 3,629,023 shares of common stock at an exercise price per share equal to \$0.2734 per share. \$25.20. The most recent adjustment to the exercise price (from \$0.2957 to \$0.2734 per share) occurred during September 2020 Warrants became exercisable beginning on March 9, 2021 and will expire on March 9, 2026.

During the three months ended September 30, 2023 March 31, 2024, as a result of the announcement of the no September 2023 RDO. The Series A Warrants were immediately exercisable upon issuance and will expire on January 31, 2024.

During the nine months ended September 30, 2023 and 2022, no Series A 2020 Warrants were exercised. As of September 30, 2023 March 31, 2024, Series A September 2020 Warrants exercisable for 0.3 million to purchase 33,625 shares of common stock remain outstanding at an exercise price of \$0.2734 \$25.20 per share. The exercise price of the Series A Warrants was adjusted in September 2023 due to the adjustment provisions in the Series A Warrants as a result of the September 2023 RDO.

A summary of warrant activity during the nine three months ended September 30, 2023 March 31, 2024 is as follows (share amounts in thousands):

	Warrants	Weighted-Average		Weighted-Average			
		Weighted-Average	Remaining	Weighted-Average	Remaining		
		Exercise	Contractual Life	Exercise	Contractual Life		
		Warrants	Price	(in years)	Warrants	Price	(in years)
Outstanding as of December 31, 2022	2,545	\$ 2.78	1.7				
Outstanding as of December 31, 2023				5,280	\$ 5.57	4.8	
Issued	50,101	\$ 0.41		3,404	\$ 1.05		
Exercised	(19,351)	\$ 0.00		—	\$ —		

Cancelled	(1,021)	\$ 3.38	(17)	\$130.00
Outstanding as of September 30, 2023	<u>32,274</u>	\$ 0.74	4.8	
Exercisable as of September 30, 2023	<u>32,274</u>	\$ 0.74	4.8	
Outstanding as of March 31, 2024			8,667	\$ 5.57 4.7
Exercisable as of March 31, 2024			<u>8,667</u>	\$ 3.55 4.7

The January 2024 Common Warrants, the December 2023 Warrants, the September 2023 Warrants, the May 2023 Warrants, the March 2023 Common Warrants, and the March 2023 Pre-Funded Warrants and the Series A Warrants were recognized as a liability at their fair value upon issuance. The warrant liability is remeasured to the then fair value prior to their exercise or at period end for warrants that are unexercised, and the gain or loss recognized in earnings during the period.

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11. Stock-based Compensation

The Company has the Seelos Therapeutics, Inc. Amended and Restated 2012 Stock Long Term Incentive Plan (the "2012 Plan"), which provides for the issuance of incentive and non-incentive stock options, restricted and unrestricted stock awards, stock unit awards and stock appreciation rights. Options and restricted stock units granted generally vest over a period of one to four years and have a maximum term of ten years from the date of grant. The 2012 Plan provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the 2012 Plan on January 1st of each year commencing on January 1, 2020 and ending on (and including) January 1, 2029. The number of shares added each year will be equal to the lesser of (a) 4% of the number of shares of common stock issued and outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31, and (b) a number of shares of common stock set by the Company's board of directors on or prior to each such January 1. On January 1, 2023 January 1, 2024, in accordance with the foregoing, an aggregate of 4,771,457 106,206 shares of common stock were added to shares authorized for issuance under the 2012 Plan. As of September 30, 2023 March 31, 2024, an aggregate of 20,589,275 792,523 shares of common stock were authorized under the 2012 Plan, of which 5.2 million 18 shares of common stock were available for future grants. No further awards may be issued under the Seelos Therapeutics, Inc. 2016 Equity Incentive Plan.

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On May 15, 2020, the Company's stockholders approved the Company's 2020 Employee Stock Purchase Plan (the "ESPP"), whereby qualified employees are allowed to purchase limited amounts of the Company's common stock at the lesser of 85% of the

market price at the beginning or end of the offering period. The stockholders have authorized an initial amount of 1.0 million shares for purchase by employees under the ESPP. The ESPP provides that an additional number of shares will automatically be added annually to the shares authorized for issuance under the ESPP on January 1st of each year commencing on January 1, 2021 and ending on (and including) January 1, 2030, which amount shall be equal to the lesser of (i) 1% of the number of shares of the Company's common stock issued and outstanding on the immediately preceding December 31, and (ii) a number of shares of common stock set by the Company's Board of Directors or the Compensation Committee of the Board of Directors (the "Compensation Committee") of the Company on or prior to each such January 1. On **January 1, 2023** **January 1, 2024**, the Company added **1,063,421** **106,206** shares for purchase by employees under the ESPP. During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, the Company sold **149,122** **3,336** shares of common stock under the ESPP. The compensation costs are calculated as the fair value of the 15% discount from market price and were approximately **\$27,000** **\$15,000** for the **nine** **three** months ended **September 30, 2023** **March 31, 2024**.

On July 28, 2019, the Compensation Committee adopted the Seelos Therapeutics, Inc. 2019 Inducement Plan (the "2019 Inducement Plan"), which became effective on August 12, 2019. The 2019 Inducement Plan provides for the grant of equity-based awards in the form of stock options, stock appreciation rights, restricted stock, unrestricted stock, stock units, including restricted stock units, performance units and cash awards, solely to prospective employees of the Company or an affiliate of the Company provided that certain criteria are met. Awards under the 2019 Inducement Plan may only be granted to an individual, as a material inducement to such individual to enter into employment with the Company, who (i) has not previously been an employee or director of the Company or (ii) is rehired following a bona fide period of non-employment with the Company. The maximum number of shares available for grant under the 2019 Inducement Plan is **1,000,000** **33,334** shares of the Company's common stock, of which **21,756** shares of the Company's common stock are available for future issuance as of March 31, 2024. The 2019 Inducement Plan is administered by the Compensation Committee and expires on August 12, 2029.

Stock options

During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, the Company granted **1,517,585** **53,083** incentive stock options and **2,959,625** **99,290** non-qualified stock options to employees with a weighted average exercise price per share of **\$0.69** **\$1.41** and a 10-year term, subject to the terms and conditions of the 2012 Plan above. The stock options are subject to time vesting requirements. The stock options granted to employees vest 25% on the first anniversary of the grant and monthly thereafter over the next three years.

During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, the Company also granted **338,135** **267** incentive stock options and **121,772** non-qualified stock options to employees who elected to forgo a portion of their cash bonus for stock options with a weighted average exercise price per share of **\$0.69** **\$1.41** and a 10-year term, subject to the terms and conditions of the 2012 Plan above. The stock options are not subject to time performance-based vesting requirements and are fully vested upon requirements. The stock options granted to employees will vest 100% solely in the date of grant, event that the Company raises at least \$15.0 million in gross proceeds in equity and/or debt financing (individually or collectively) in 2024.

During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, the Company also granted **200,000** **6,664** non-qualified stock options to non-employee directors with a weighted average exercise price per share of **\$0.81** **\$1.33** and a 10-year term, subject to the terms and conditions of the 2012 Plan above. The stock options granted to non-employee directors vest monthly over the 12 months following the grant.

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The fair value of stock option grants is estimated on the date of grant using the Black-Scholes option-pricing model. The Company was historically a private company and lacked sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on a weighted average blend of the historical volatility of a publicly traded set of peer companies, as well as its own historical volatility. Additionally, due to an insufficient history with respect to stock option activity and post-vesting cancellations, the expected term assumption for employee grants is based on a permitted simplified method, which is based on the vesting period and contractual term for each tranche of awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

During the **nine****three** months ended **September 30, 2023****March 31, 2024**, no stock options were exercised, and **73,000****2,606** options were forfeited. During the **nine****three** months ended **September 30, 2022****March 31, 2023**, **6,250****no** stock options were exercised, and **no****49,667** options were forfeited.

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The following assumptions were used in determining the fair value of the stock options granted during the **nine****three** months ended **September 30, 2023****March 31, 2024** and **2022****2023**:

	Nine Months Ended			Three Months Ended	
	September 30, 2023	September 30, 2022		March 31, 2024	March 31, 2023
Risk-free interest rate	3.5%-3.9%	1.6%-3.4%		3.9%-4.0%	3.6%-3.9%
Volatility	116%-119%	111%-113%		114%	117%-119%
Dividend yield	—%	—%		—%	—%
Expected term (years)	5-6	5-6		5-6	5-6
Weighted-average fair value	\$ 0.60	\$ 1.22		\$ 1.41	\$ 20.94

A summary of stock option activity during the **nine****three** months ended **September 30, 2023****March 31, 2024** is as follows (share amounts in thousands):

	Weighted-				Weighted-			
	Weighted-	Average	Total	Weighted-	Average	Total	Weighted-	Total
		Average	Remaining		Average	Remaining		
	Stock Options	Exercise Price	Contractual Life (in years)	Intrinsic Value	Stock Options	Exercise Price	Contractual Life (in years)	Intrinsic Value
Outstanding as of December 31, 2022	10,400	\$ 2.26						

Outstanding as of December 31,						
2023						
Granted	5,015	0.70		281	1.41	
Exercised	—	—		—	—	
Forfeited	(47)	1.91		(3)	42.18	
Expired	(26)	87.60		—	—	
Outstanding as of September 30,						
2023	<u>15,342</u>	<u>\$ 1.60</u>	8.0	<u>\$ —</u>		
Vested and expected to vest as of						
September 30, 2023	<u>15,342</u>	<u>\$ 1.60</u>	8.0	<u>\$ —</u>		
Exercisable as of September 30,						
2023	<u>7,495</u>	<u>\$ 1.97</u>	7.2	<u>\$ —</u>		
Outstanding as of March 31, 2024				<u>789</u>	<u>\$ 31.53</u>	8.3
Vested and expected to vest as of				<u>789</u>	<u>\$ 31.53</u>	8.3
March 31, 2024				<u>328</u>	<u>\$ 54.28</u>	6.9
Exercisable as of March 31, 2024						

As of **September 30, 2023** **March 31, 2024**, unrecognized stock-option compensation expense of **\$7.5 million** **\$5.7 million** is expected to be realized over a weighted-average period of 2.07 years.

Performance Stock Award

During the year ended December 31, 2021, the Company's Board of Directors awarded a performance stock unit award to the Company's Chief Executive Officer for 2,400,000 shares of common stock, with a grant date fair value of \$4.31 per unit. Vesting of this award was subject to the Company achieving certain performance criteria established at the grant date and the individual fulfilling a service condition (continued employment). As of December 31, 2021, all performance stock unit awards were unvested and three of the five performance conditions had been satisfied. The Company recognized stock-based compensation related to this award of \$4.9 million during the fourth quarter of 2021, which was recorded in general and administrative expense. In 2022, the Company and its Chief Executive Officer entered into an agreement to cancel the performance stock unit award for no consideration. In connection with the cancellation of the award, no replacement awards were granted or authorized. At the time of cancellation, the Company recognized the remaining compensation expense of the three achieved milestones of \$1.3 million. The two remaining milestones were not deemed probable of achievement at the time of cancellation, and no compensation cost related to these milestones was recognized.

The following table summarizes the total stock-based compensation expense resulting from share-based awards recorded in the Company's condensed consolidated statements of operations (in thousands):

	Three Months Ended		Nine Months Ended		Three Months Ended	
	September 30,		September 30,		March 31,	
	2023	2022	2023	2022	2024	2023
Research and development	\$ 267	\$ 261	\$ 770	\$ 721	\$ 274	\$ 235
General and administrative	707	712	2,254	3,445	681	827
	<u>\$ 974</u>	<u>\$ 973</u>	<u>\$ 3,024</u>	<u>\$ 4,166</u>	<u>\$ 955</u>	<u>\$ 1,062</u>

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12. Commitments and Contingencies

Leases

In **March 2021, October 2022**, the Company entered into an eighteen-month office space rental agreement for its headquarters at 300 Park Avenue, New York, NY, which ended in **September 2022, March 2024**. In **October 2022, March 2024**, the Company entered into a new **eighteen-month twelve-month** office space rental agreement for its existing space, which provides for a base rent starting at approximately **\$4,500 \$6,000** per **month** subject to periodic increases. **month**.

Under the new office space rental agreement in **October 2022, March 2024**, in exchange for the new operating lease liability, the Company recognized a right-of-use asset of approximately **\$86,000, \$62,000**. As of **September 30, 2023** **March 31, 2024**, the weighted-average remaining lease term of the operating lease was **6.12** months, and the weighted-average discount rate was 8.0%.

As of **September 30, 2023** **March 31, 2024**, future minimum lease payments for the Company's operating lease with a non-cancelable term is as follows (in thousands):

	Operating Leases	Operating Leases
Year Ended December 31, 2023	\$ 16	
Year Ended December 31, 2024	16	\$ 48
Year Ended December 31, 2025		\$ 16
Total	32	64
Less present value discount	(2)	(2)
Operating lease liabilities	<u>\$ 30</u>	<u>\$ 62</u>

For each of the **nine** **three** months ended **September 30, 2023** **March 31, 2024** and **2022, 2023**, rent expense totaled **\$47,000** and **\$42,000**, respectively. **\$15,000**.

Contractual Commitments

The Company has entered into long-term agreements with certain manufacturers and suppliers that require it to make contractual payment to these organizations. The Company expects to enter into additional collaborative research, contract research, manufacturing, and supplier agreements in the future, which may require up-front payments and long-term commitments of cash.

Litigation

As **On March 22, 2024**, **Empery Asset Master Ltd.** And other related entities commenced an action against the Company in the Supreme Court of **September 30, 2023** the State of New York, County of New York, entitled **Empery Asset Master Ltd., et al. v. Seelos Therapeutics, Inc.** (case No. 651525/2024), asserting a claim of fraudulent inducement. The complaint alleges that the

Company made material misrepresentations to the plaintiffs regarding the Phase II study of SLS-002 (intranasal racemic ketamine) for ASIB in patients with MDD. The Company intends to vigorously defend itself against the claims asserted against it. However, there can be no assurances that the Company will prevail in any adverse determination against the Company in these proceedings, or even the allegations contained in the claims, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions or damages that could have a material adverse effect on the Company's business, financial condition, and results of operations.

On January 30, 2024, Altasciences Clinical Los Angeles, Inc. and Altasciences Professional Los Angeles, P.C. (together "AltaSciences") filed a complaint in the Superior Court for the State of Delaware (C.A. No. N24C-01-242 FJJ) alleging breach of contract and unjust enrichment in connection with unpaid invoices. The Company was no material litigation against or involving not aware of the Company suit (due to a delay in notice) until after AltaSciences had already moved for entry of a default. Upon notice, the Company engaged Delaware counsel, who have been in discussions with counsel for AltaSciences concerning an agreement for payment of the non-disputed invoices. No default judgment order has been entered. The Company has made the first payment which was due on May 1, 2024.

13. Subsequent Events

Announcement of Strategic Focus on Mental Health and Appointment of Richard Pascoe as Chairman of the Board

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On April 29, 2024, the Company announced its strategic focus on mental health initiatives and that Richard Pascoe has been appointed as the Chairman of the Board of Directors of the Company to lead the ongoing strategic process and business development discussions and negotiations. Mr. Pascoe has served as member of the Company's Board of Directors since 2019.

Amendment No. 6 to 2021 Note

Effective May 1, 2024, the Company and Lind entered into an Amendment No. 6 to Convertible Promissory Note ("Amendment No. 6"), which amended the 2021 Note. Pursuant to Amendment No. 6, the Company and Lind agreed, among other things, that: (A) the Company shall not be required to maintain any minimum balance of cash or cash equivalents with one or more financial institutions prior to May 31, 2024, and that it shall thereafter be required to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the 2021 Note or more in cash or cash equivalents with one or more financial institutions; (B) that all payments of accrued interest and monthly payments of the outstanding principal amount payable by the Company under the 2021 Note in shares of common stock shall be reduced from ninety percent (90%) to eighty-five percent (85%) of the average of the five lowest daily volume weighted average price of common stock during the 20 trading days prior to each respective payment date; (C) Lind will, through May 31, 2024, forebear from exercising any right to assert or claim that a Material Adverse Effect (as defined in the 2021 Note) has occurred as a result of any event, occurrence, fact, condition or change that occurred on or prior to May 1, 2024.

Reduction in Force

On April 30, 2024, the Company announced a reduction in its workforce that affected approximately 33% of its current employees (the "RIF"), along with a reduction in working hours and related compensation for all of its remaining employees. This decision relates to the Company's recent announcement of its strategic focus on its mental health initiatives and serves to reduce ongoing operating expenses not related to such initiatives and extend the Company's cash runway. Total annualized cost savings from the RIF are estimated at approximately \$0.8 million and total annualized cost savings from the reduction in working hours are estimated at approximately \$1.6 million. The RIF was substantially completed on April 30, 2024.

The Company expects to recognize approximately \$50,000 in total charges for related benefits for employees whose employment was terminated pursuant to the RIF. These are one-time termination benefits and are cash charges. The estimates of costs and expenses that the Company expects to incur in connection with the RIF are subject to a number of assumptions and actual results may differ materially from those estimates. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the RIF.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Disclosures Regarding Forward-Looking Statements

The following should be read in conjunction with the unaudited condensed consolidated financial statements and the related notes that appear elsewhere in this report as well as in conjunction with the Risk Factors section and in our Annual Report on Form 10-K for the year ended **December 31, 2022** **December 31, 2023** as filed with the United States Securities and Exchange Commission ("SEC") on **March 10, 2023** **March 6, 2024** (the "Form 10-K"). This report and the Form 10-K include forward-looking statements made based on current management expectations pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended.

This report includes "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Those statements include statements regarding the intent, belief or current expectations of Seelos Therapeutics, Inc. and its subsidiaries ("we," "us," "our," the "Company" or "Seelos") and our management team. Any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and actual results may differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to those risks and uncertainties set forth in Part II, Item 1A of this report. In light of the significant risks and uncertainties inherent in the forward-looking statements included in this report, the inclusion of such statements should not be regarded as a representation by us or any other person that our objectives and plans will be achieved. Further, these forward-looking statements reflect our view only as of the date of this report. Except as required by law, we undertake no obligations to update any forward-looking statements and we disclaim any intent to update forward-looking statements after the date of this report to reflect subsequent developments. Accordingly, you should also carefully consider the factors set forth in other reports or documents that we file from time to time with the SEC.

We have common law trademark rights in the unregistered marks "Seelos Therapeutics, Inc.," "Seelos," and the Seelos logo in certain jurisdictions. Solely for convenience, trademarks and tradenames referred to in this Quarterly Report on Form 10-Q appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Overview

We are a clinical-stage biopharmaceutical company focused on achieving efficient development of products that address significant unmet needs in Central Nervous System ("CNS") disorders and other rare disorders.

Recent Developments

Top Line Results from SLS-002 Data of the Phase 2 Study in Adults 2/3 HEALEY ALS Platform trial with Major Depressive Disorder at Imminent Risk of Suicide SLS-005

On September 20, 2023 March 19, 2024, we announced provided an update on top line results data of the Phase 2/3 HEALEY ALS Platform trial. The study was designed to evaluate SLS-005 (IV trehalose), a low molecular weight disaccharide that stabilizes misfolded proteins and activates autophagy, in decreasing the slope of the ALS Functional Rating Scale (ALSFRS-R) and separation from our double-blind, placebo-controlled cohort (Part 2) placebo in Function and Mortality in an all-comers population of our Phase 2 Persons with ALS (PALS).

While the study did not meet statistical significance in the primary and secondary endpoint in the Full Analysis Set (FAS)2, by showing a 13% improvement in Function and Mortality with an 88% success probability (versus the pre-specified 98%), it showed a potential signal of SLS-002 (intranasal racemic ketamine) for Acute Suicidal Ideation and Behavior efficacy in adults a pre-specified subgroup (ERF)1.

In the pre-specified subgroup of PALS treated with Major SLS-005, without RELYVRIO®, the top-line data favored SLS-005 versus placebo in efficacy measures in the Efficacy RELYVRIO® Free (ERF)1 data set (n=130), including:

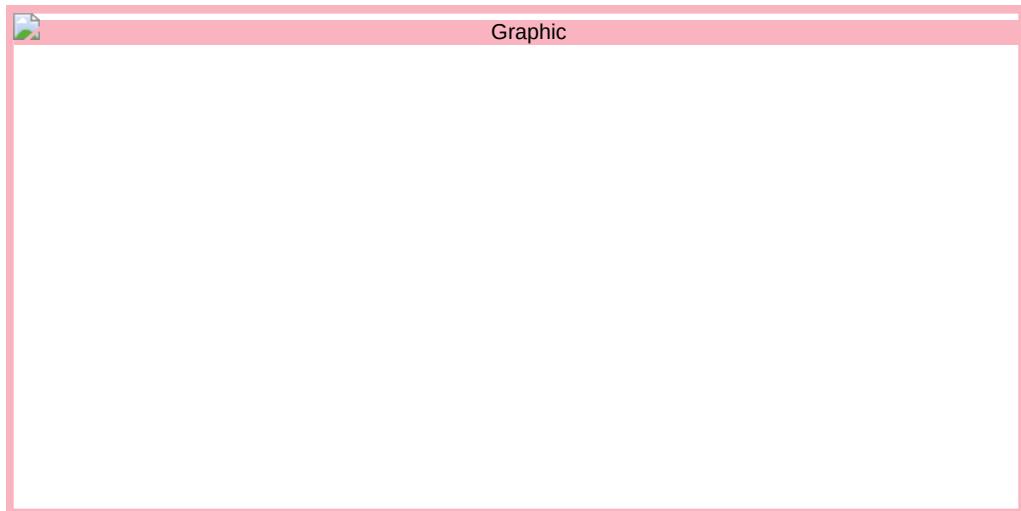
- a 22% improvement in slope of change in ALSFRS-R assessment adjusted for mortality, with an 89% success probability, at 24 weeks
- the rate of decline in ALSFRS-R slope (points per month) also favored the SLS-005 treatment group versus placebo over 6 months (-0.80 and -1.07 points per month, respectively)
- a 25% slowing of Slow Vital Capacity (SVC) decline versus placebo (-11.5% for SLS-005 and -15.4% for placebo) at 24 weeks

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Depressive Disorder. SLS-002 versus We have not yet received the full dataset and upon receiving it in the near future, we plan to run additional analyses, including biomarkers of neurodegeneration, neurofilament light chain (NFL), exploratory efficacy results, subgroups and post-hoc analyses. SLS-005 was generally well-tolerated and comparable to placebo demonstrated early and persistent reductions in symptoms safety. There was an imbalance of depression as assessed by the Montgomery-Åsberg

Depression Rating Scale ("MADRS").¹ The graph below presents results from the mixed model for repeated measures ("MMRM") analysis of change from baseline deaths/death equivalents observed in MADRS total score.



Target enrollment of this study was 220 patients, however, due to financial constraints, only 147 patients diagnosed with MDD requiring psychiatric hospitalization due to significant risk of suicide were randomized. The data from the 147 subjects (67% of target enrollment) were evaluated using the protocol-defined methods of analysis. Due to the limited sample size, the study did not meet the pre-defined primary endpoint (MADRS ANCOVA at 24 hours post dosing). However, assuming the same treatment difference and standard deviation, analyses showed that the study would have achieved statistical significance for the primary endpoint, had the study reached full enrollment (220 patients).

Detailed Summary of Key Efficacy Endpoints

- MADRS results at 4 hours after dosing demonstrated a statistically significant change relative to placebo ($p <0.001$, 5.9 point LS² mean treatment difference)
- MADRS results at 24 hours after dosing utilizing 2-way ANCOVA³ with baseline MADRS as a covariate (the pre-defined primary endpoint/analysis) demonstrated clinically meaningful results, but did not achieve statistical significance under the methodology used ($p=0.069$, 3.3 point LS mean treatment difference)
 - MADRS results at 24 hours after dosing utilizing an exploratory ANOVA (t-test) analysis demonstrated statistically significant change relative to placebo ($p=0.049$, 3.6 point mean treatment difference)
- MADRS results at Day 16 demonstrated a statistically significant change relative to placebo ($p=0.012$, 4.4 point LS mean treatment difference) – demonstrating persistence of effect
- Meaningful results further supported by (proportion of SLS-002 subjects versus placebo, respectively):
 - MADRS Response Rate, defined as $\geq 50\%$ reduction from baseline, at Day 16 (75.7% versus 47.9%) $p<0.001$
 - MADRS Remission Rate, defined as a total score ≤ 12 , at Day 16 (62.2% versus 32.9%) $p<0.001$

¹ Montgomery-Åsberg Depression Rating Scale (MADRS) scale range 0-60, higher scores indicating more severe depression.

² Least Squares (LS) Means are means estimated from a linear model that are adjusted for other effects defined events seen in the model.

³ ANCOVA is short for Analysis of Covariance. The analysis of covariance is a combination of an ANOVA and a regression analysis.

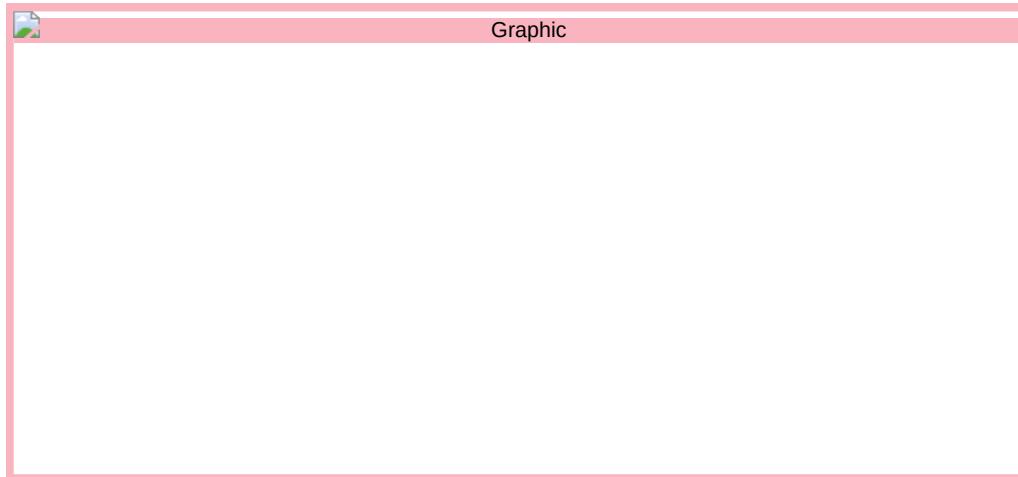
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- MADRS at end of 2-week safety follow up (Day 29/30) revealed continued improvement, demonstrating no evidence of return of symptoms.

Clinically meaningful reduction in acute suicidality was demonstrated with SLS-002 over placebo. Both groups continued SLS-005 group compared to improve over time.

- Sheehan-Suicidality Tracking Scale ("S-STS") Total Score⁴: (Mean baseline total scores were 21.4 for SLS-002 and 21.0 for placebo)
 - 4 hour change from baseline was -15.1 for SLS-002 and -12.0 for placebo (p=0.022)
 - 24 hour change from baseline was -15.5 for SLS-002 and -12.1 for placebo (p=0.008)
- Clinical Global Impression of Severity for Suicidal Ideation and Behavior ("CGIS-S/I/B")⁵ : (Mean baseline scores were 4.0 for both SLS-002 and placebo)
 - 4 hour change from baseline was -1.5 for SLS-002 and -1.1 for placebo (p=0.011)
 - 24 hour change from baseline was -1.7 for SLS-002 and -1.4 for placebo (p=0.102)

The table below represents the observed MADRS summary statistics, including the assessments collected at the safety follow-up visits.



Detailed Summary of Safety Results

SLS-002 was well-tolerated with no new or unique safety signals identified and there placebo, all were no deaths reported in the study. At least one treatment-emergent adverse event was reported in 52.7% of subjects treated with SLS-002 versus 39.7% treated with placebo; the majority of adverse events were mild or moderate and transient in nature. The most common treatment-emergent adverse events (≥5% and >placebo) were dizziness (18.9% versus 2.7%), euphoric mood (6.8% versus 0%) and suicidal ideation (5.4% versus 2.7%). There were 5 serious adverse events (3 with SLS-002, 2 with placebo), all for suicidality, all judged considered unrelated to the study drug, drug.

Populations - ERF1 and FAS2:

We received top-line results for Regimen E (RGE). This included a Full Analysis Set (FAS), an Efficacy Regimen Only (ERO) population and an Efficacy RELYVRIO® Free (ERF) population. FAS includes shared placebo from all resolved.

⁴ Sheehan-Suicidality Tracking Scale (S-STS) is a clinician-rated scale, which regimens, including RGE (n=204) and the RGE SLS-005 participants (n=120). The Efficacy Regimen Only (ERO) population includes 13 suicidality items that are rated on a scale ranging 120 RGE SLS-005 and 41 RGE placebo participants. 31 participants in the ERO population received RELYVRIO® during the SLS-005 RGE study, thus confounding results from 0 (not at all) to 4 (extremely) this population. The ERF analyses exclude participants who initiated RELYVRIO® during the study. ERF represents the participants who followed the protocol as envisioned (n=130, i.e., which yields a total score ranging from 0 to 52).

⁵ Clinical Global Impression the ERF population comprises 81% of Severity for Suicidal Ideation and Behavior (CGIS-SI/B) is a 5-point clinician-rated measure of suicidality-specific symptom severity, ranging from 1 (not at all suicidal) to 5 (among the most extremely suicidal) ERO/RGE participants.

[Table Announcement of Contents](#) Strategic Focus on Mental Health and Appointment of Richard Pascoe as Chairman of the Board

Specific scales were utilized On April 29, 2024, we announced our strategic focus on mental health initiatives and that Richard Pascoe has been appointed as the Chairman of our Board of Directors to measure lead the three most common known adverse events associated with ketamine treatments, which are dissociation, hemodynamic effects ongoing strategic process and sedation. The data below support that SLS-002 may reduce the frequency business development discussions and severity negotiations. Mr. Pascoe has served as member of these most common effects compared to what is reported with other ketamine treatments. our Board of Directors since 2019.

Clinician-Administered Dissociative States Scale ("CADSS")⁶

- At no point did the placebo-adjusted mean change from pre-dose baseline exceed the threshold of clinically meaningful dissociation (>4)
- Placebo-adjusted mean change from pre-dose baseline (at 40 minutes – correlating roughly with maximum plasma concentrations) = 3.9 after first dose and 1.8 at 1 hour post first dose
- Placebo-adjusted mean change from pre-dose baseline 2.5 on Day 4 (at 40 minutes) after second dose and 1.4 on Day 8 (at 40 minutes) after third dose

Hemodynamic Effects

- 6 subjects who received SLS-002 had an adverse event reported of either increased blood pressure or hypertension, all events were mild (except 1 moderate), all were transient and resolved
- In review of mean vital sign data for SLS-002, minimal changes were observed
 - Systolic blood pressure at Baseline was 122.7 mmHg, with maximum mean values of 126.7 mmHg on days 1 and 11 (1 hour post dose)
 - Diastolic blood pressure at Baseline was 77.7 mmHg, with maximum mean values of 81.1 mmHg on Day 8 (1 hour post dose)

Modified Observer's Assessment of Alertness/Sedation Scale ("MOAA/S")⁷

- Maximum sedation (MOAA/S score < 5) occurred approximately 15 minutes after dosing on day 1 (placebo adjusted % of subjects 25.5%) with attenuation over time

This study randomized 147 subjects diagnosed with MDD requiring psychiatric hospitalization due to significant risk of suicide and severe depression as confirmed by the rating scales as discussed above. In addition, subjects had to have at least one suicide

attempt.

After admission to the emergency room or hospital, each subject participated in a 1- to 2-day screening phase, a 16-day treatment phase, including clinical standard of care, during which the study drug was administered 2 times per week (total of 5 doses), and a 2-week safety follow-up phase for a total of up to 5 weeks of study participation. Subjects were treated as inpatients for approximately 7 days (including screening), and assuming the subject met readiness for discharge criteria, were discharged on Day **Amendment No. 6** to *continue the trial as outpatients. At study completion, all subjects were well-connected with follow-up care to ensure their safety.*

Registered Direct Offering

On September 21, 2023, we entered into a securities purchase agreement (the "September 2023 Securities Purchase Agreement") with certain purchasers identified on the signature pages thereto, pursuant to which we agreed to issue and sell 15,000,000 shares (the "RDO Shares") of our common stock and accompanying common stock warrants to purchase up to 10,010,010 shares of our common stock (the "September 2023 Warrants") in a registered direct offering (the "September 2023 RDO"). The RDO Shares and the September 2023 Warrants were offered by us pursuant to our shelf registration statement on Form S-3 (File No. 333-251356) filed with the SEC on December 15, 2020, as amended by Amendment No. 1 thereto filed with the SEC on December 22, 2020 and declared effective on December 23, 2020 (the "Registration Statement").

⁶ Clinician-Administered Dissociative States Scale (CADSS) is a standardized instrument used to measure present-state dissociative symptoms. The scale includes 23 subjective items to be answered by the subject according to a 5-point scale (0 = not at all, 1 = mild, 2 = moderate, 3 = severe, and 4 = extreme). CADSS total score range is 0-92; a higher score reflects a more severe condition.

⁷ Modified Observer's Assessment of Alertness/Sedation Scale (MOAA/S) is a 6 point scale with a score of 5 defined as responds readily to name, and a score of 0 defined as does not respond to painful stimulus.

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The exercise price of the September 2023 Warrants was \$0.325 per share, subject to adjustment as provided therein, and the September 2023 Warrants were immediately exercisable upon issuance and were to expire on the date that is five years following the original issuance date. In addition, the September 2023 Warrants contained an alternative "cashless exercise" provision whereby a September 2023 Warrant could be exchanged cashlessly for shares of our common stock at the rate of 0.999 of a share of our common stock per full share otherwise issuable upon a cash exercise. On September 26, 2023 and September 27, 2023, the holders of the September 2023 Warrants cashlessly exchanged their September 2023 Warrants in full for an aggregate of 2,222,222 and 7,777,778 shares of common stock, respectively, and no September 2023 Warrants remain outstanding

The combined purchase price for one RDO Share and accompanying September 2023 Warrants to purchase shares of our common stock for each RDO Share purchased was \$0.30. The closing of the September 2023 RDO occurred on September 25, 2023. The aggregate net proceeds from the September 2023 RDO, after deducting the fees payable to financial advisors and other estimated offering expenses, were approximately \$4.1 million. We intend to use the aggregate net proceeds to repay \$0.7 million of principal and accrued interest under that certain Convertible Promissory Note No. 1 issued to Lind Global Asset Management V,

LLC ("Lind") on November 23, 2021, as amended on December 10, 2021, February 8, 2023 and May 19, 2023 (as so amended, the "2021 Note") as required by the Letter Agreement (as defined below) and the remainder for general corporate purposes and to advance the development of our product candidates. We may also use the net proceeds from the September 2023 RDO to make periodic principal and interest payments under, or to repay a portion of, the 2021 Note.

Letter Agreement Regarding 2021 Note

On September 21, 2023, and concurrently with the execution of the September 2023 Securities Purchase Agreement, we entered into the Letter Agreement with Lind related to the 2021 Note. Pursuant to the Letter Agreement, we and Lind agreed that, in lieu of, and in full satisfaction of, both the monthly principal payment that would otherwise have been due under the 2021 Note on September 23, 2023 and the interest payment that would otherwise have been due on September 29, 2023, (i) we would, by no later than September 29, 2023, pay to Lind cash in an aggregate amount of \$0.7 million and (ii) Lind will have the right, at any time and from time to time, between the date of the closing of the September 2023 RDO and the date that is 45 days after the closing of the September 2023 RDO, to convert the remaining amount of the monthly payment that would have otherwise been due on September 24, 2023 in the aggregate amount of up to \$0.4 million into shares of our common stock at the lower of (a) the then-current Conversion Price (as defined in the 2021 Note, which is currently \$6.00 per share) and (b) 85% of the average of the five (5) lowest daily volume-weighted average price during the twenty (20) trading days prior to the delivery by Lind of the applicable conversion notice (the "Subsequent Conversion Right"). Pursuant to the Letter Agreement, Lind further agreed that (A) the payment date for the monthly payment under the 2021 Note that would otherwise have been due on October 23, 2023, and (B) the interest payment date for the interest payment under the 2021 Note that would otherwise have been due on October 31, 2023, shall be November 9, 2023.

Amendment No. 4 to 2021 Note

On September 30, 2023 Effective May 1, 2024, we and Lind entered into an Amendment No. 46 to Convertible Promissory Note ("Amendment No. 6"), which amended the 2021 Note and Note. Pursuant to Amendment to Letter Agreement (the "Amendment"), pursuant to which No. 6, we and Lind agreed, among other things, that: (A) effective as of September 30, 2023, the outstanding principal amount of the 2021 Note was increased by \$3,631,528 to \$16,837,084; (B) commencing October 1, 2023, the 2021 Note will bear interest at an annual rate of 12% per annum; (C) we shall not be required to maintain any minimum balance of cash or cash equivalents with one or more financial institutions prior to March 28, 2024 May 31, 2024, and that we shall thereafter be required to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the 2021 Note or more in cash or cash equivalents with one or more financial institutions; (D) subject to certain exceptions, if we issue securities for cash consideration, we will be required utilize 25%; (B) that all payments of accrued interest and monthly payments of the net cash proceeds to repay outstanding principal amount payable by us under the 2021 Note unless Lind elects not in shares of common stock shall be reduced from ninety percent (90%) to be repaid; (E) eighty-five percent (85%) of the average of the five lowest daily volume weighted average price of common stock during the 20 trading days prior to each respective payment date; (C) Lind will, through March 28, 2024 May 31, 2024, forebear from exercising any right to assert or claim that a Material Adverse Effect (as defined in the 2021 Note) has occurred as a result of any event, occurrence, fact, condition or change that occurred on or prior to September 30, 2023; (F) we shall use our reasonable best efforts to seek, at a special or annual meeting of our stockholders to be scheduled to be held no later than January 16, 2024, the stockholder approval as contemplated by May 1, 2024.

Nasdaq Listing Rule 5635(d) with respect to the approval of the issuance of shares of common stock in excess of the limitation on the number of shares issuable under the 2021 Note as set forth in the 2021 Note and 2021 Lind Securities Purchase Agreement; and (G) subject to certain exceptions, as long as the 2021 Note remains outstanding, Lind will have the right to participate in any equity or debt financing by us in an amount equal to the lesser of 50% of the securities to be offered and \$5,000,000 of the securities to be offered in such financing. The Amendment provides that the number of shares issuable pursuant to the Subsequent Conversion Right shall be limited to an aggregate of 1,877,084 shares of common stock, and we issued 1,877,084 shares of common stock in connection with Lind's exercise of the Subsequent Conversion Right on October 5, 2023.

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Nasdaq Minimum Bid Notice and Minimum Market Value Notice~~Delisting~~

On ~~November 1, 2023~~ April 30, 2024, we received written notice (the "First Bid Notice") from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until ~~April 29, 2024~~ October 28, 2024, to regain compliance. The First Bid Notice states that the Nasdaq staff will provide written confirmation that we have achieved compliance with Rule 5550(a)(2) if at any time before ~~April 29, 2024~~ October 28, 2024, the bid price of our common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days.

~~In addition, on November 2, 2023, we received written notice (the "Second Notice" and, together with the First Notice, the "Notices") from Nasdaq indicating that, for the last thirty-two consecutive business days, the market value~~ 27

[Table of our listed securities has been below the minimum requirement of \\$35 million for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550\(b\)\(2\) \("Rule 5550\(b\)\(2\)"\). In accordance with Nasdaq Listing Rule 5810\(c\)\(3\)\(C\), we have been provided a period of 180 calendar days, or until April 30, 2024, to regain compliance. The Second Notice states that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550\(b\)\(2\) if at any time before April 30, 2024, the market value of our common stock closes at \\$35 million or more for a minimum of ten consecutive business days.](#)
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~~The Notices have no immediate effect on the listing or trading of our common stock and the common stock will continue to trade on the Nasdaq Capital Market under the symbol "SEEL."~~

If we do not regain compliance with Rule 5550(a)(2) by ~~April 29, 2024~~ October 28, 2024, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that ~~our~~ its securities will be subject to delisting.

Additionally, ~~if on May 1, 2024, we do not regain compliance~~ received written notice (the "Delist Notice" and, together with the Bid Notice, the "Notices") from Nasdaq indicating that, based upon our continued non-compliance with Nasdaq Listing Rule 5550(b)(2) by April 30, 2024 ("Rule 5550(b)(2)"), we will receive written notification that our securities are subject to delisting. In the event we receive any such notification, we may appeal the Nasdaq staff's determination staff has determined to delist our ~~securities, but~~ common stock from the Nasdaq Capital Market effective May 10, 2024 unless we timely request an appeal of this determination before the Panel by May 8, 2024. We timely requested a hearing before the Panel, which had the effect of staying the suspension

of our common stock pending the Panel's final written decision. During the pendency of any requested hearing before the Panel, our common stock will remain listed and trading on Nasdaq.

We are diligently working to evidence compliance with all applicable requirements for continued listing on the Nasdaq Capital Market and we expect to submit a plan to that effect to the Panel as part of the hearing process; however, there can be no assurances that assurance the Nasdaq staff would Panel will grant any request for continued listing listing or that we will be able to regain compliance with the applicable listing criteria within the period of time that may be granted by the Panel. The Notices have no immediate effect on the listing or trading of our common stock and the common stock will continue to trade on the Nasdaq Capital Market under the symbol "SEEL."

We intend to monitor the bid price and market value of our common stock and consider available options if our common stock does not trade at a level likely to result in us regaining compliance with Nasdaq's minimum bid price rule by April 29, 2024 October 28, 2024, or the minimum market value of listed securities rule, by April 30, 2024, which may include, among other options, effectuating a reverse stock split. There can be no assurances assurance that we will be able to regain compliance with Nasdaq's minimum bid price rule or Nasdaq's minimum market value of listed securities rule or that we will otherwise be in compliance with the other listing standards for the Nasdaq Capital Market.

Business Update

Our business model is to advance multiple late-stage therapeutic candidates with proven mechanisms of action that address large markets with unmet medical needs and for which there is a strong economic and scientific rationale for development.

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Our product development pipeline is as follows:

Product	Indication	Development	
		Phase	Development Status
SLS-002	Acute Suicidal Ideation and	Phase II	Completed open-label patient enrollment and
Intranasal Racemic Ketamine	Behavior (ASIB) ("ASIB") in Major Depressive Disorder (MDD) ("MDD")		announced the initial topline data from Part 1 of the proof-of-concept ("PoC") study on May 17, 2021; enrollment of Part 2 of a Phase II study closed in June 2023; topline data for Part 2 announced on September 20, 2023
SLS-005 IV Trehalose	Amyotrophic Lateral Sclerosis (ALS) ("ALS")	Phase II/III	Completed enrollment of final participants in February 2023 in the registrational study; topline data readout expected in late 2023 announced on March 19, 2024

	Spinocerebellar Ataxia (SCA) ("SCA")	Phase IIb/III	In October 2022, we announced Announced dosing of the first participant in the registrational study; study in October 2022; enrollment of additional patients temporarily paused on March 29, 2023
	Huntington's Disease (HD) ("HD") and Alzheimer's Disease (AD) ("AD")	Phase II	Obtaining biomarker activity
SLS-004 Gene Therapy	Parkinson's Disease (PD) ("PD")	Pre-IND	Preclinical in vivo studies ongoing; in December 2022, we announced partial results from a study demonstrating downregulation of α -synuclein; α -synuclein in December 2022; currently analyzing data while temporarily pausing additional spend
SLS-007 Peptide Inhibitor	Parkinson's Disease (PD) PD	Pre-IND	Preclinical study completed and analysis of the results ongoing; next steps for development of this program will be decided in concert with SLS-004 results and readouts, as both target the same pathway upstream; temporarily pausing additional spend
SLS-009	HD, AD, ALS	Pre-IND	Preclinical <i>in vivo</i> studies ongoing

Lead Programs

Our lead programs are currently SLS-002 for the potential treatment of ASIB in adults with MDD and SLS-005 for the potential treatment of ALS and SCA. SLS-005 for the potential treatment of Sanfilippo Syndrome currently requires additional natural history data, which is being considered.

SLS-002 is intranasal racemic ketamine with two investigational new drug applications ("INDs"). The lead program is focused on the treatment of ASIB in MDD. SLS-002 was originally derived from a Javelin Pharmaceuticals, Inc./Hospira, Inc. program with 16 clinical studies involving approximately 500 subjects. SLS-002 is being developed to address an unmet need for an efficacious drug to treat suicidality in the United States. Traditionally, anti-depressants have been used in this setting but many of the existing treatments are known to contribute to an increased risk of suicidal thoughts in some circumstances, and if and when they are effective, it often takes weeks for the full therapeutic effect to be manifested. We believe there is a large opportunity in the United States and European markets for products in this space. Based on information gathered from the databases of the Agency for Healthcare Research and Quality, there were approximately 1.48 million visits to emergency rooms for suicidal ideation or suicide attempts in 2017 in the United States alone. Experimental studies suggest ketamine has the potential to be a rapid, effective treatment for depression and suicidality.

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The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I). We announced interim data from our Phase I study of SLS-002 during the quarterly period ended March 31, 2020. As a result, in March 2020, we completed a Type C meeting with the U.S. Food and Drug Administration (**FDA**) (the “FDA”) and received guidance to conduct a **Phase II proof of concept (“PoC”)** PoC study of SLS-002 for ASIB in adults with MDD, to support the further clinical development of this product candidate, together with nonclinical data under development.

As a result of the Type C meeting and the Fast Track designation for SLS-002 for the treatment of ASIB in patients with MDD, we believe we are well positioned to pursue the FDA’s expedited programs for drug development and review.

On June 23, 2020, we announced the final safety data from our Phase I pharmacokinetics/pharmacodynamics study of intranasal racemic ketamine (SLS-002) as well as the planned design of a Phase II double blind, placebo-controlled PoC study for ASIB in subjects with MDD. We initiated this PoC study in two parts: Part 1 was an open-label study of 17 subjects, and was followed by Part 2, which is a double blind, placebo-controlled study of approximately 175 subjects. On January 15, 2021, we announced dosing of the first subjects in Part 1 of the PoC study. On March 5, 2021, we announced the completion of open-label enrollment of subjects in Part 1 of the PoC study. On May 17, 2021, we announced positive topline data from Part 1 of the PoC study, the open-label cohort, of our study of SLS-002 (intranasal racemic ketamine), demonstrating a significant treatment effect and a well-tolerated safety profile for ASIB in patients with MDD. This study enrolled 17 subjects diagnosed with MDD requiring psychiatric hospitalization due to significant risk of suicide with a baseline score of ≥ 28 points on the Montgomery-Åsberg Depression Rating Scale (“MADRS”), a score of 5 or 6 on MADRS Item-10, a score of ≥ 15 points on the Sheehan-Suicidality Tracking Scale (S-STS) total score and a history of previous suicide attempt(s), as confirmed on the Columbia Suicide Severity Rating Scale (C-SSRS) with a history of at least one actual attempt, or if the attempt was interrupted or aborted, is judged to have been serious in intent. SLS-002 demonstrated a 76.5% response rate (response meaning 50% reduction from baseline) in the primary endpoint on MADRS twenty-four hours after first dose, with a mean reduction in total score from 39.4 to 14.5 points.

On July 6, 2021, we announced dosing of the first subject in Part 2 of the Phase II study. Based on feedback from a Type C meeting with the FDA in June 2021, we increased the subjects in Part 2 to increase the sample size and power to support a potential marketing application. On June 20, 2023, we announced the close of enrollment of this study and released the topline results on September 20, 2023.

SLS-005 is IV trehalose, a protein stabilizer that crosses the blood-brain-barrier and activates autophagy and the lysosomal pathway. Based on preclinical and in vitro studies, there is a sound scientific rationale for developing trehalose for the treatment of ALS, SCA and other indications such as Sanfilippo Syndrome. Trehalose is a low molecular weight disaccharide (0.342 kDa) that protects against pathological processes in cells. It has been shown to penetrate muscle and cross the blood-brain-barrier. In animal models of several diseases associated with abnormal cellular protein aggregation, it has been shown to reduce pathological aggregation of misfolded proteins as well as to activate autophagy pathways through the activation of Transcription Factor EB (“TFEB”), a key factor in lysosomal and autophagy gene expression. Activation of TFEB is an emerging therapeutic target for a number of diseases with pathologic accumulation of storage material.

Trehalose 90.5 mg/mL IV solution has demonstrated promising clinical potential in prior Phase II clinical development for oculopharyngeal muscular dystrophy (“OPMD”) and spinocerebellar ataxia type 3 (“SCA3”), also known as Machado Joseph disease, with no significant safety signals to date and encouraging efficacy results. Pathological accumulation of protein aggregates within cells, whether in the CNS or in muscle, eventually leads to loss of function and ultimately cell death. Prior preclinical studies indicate that this platform has the potential to prevent mutant protein aggregation in other devastating PolyA/PolyQ diseases.

We own three United States patents for parenteral administration of trehalose for patients with OPMD and SCA3, all of which are expected to expire in 2034. In addition, Orphan Drug Designation ("ODD") for OPMD and SCA3 has been secured in the United States and in the European Union ("EU"). In February 2019, we assumed a collaborative agreement, turned subsequently into a research grant, with Team Sanfilippo Foundation ("TSF"), a nonprofit medical research foundation founded by parents of children with Sanfilippo Syndrome. On April 30, 2020, we were granted ODD for SLS-005 in Sanfilippo Syndrome from the FDA. SLS-005 was previously granted ODD from the FDA and European Medicines Agency for SCA3 and OPMD as well as Fast Track designation for OPMD. On August 25, 2020, we were issued U.S. patent number 10,751,353 titled "COMPOSITIONS AND METHODS FOR TREATING AN AGGREGATION DISEASE OR DISORDER" which relates to trehalose (SLS-005). The issued patent covers the method of use for trehalose (SLS-005) formulation for treating a disease or disorder selected from any one of the following: spinal and bulbar muscular atrophy, dentatobrachial-pallidolysian atrophy, Pick's disease, corticobasal degeneration, progressive supranuclear palsy, frontotemporal dementia or parkinsonism linked to chromosome 17. On May 15, 2020, we were granted Rare Pediatric Disease

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Designation ("RPDD") for SLS-005 in Sanfilippo Syndrome from the FDA. RPDD is an incentive program created under the Federal Food, Drug, and Cosmetic Act to encourage the development of new therapies for the prevention and treatment of certain rare pediatric diseases. On May 27, 2021, we announced that we were granted ODD for SLS-005 in ALS from the European Medicines Agency. In December 2020, we announced the selection of SLS-005 for the Healey ALS platform trial led by Harvard Medical School, Massachusetts. The Healey ALS platform trial is designed to study multiple potential treatments for ALS simultaneously. The platform trial model aims to greatly accelerate the study access, reduce costs and shorten development timelines. On February 28, 2022, we announced the dosing of the first participants in the Healey ALS platform trial. In November 2021, we announced the FDA acceptance of an IND and grant of Fast Track designation for SLS-005 for the treatment of SCA. In July 2022, we also announced dosing of the first patient in an open-label basket study in Australia for the treatment of patients with ALS, SCA, and Huntington's disease ("HD"). In October 2022, we also announced the dosing of the first participant in the registrational Phase II/III study for the treatment of SCA. In March 2023, we announced that in order to focus the majority of our resources on the Phase II study of SLS-002 (intranasal racemic ketamine) for ASIB in adults with MDD and the fully enrolled Phase II/III study of SLS-005 in ALS, we have temporarily paused additional enrollment of patients in the SLS-005-302 study in SCA. Patients already enrolled will continue in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. This temporary pause has been implemented as a business decision due to financial considerations and is not based on any data related to safety or therapeutic effects.

Additionally, we are developing several preclinical programs, most of which have well-defined mechanisms of action, including SLS-004, licensed from Duke University, and SLS-007, licensed from The Regents of the University of California, for the potential treatment of Parkinson's Disease ("PD").

Strategy and Ongoing Programs

SLS-002: The clinical development program for SLS-002 includes two parallel healthy volunteer studies (Phase I). Following these Phase I studies, we completed a Type C meeting with the FDA in March 2020 and received guidance to conduct a Phase II PoC study of SLS-002 for ASIB in adults with MDD. We released topline data for Part 1 of our open-label study on May 17, 2021. We

initiated enrollment in Part 2 of the Phase II study on July 6, 2021, closed enrollment in June 2023, and released the topline results in the third quarter of 2023. See “—Recent Developments – Top Line Results from SLS-002 Phase II Study in Adults with Major Depressive Disorder at Imminent Risk of Suicide” above.

SLS-005: We completed enrollment in February 2023 for a clinical study in ALS and began enrollment for a clinical study in SCA in October 2022. In December 2020, we announced the selection of SLS-005 for the Healey ALS platform trial led by Harvard Medical School, Massachusetts. The Healey ALS platform trial is designed to study multiple potential treatments for ALS simultaneously. The platform trial model aims to greatly accelerate the study access, reduce costs, and shorten development timelines. On February 28, 2022, we announced dosing of the first participants in the Healey ALS platform trial. In February 2023, we announced the completion of enrollment of the study and released the topline data readout is expected in late 2023. results on March 19, 2024. See “—Recent Developments – Top Line Data of the Phase 2/3 HEALEY ALS Platform trial with SLS-005” above.

In November 2021, we announced the FDA acceptance of an IND and grant of Fast Track designation for SLS-005 for the treatment of SCA. In July 2022, we announced dosing of the first patient in an open-label basket study in Australia for the treatment of patients with ALS, SCA, and HD. In October 2022, we also announced the dosing of the first participant in the registrational Phase II/III study for the treatment of SCA.

During 2022, we received regulatory approval in Australia to commence a study pursuing the collection of certain biomarker data in patients with Alzheimer’s Disease.

We are also continuing to consider trials in Sanfilippo Syndrome and are seeking more natural history data based on the guidance from regulatory agencies.

In March 2023, we announced that in order to focus the majority of our resources on the Phase II study of SLS-002 (intranasal racemic ketamine) for ASIB in patients with MDD and the fully enrolled Phase II/III study of SLS-005 in ALS, we have temporarily paused additional enrollment of patients in the SLS-005-302 study in SCA. Patients already enrolled will continue in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. This temporary pause has been implemented as a business decision due to financial considerations and is not based on any data related to safety or therapeutic effects.

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SLS-004 is an all-in-one lentiviral vector, targeted for gene editing through DNA methylation within intron 1 of the synuclein alpha (“SNCA”) gene that expresses alpha-synuclein protein. SLS-004, when delivered to dopaminergic neurons derived from human induced pluripotent stem cells of a PD patient, modified the expression on alpha-synuclein (“ α -synuclein”) and exhibited reversal of the disease-related cellular-phenotype characteristics of the neurons. The role of mutated SNCA in PD pathogenesis and the need to maintain the normal physiological levels of α -synuclein protein emphasize the yet unmet need to develop new therapeutic strategies, such as SLS-004, targeting the regulatory mechanism of α -synuclein expression. On May 28, 2020, we announced the initiation of a preclinical study of SLS-004 in PD through an all-in-one lentiviral vector targeting the SNCA gene. We are constructing a bimodular viral system harboring an endogenous α -synuclein transgene and inducible regulated repressive CRISPR/dCas9-unit to achieve suppression of PD-related pathologies. On July 7, 2021, we announced positive in vivo data demonstrating down-regulation of SNCA mRNA and protein expression under this study. In December 2022, we announced in vivo

data demonstrating that a single dose of SLS-004 was successful in reversing some of the key hallmarks of PD in a humanized mouse model. These findings observed in an in vivo humanized PD model validate and extend prior findings from in vitro data using SLS-004. SLS-004 demonstrated therapeutically desirable change in SNCA expression that led to reversing the key hallmarks of PD in the model towards normal physiological levels, indicating disease modifying effect of single dose administration of SLS-004, a CRISPR/dCas-9 based gene therapy for PD. We have halted any further investment in this program until additional funding is received.

SLS-007 is a rationally designed peptide-based approach, targeting the nonamyloid component core ("NACore") of α -synuclein to inhibit the protein from aggregation. Recent in vitro and cell culture research has shown that SLS-007 has the ability to stop the propagation and seeding of α -synuclein aggregates. We will evaluate the potential for in vivo delivery of SLS-007 in a PD transgenic mice model. The goal will be to establish in vivo pharmacokinetics/pharmacodynamics and target engagement parameters of SLS-007, a family of anti- α -synuclein peptidic inhibitors. On June 25, 2020, we announced the initiation of a preclinical study of SLS-007 in PD delivered through an adeno associated viral ("AAV") vector targeting the non-amyloid component core of α -synuclein. We have initiated an in vivo preclinical study of SLS-007 in rodents to assess the ability of two specific novel peptides, S62 and S71, delivered via AAV1/2 viral vector, to protect dopaminergic function in the AAV A53T overexpression mice model of PD. Production of AAV1/2 vectors encoding each of the two novel peptides incorporating hemagglutinin tags has already been completed. The results are currently being analyzed and the next steps for development of this program will be decided in concert with SLS-004 results and readouts, as both target the same pathway upstream.

SLS-009 is our first internally created program, which follows the mechanism of action known as PROTACs (protein-targeting chimeric molecules), which uses the body's own natural process of autophagy and lysosomal degradation to clear out mutant and misfolded proteins in the body. SLS-009 induces autophagy and enhances lysosomal clearance by augmenting existing endogenous cellular degradation pathways to remove only the mutant and neurotoxic proteins.

We intend to become a leading biopharmaceutical company focused on neurological and psychiatric disorders, including orphan indications. Our business strategy includes:

- advancing SLS-002 in ASIB in MDD and post-traumatic stress disorder;
- advancing SLS-004 in PD;
- advancing SLS-005 in ALS, SCA, HD and Sanfilippo Syndrome;
- advancing new formulations of SLS-005 in neurological diseases; and
- acquiring synergistic assets in the CNS therapy space through licensing and partnerships.

We also have two legacy product candidates: a product candidate in the United States for the treatment of erectile dysfunction, which we in-licensed from Warner Chilcott Company, Inc., now a subsidiary of Allergan plc; and a product candidate which has completed a Phase IIa clinical trial for the treatment of Raynaud's Phenomenon, secondary to scleroderma, for which we own worldwide rights.

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Liquidity, Capital Resources and Financial Condition

Liquidity

We have generated limited revenues, incurred operating losses since inception, and we expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of **September 30, 2023** **March 31, 2024**, we had **\$2.6 million** **\$0.5 million** in cash and an accumulated deficit of **\$247.2 million** **\$255.3 million**. We have historically funded our operations through the issuance of convertible notes (the "Notes") (see Note 9 to our condensed consolidated financial statements), the sale of common stock and warrants (see Note 6 to our condensed consolidated financial statements) and the exercise of warrants (see Note 10 to our condensed consolidated financial statements).

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Table On January 26, 2024, we entered into a securities purchase agreement (the "January 2024 Securities Purchase Agreement"), with certain institutional investors (the "January Investors"), pursuant to which, on January 30, 2024, we issued and sold 3,404,256 shares (the "January Shares") of **Contents** common stock in a registered direct offering (the "January 2024 RDO"). In a concurrent private placement (the "January 2024 Private Placement" and together with the January 2024 RDO, the "January 2024 Offering"), we also agreed to issue and sell to the January Investors the warrants to purchase up to 3,404,256 shares of common stock (the "January 2024 Common Warrants"). The combined purchase price for one January Share and accompanying January 2024 Common Warrant to purchase one share for each share of common stock purchased was \$1.175.

The January 2024 Common Warrants have an exercise price of \$1.05 per share of common stock, are exercisable immediately upon issuance and expire five years following the initial date of exercise. The exercise price and number of shares of common stock issuable upon the exercise of the January 2024 Common Warrants will be subject to adjustment in the event of any stock dividend, stock split, reverse stock split, recapitalization, reorganization or similar transaction, as described in the January 2024 Common Warrants. If at any time after the six-month anniversary of the date of issuance, a registration statement covering the issuance of the shares of common stock issuable upon exercise of the January 2024 Common Warrants is not available for the issuance, then the holders may exercise the January 2024 Common Warrants by means of a "cashless exercise."

Pursuant to an underwriting agreement (the "Underwriting Agreement") with Titan Partners Group, LLC, a division of American Capital Partners, LLC ("Titan"), on December 1, 2023, we sold to Titan, in an underwritten public offering (i) 1,781,934 shares of our common stock, (ii) pre-funded warrants to purchase up to 2,422,612 shares of common stock (the "December 2023 Pre-Funded Warrants") and (iii) accompanying common stock warrants to purchase up to 4,204,546 shares of common stock (the "December 2023 Common Warrants" and together with the December 2023 Pre-Funded Warrants, the "December 2023 Warrants"). The combined public offering price for each share of common stock and accompanying December 2023 Common Warrant to purchase one share of common stock was \$1.32 and the combined public offering price for each share of common stock subject to a December 2023 Pre-Funded Warrant and accompanying December 2023 Common Warrant to purchase one share of common stock was \$1.319. The net proceeds to us were approximately \$5 million, after deducting the underwriting discounts and commissions and other estimated offering expenses payable by us. The December 2023 Pre-Funded Warrants were exercised in full during the year ended December 31, 2023.

The per share exercise price for the December 2023 Common Warrants is \$1.32, subject to adjustment as provided therein. The December 2023 Common Warrants were exercisable immediately and expire on December 1, 2028. Each holder of a December 2023 Common Warrant does not have the right to exercise any portion of its December 2023 Common Warrant if the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the purchaser, 9.99%) of the number of shares of the common stock outstanding immediately after giving effect to such exercise (the "Common Warrant Beneficial Ownership Limitation"); provided, however, that upon 61 days' prior notice to us, the holder may increase the Common Warrant Beneficial Ownership Limitation, but not to above 9.99%. The exercise price and number of shares of common stock issuable upon

the exercise of the December 2023 Common Warrants is subject to adjustment in the event of any stock dividend, stock split, reverse stock split, recapitalization, reorganization or similar transaction, as described in the December 2023 Common Warrants. If a registration statement covering the issuance of the shares of common stock issuable upon exercise of the December 2023 Common Warrants is not available for the issuance, then the holders may exercise the Common Warrants by means of a "cashless exercise."

On September 21, 2023, we entered into a Securities Purchase Agreement (the "September 2023 Securities Purchase Agreement") with certain purchasers identified on the signature pages thereto (the "Purchasers"), pursuant to which, on September 25, 2023, we issued and sold 15,000,000 500,000 shares (the "Shares") of our common stock and accompanying common stock warrants to purchase up to 10,010,010 333,667 shares of common stock (the "September 2023 Warrants") in a registered direct offering (the "September 2023 RDO"). The Shares shares of common

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stock and the September 2023 Warrants were offered by us pursuant to our Registration Statement. The exercise price of the September 2023 Warrants was \$0.325 \$9.75 per share, subject to adjustment as provided therein, and the September 2023 Warrants were immediately exercisable upon issuance and were to expire on the date that is five years following the original issuance date. In addition, the September 2023 Warrants contained an alternative "cashless exercise" provision whereby a September 2023 Warrant may be exchanged cashlessly for shares of common stock at the rate of 0.999 of a share of common stock per full share otherwise issuable upon a cash exercise. The combined purchase price for one Share share of common stock and accompanying September 2023 Warrants to purchase shares of common stock for each Share share purchased was \$0.30. \$9.00. The aggregate net proceeds from the Offering, after deducting the fees payable to financial advisors and other estimated offering expenses, were approximately \$4.1 million. We intend to use the aggregate net proceeds (excluding proceeds from any September 2023 Warrant exercises) to repay \$0.7 million of principal and accrued interest under the 2021 Note as required by the Letter Agreement and the remainder for general corporate purposes and to advance the development of our product candidates. We may also use the net proceeds from the September 2023 RDO to make periodic principal and interest payments under, or to repay a portion of, the 2021 Note. The fair value of these warrants the September 2023 Warrants upon issuance was \$1.9 million and such amount was included within warrant liabilities, at fair value on the condensed consolidated balance sheets on the condensed consolidated balance sheets. On September 26, 2023 and September 27, 2023, the holders of the September 2023 Warrants cashlessly exchanged their September 2023 Warrants in full for an aggregate of 2,222,222 74,075 and 7,777,778 259,260 shares of common stock, respectively, and no September 2023 Warrants remain outstanding. As a result of the exercise of the September 2023 Warrants, we recognized a \$100,000 expense within change in fair value of warrant liabilities on the condensed consolidated statement of operations.

On March 10, 2023, we entered into a Securities Purchase Agreement (the "2023 March 2023 Securities Purchase Agreement") with a life sciences-focused investment fund (the "Investor" "March Investor"), pursuant to which we issued and sold an aggregate of 12,059,298 401,977 shares of common stock, pre-funded warrants exercisable for an aggregate of 9,340,702 311,357 shares of common stock and accompanying common warrants exercisable for an aggregate of 26,750,000 891,667 shares of common stock in a registered direct offering, resulting in total net proceeds of \$10.4 million, after deducting financial advisor fees and other offering expenses. On May 19, 2023, we entered into Amendment No. 1 to the March 2023 Securities Purchase Agreement Amendment (the "2023 Purchase Agreement Amendment") pursuant to which the March Investor agreed to, among other things,

waive certain restrictions on issuing and registering shares of common stock contained within the March 2023 Securities Purchase Agreement to permit us to make the May Through September Payments in a combination of cash and shares of common stock as contemplated in the 2021 Note Amendment. In consideration for entering into the 2023 Purchase Agreement Amendment, on May 19, 2023, we issued to the March Investor warrants to purchase up to an aggregate of 4,000,000 133,334 shares of common stock. The fair value of these warrants upon issuance was \$3.2 million and is included within loss on extinguishment of debt on the condensed consolidated statement of operations.

On May 12, 2022 As of March 31, 2024, we entered into an Open Market Sale Agreements had \$246.0 million available under a shelf registration statement on Form S-3 (File No. 333-276119) filed with the SEC on December 18, 2023, which was declared effective on December 27, 2023 (the "Sale Agreement" "Registration Statement") with Jefferies LLC,. However, for so long as sales agent (the "Agent") our public float remains less than \$75 million, in no event will we sell securities pursuant to which we may offer and sell shares shelf registration statements, including pursuant to the Shelf Registration Statement, with a value more than one-third of the aggregate market value of our common stock from time to time through the Agent (the "Offering"). We also filed a prospectus supplement, dated May 12, 2022, with the SEC held by non-affiliates in connection with the Offering (the "Prospectus Supplement") under our existing shelf Registration Statement on Form S-3, as amended (File No. 333-251356), which became effective on December 23, 2020 (the "Registration Statement"). Pursuant to the Prospectus Supplement, we may offer and sell shares having an aggregate offering price of up to \$50.0 million. Under the terms of the Sale Agreement, the Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sale Agreement. We also reimburse the Agent for certain expenses incurred in connection with the Sale Agreement and agreed to provide indemnification and contribution to the Agent with respect to certain liabilities, including liabilities under the Securities Act of 1933, as amended (the "Securities Act"), and the Exchange Act. During the nine months ended September 30, 2023, we sold an aggregate of 75,768 shares under the Sale Agreement, receiving net proceeds of \$68,000. However, we agreed in the 2023 Securities Purchase Agreement that we would not, subject to certain exceptions (including in relation to the satisfaction of the May Through September Payments), effect or enter into an agreement to effect any issuance of shares of common stock or common stock equivalents involving a variable rate transaction, which includes the Sale Agreement, until the earlier of: (a) such time as no investor holds any warrants issued in the Registered Direct Offering, and (b) September 21, 2026 (or, in the case of an at-the-market offering, September 21, 2024).

As of September 30, 2023, we had approximately \$59.4 million available under the Registration Statement (inclusive of the \$49.5 million that remained allocated to sales of shares of our common stock pursuant to the Sale Agreement as of such date). 12-month period.

On November 23, 2021, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with Lind Global Asset Management V, LLC ("Lind") pursuant to which, among other things, on November 23, 2021, we issued and sold to Lind, V, in a private placement transaction, in

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exchange for the payment by Lind of \$20.0 million, (1) a convertible promissory note (the "2021 Note") in an initial aggregate principal amount of \$22.0 million, which will bear bore no interest until the first anniversary of the issuance of the 2021 Note and will

thereafter bear bore interest at a rate of 5% per annum until October 1, 2023 when the 2021 Note began to bear interest at an annual rate of 12% per annum, and will mature on November 23, 2024, and (2) 534,759 17,826 shares of our common stock.

We evaluated whether there are any conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year beyond the filing of this Quarterly Report on Form 10-Q. Based on such evaluation and our current plans (including the ongoing clinical programs for SLS-002, SLS-005, and other product candidates), which are subject to change, management believes that our existing cash and cash equivalents as of September 30, 2023 March 31, 2024 are not sufficient to satisfy our operating cash needs and that there is substantial doubt about our ability to continue as a going concern for the year after the filing of this Quarterly Report on Form 10-Q.

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The accompanying unaudited condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to our ability to continue as a going concern.

Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our ability to raise additional funds to finance our operations;
- our ability to maintain compliance with the listing requirements of the Nasdaq Capital Market;
- the outcome, costs and timing of any clinical trial results for our current or future product candidates;
- potential litigation expenses;
- the emergence and effect of competing or complementary products or product candidates;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our ability to retain our current employees and the need and ability to hire additional management and scientific and medical personnel;
- the terms and timing of any collaborative, licensing or other arrangements that we have or may establish;
- the trading price of our common stock; and
- our ability to increase the number of authorized shares as may be required to facilitate future financing events.

The 2021 Note contains certain restrictive covenants and event of default provisions, including a covenant requiring us to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the 2021 Note or more in cash and cash equivalents commencing on March 28, 2024 May 31, 2024. As of September 30, 2023 May 8, 2024, the outstanding principal amount of the 2021 Note was \$16.8 million \$12.6 million. Based on our current operating plan and our cash balance as of September 30, 2023 March 31, 2024, we do not expect be able to maintain the minimum cash balance required to satisfy the minimum cash covenant if we do not raise additional financing by March 28, 2024 May 31, 2024. If we are unable to cure such default within fifteen business days from its occurrence or otherwise obtain a waiver from Lind or amend the terms of the 2021 Note, we would trigger a default under the 2021 Note. If we are not able to comply or regain compliance with any of the covenants in, or otherwise trigger a default under, the 2021 Note, Lind could declare the 2021 Note immediately due and payable, which would require us to pay 120% of the outstanding principal amount of the 2021 Note and would have a material adverse effect on our liquidity, financial condition, operating results, business and prospects, and could cause the price of our common stock to

decline. In addition, since the borrowings under the 2021 Note are secured by a first priority lien on our assets, Lind would be able to foreclose on our assets if we do not cure any default or pay any amounts due and payable under the 2021 Note. In addition, upon an Event of Default (as defined in the 2021 Note), Lind shall have the right to convert the then outstanding principal amount of the 2021 Note into shares of our common stock at the lower of (x) the then-current conversion price (which is currently **\$6.00** \$180.00 per share, subject to adjustment in certain circumstances as described in the 2021 Note) and (y) 85% of the average of the five lowest daily volume weighted average price of our common stock during the 20 trading days prior to the delivery by Lind of a notice of conversion.

Accordingly, we will need to raise substantial additional funds, and if we do so, we may do so through one or more of the following: issuance of additional debt, equity, or both and/or the completion of a licensing or other commercial transaction for one or more of our product candidates. If we are unable to maintain sufficient financial resources, our business, financial condition, and results of operations will be materially and adversely affected. This could adversely affect future development and business activities, operations, and business plans, such as future clinical studies and/or other future ventures. There can be no assurance that we will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or convertible debt financings may have a

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dilutive effect on the holdings of our existing stockholders. No assurances can be given that we will be able to obtain additional financing.

Critical Accounting Estimates and Policies

The preparation of financial statements in accordance with United States generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in our unaudited condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience, market and other conditions, and various other assumptions it believes to be reasonable. Although these estimates are based on management's best knowledge of current events and actions that may impact us in the future, the estimation process is, by its nature, uncertain given that estimates

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depend on events over which we may not have control. If market and other conditions change from those that we anticipate, our unaudited condensed consolidated financial statements may be materially affected. In addition, if our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material effect in our unaudited condensed consolidated financial statements. We review our estimates, judgments, and assumptions used in our accounting

practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, our actual results may differ from these estimates.

Our critical accounting policies and estimates are discussed in our Annual Report on Form 10-K for the fiscal year ended **December 31, 2022** **December 31, 2023**, and there have been no material changes to such policies or estimates during the **nine** **three** months ended **September 30, 2023** **March 31, 2024**.

Recent Accounting Pronouncements

Please refer to the notes to the unaudited condensed consolidated financial statements for a discussion of recent accounting pronouncements.

Comparison of the Three Months Ended **September 30, 2023** **March 31, 2024** and **2022** **2023**

Operating Expense

Operating expense was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Three Months Ended March 31,			
	Three Months Ended September 30,		2023 vs 2022		Three Months Ended March 31,		2024 vs 2023	
	2023	2022	\$ Change	% Change	2024	2023	\$ Change	% Change
Operating expense								
Research and development	\$ 10,022	\$ 14,750	\$ (4,728)	-32%	\$ 3,525	\$ 5,668	\$ (2,143)	-38%
General and administrative	2,987	2,660	327	12 %	3,109	4,072	(963)	-24%
Total operating expense	\$ 13,009	\$ 17,410	\$ (4,401)	-25%	\$ 6,634	\$ 9,740	\$ (3,106)	-32%

Research and Development Expenses

Research and development expenses were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Three Months Ended March 31,			
	Three Months Ended September 30,		2023 vs 2022		Three Months Ended March 31,		2024 vs 2023	
	2023	2022	\$ Change	% Change	2024	2023	\$ Change	% Change
Research and development expenses								
Clinical trial expenses	\$ 6,494	\$ 10,913	\$ (4,419)	-40%	\$ 1,749	\$ 2,505	\$ (756)	-30%
Manufacturing expenses	2,072	2,064	8	0 %	310	1,483	(1,173)	-79%
Employee compensation	1,096	1,234	(138)	-11%	1,323	1,200	123	10 %

Contract consulting expenses	360	535	(175)	-33%	143	480	(337)	-70%
Other research and development expenses	—	4	(4)	-100%				
Total research and development expenses	\$ 10,022	\$ 14,750	\$ (4,728)	-32%	\$ 3,525	\$ 5,668	\$ (2,143)	-38%

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Research and development ("R&D") costs are expensed as they are incurred and include the cost of compensation and related expenses, as well as expenses for third parties who conduct R&D on our behalf. The \$4.7 million \$2.1 million decrease in R&D expenses during the three months ended September 30, 2023 March 31, 2024, as compared to the same period in 2022, 2023, resulted primarily from a decrease in clinical trial expenses of approximately \$4.4 million, mainly \$0.8 million and a decrease in manufacturing expenses of approximately \$1.2 million due to the completion wind down of enrollment for the ongoing SLS-005 HEALEY clinical trial and the SLS-002 study in ASIB with MDD trials.

General and Administrative Expenses

General and administrative ("G&A") costs include expenses for personnel, finance, legal, business development and investor relations. G&A expenses increased decreased by \$327,000 \$1.0 million during the three months ended September 30, 2023 March 31, 2024, as compared to the same period in 2022, 2023. This increase was primarily from an increase a decrease in legal financial costs in the three months ended September 30, 2023 March 31, 2024 compared to the three months ended September 30, 2022 March 31, 2023.

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Other Income and Expense

Other income and expense were as follows (in thousands):

	Three Months Ended September 30,			Three Months Ended March 31,		
	2023	2022	\$ Change	2024	2023	\$ Change
Other income (expense)						
Interest income	\$ 36	\$ 36	\$ —	\$ 10	\$ 67	\$ (57)
Interest expense	(42)	(2)	(40)	(23)	(7)	(16)
Change in fair value of convertible notes	(799)	(2,137)	1,338	(203)	66	(269)
Loss on extinguishment of debt	(3,631)	—	(3,631)	(1,493)	(13)	(1,480)
Loss on issuance of common stock and warrants				—	(4,301)	4,301
Change in fair value of warrant liabilities	27,537	(91)	27,628	5,100	(311)	5,411
Total other income (expense)	\$ 23,101	\$ (2,194)	\$ 25,295	\$ 3,391	\$ (4,499)	\$ 7,890

Interest Income

Interest income was \$36,000 \$10,000 and \$67,000 for each of the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively.

Interest Expense

Interest expense was \$42,000 \$23,000 and \$2,000 \$7,000 for the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively.

Change in Fair Value of Convertible Notes

Change in fair value of convertible notes was an expense of \$0.8 million \$0.2 million and \$2.1 million a gain of \$0.1 million for the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. This change was due to our 2021 convertible notes issued in November 2021 and December 2021, which have been accounted for under the fair value option and are revalued at each reporting period, with changes in fair value reflected in earnings.

Loss on Extinguishment of Debt

Loss on extinguishment of debt for was an expense of \$1.5 million and \$13,000 for the three months ended September 30, 2023 March 31, 2024 and 2023, respectively. The March 2024 expense was due to the increase in principal amount of the 2021 Note of \$3.6 million \$1.5 million in connection with the amendment of the 2021 Note in September of 2023, March 2024.

Change in Fair Value of Warrant Liabilities

The fair value of warrant liability was \$4.1 million at September 30, 2023 \$3.8 million and \$5.8 million as of March 31, 2024 and December 31, 2023, respectively. For the three months ended September 30, 2023 March 31, 2024, the change in fair value of warrant liabilities was \$27.5 million \$5.1 million, which income loss was due to the revaluation of warrants during such period. period and the issuance of the January 2024 Common Warrants. The change in fair value of the warrant liability during the three months ended September 30, 2023 March 31, 2024 was comprised of \$0.3 million for the Series A Warrants, \$24.0 million \$0.4 million for the March 2023 Warrants, and \$3.4 million \$28,000 for the May 2023 Warrants, \$1.9 million for the December 2023 Warrants and \$1.5 million for the January 2024 Common Warrants. For the three months ended September 30, 2022 March 31, 2023, the change in fair value of warrant liabilities was \$91,000, which income was due to the revaluation of the Series A Warrants during such period.

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Comparison of the Nine Months Ended September 30, 2023 and 2022
Operating Expense

Operating expense was as follows (in thousands, except percentages):

	Nine Months Ended September 30,			
	Nine Months Ended September 30,		2023 vs 2022	
	2023	2022	\$ Change	% Change
Operating expense				
Research and development	\$ 24,199	\$ 43,115	\$ (18,916)	-44%
General and administrative	9,839	9,544	295	3 %
Total operating expense	\$ 34,038	\$ 52,659	\$ (18,621)	-35%

Research and Development Expenses

Research and development expenses were as follows (in thousands, except percentages):

	Nine Months Ended September 30,			
	Nine Months Ended September 30,		2023 vs 2022	
	2023	2022	\$ Change	% Change
Research and development expenses				
License payments	\$ —	\$ 5,840	\$ (5,840)	-100%
Clinical trial expenses	15,083	26,657	(11,574)	-43%
Manufacturing expenses	4,142	5,476	(1,334)	-24%
Employee compensation	3,612	3,556	56	2 %
Contract consulting expenses	1,362	1,586	(224)	-14%
Total research and development expenses	\$ 24,199	\$ 43,115	\$ (18,916)	-44%

R&D costs are expensed as they are incurred and include the cost of compensation and related expenses, as well as expenses for third parties who conduct R&D on our behalf. The \$18.9 million decrease in R&D expenses during the nine months ended September 30, 2023, as compared to the same period in 2022, resulted primarily from (i) a decrease of \$5.8 million in R&D license expenses pursuant to the Vyera Purchase Agreement which occurred in the second quarter of 2022, (ii) a decrease in clinical trial expenses of approximately \$11.6 million, mainly due to the completion of enrollment for the ongoing SLS-005 HEALEY clinical trial and the SLS-002 study in ASIB with MDD, and (iii) a decrease in manufacturing expenses of approximately \$1.3 million, mainly related to clinical supplies needed to support the SLS-005 clinical programs.

General and Administrative Expenses

G&A costs include expenses for personnel, finance, legal, business development and investor relations. G&A expenses increased by \$0.3 million during the nine months ended September 30, 2023, as compared to the same period in 2022.

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Other Income and Expense

Other income and expense were as follows (in thousands):

	Nine Months Ended September 30,		
	2023	2022	\$ Change
Other income (expense)			
Interest income	\$ 186	\$ 81	\$ 105
Interest expense	(56)	(14)	(42)
Change in fair value of convertible notes	(1,349)	(2,477)	1,128
Loss on extinguishment of debt	(9,151)	—	(9,151)
Loss on issuance of common stock and warrants	(4,301)	—	(4,301)
Change in fair value of warrant liabilities	14,730	192	14,538
Total other income (expense)	\$ 59	\$ (2,218)	\$ 2,277

Interest Income

Interest income was \$186,000 and \$81,000 for the nine months ended September 30, 2023 and 2022, respectively. The increase in interest income primarily related to the higher interest rate earned during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022.

Interest Expense

Interest expense was \$56,000 and \$14,000 for the nine months ended September 30, 2023 and 2022, respectively.

Change in Fair Value of Convertible Notes

Change in fair value of convertible notes was \$1.3 million, and \$2.5 million for the nine months ended September 30, 2023 and 2022, respectively.

Loss on Extinguishment of Debt

Loss on extinguishment of debt for the nine months ended September 30, 2023 was due to the issuance of 1.0 million shares (fair value of \$1.0 million), 4.0 million warrants (fair value of \$3.2 million) and an increase in principal amount of the 2021 Note of \$1.3 million and \$3.6 million in connection with the amendments of the 2021 Note in May and September of 2023, respectively.

Loss on Issuance of Common Stock and Warrants

Loss on issuance of warrants were \$4.3 million for the nine months ended September 30, 2023. This loss is attributable to the valuation of the warrants associated with the March 2023 RDO that closed in March 2023.

Change in Fair Value of Warrant Liabilities

The fair value of warrant liability was \$4.1 million at September 30, 2023. For the nine months ended September 30, 2023, the change in fair value of warrant liabilities was \$14.7 million, which income was due to the revaluation of the warrants during such period. The change in fair value of the warrant liability during the nine months ended September 30, 2023 was comprised of \$0.1 million for the Series A Warrants, \$12.0 million for the March 2023 Warrants and \$2.8 million for the May 2023 Warrants. For the nine months ended September 30, 2022, the change in fair value of warrant liabilities was \$192,000, which income was due to the revaluation of the Series A Warrants during such period.

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Cash Flow Summary

The following table summarizes selected items in our unaudited condensed consolidated statements of cash flows (in thousands):

	Nine Months Ended		Three Months Ended	
	September 30,	2023	March 31,	2024
2022	2024	2023	2023	
Net cash (used in) provided by operations				
Net cash used in operating activities	\$ (22,001)	\$ (48,514)	\$ (4,642)	\$ (10,348)
Net cash provided by financing activities	9,052	291	2,170	8,874
Net decrease in cash	\$ (12,949)	\$ (48,223)	\$ (2,472)	\$ (1,474)

Operating Activities

Cash used in operating activities of \$22.0 million \$4.6 million during the nine three months ended September 30, 2023 March 31, 2024 was primarily due to a net loss of \$32.3 million \$2.7 million and change in fair value of warrant liability of \$14.7 million, \$5.1 million which was partially offset by non-cash adjustment related to changes in operating assets and liabilities of \$7.3 million \$0.5 million, loss on extinguishment of debt of \$9.2 million \$1.5 million, loss on issuance of common stock and warrants of \$4.3 million, stock-based compensation expense of \$3.0 million and change in fair value of convertible notes payable of \$1.3 million \$0.2 million, and stock-based compensation expense of \$1.0 million.

Cash used in operating activities of \$48.5 million \$10.3 million during the nine three months ended September 30, 2022 March 31, 2023 was primarily due to a net loss of \$54.9 million \$13.4 million and changes in operating assets and liabilities of \$1.0 million \$2.6 million, which was partially offset by non-cash adjustment related to stock-based compensation expense of \$4.2 million \$1.1 million, loss on issuance of common stock and warrants of \$4.3 million and change in fair value of our convertible notes payable warrant liability of \$2.5 million \$0.3 million.

Financing Activities

Cash provided by financing activities of **\$9.1 million** **\$2.2 million** during the **nine** three months ended **September 30, 2023** **March 31, 2024** was primarily due to proceeds from issuances of common stock and warrants of **\$15.6 million** **\$3.5 million**, which was partially offset by principal and interest payments of our convertible debt of **\$5.5 million** **\$1.3 million**.

Cash provided by financing activities of **\$8.9 million** during the three months ended March 31, 2023 was primarily due to proceeds from issuances of common stock and warrants of **\$11.2 million**, which was partially offset by principal and interest payments of our convertible debt of **\$1.3 million** and the repurchase of common stock under the Vyera Repurchase Agreement of **\$1.2 million**.

Cash provided by financing activities of **\$0.3 million** during the nine months ended September 30, 2022 was primarily due to proceeds from issuances of common stock pursuant to the Sale Agreement.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our disclosure controls and procedures are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, communicated to our management to allow timely decisions regarding required disclosure, summarized and reported within the time periods specified in the SEC's rules and forms.

Under the supervision and with the participation of our management, including the Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of **September 30, 2023** **March 31, 2024**. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of **September 30, 2023** **March 31, 2024** at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no material changes to our internal control over financial reporting during the **nine** three months ended **September 30, 2023** **March 31, 2024**.

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PART II.

ITEM 1. LEGAL PROCEEDINGS

We are not currently party to information pertaining to and none legal proceedings can be found in Note 12 of our property is currently the subject of, any material legal proceedings. We may be a party to certain litigation that is either judged to be not material or that arises in the ordinary course of business from time to time. We intend to vigorously defend our interests in these matters. We expect that the resolution of these matters will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in the Condensed Consolidated Financial Statements included elsewhere in litigation, no assurance can be given as to the outcome of these proceedings. this Quarterly Report on Form 10-Q and is incorporated by reference herein.

ITEM 1A. RISK FACTORS

We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Quarterly Report on Form 10-Q and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below, and should be carefully considered, together with all of the other information appearing in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the SEC before making investment decisions regarding the common stock. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition, and results of operations.

- We are a clinical-stage company, we have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable.
- We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.
- If development of our product candidates does not produce favorable results, or encounters challenges, we and our collaborators, if any, may be unable to commercialize these products.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.
- Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable.
- Given our lack of current cash flow, we will need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution, or place significant restrictions on our ability to operate our business. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates or continue our development programs.
- Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition, and results of operations.
- Interim and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to additional audit, validation and verification procedures that could result in material changes in the final data.
- Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.
- Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

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- We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

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- Our product candidates are subject to extensive regulation under the U.S. Food and Drug Administration (“FDA”), the European Medicines Agency (the “EMA”) or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile, or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.
- We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product or fail to do so at acceptable quality levels or prices.
- The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.
- If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates.
- We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.
- If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.
- We may not be able to protect our proprietary or licensed technology in the marketplace.
- The market price of our common stock is expected to be volatile.

Risk Factors

The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing material changes from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the year ended **December 31, 2022** December 31, 2023, as filed with the SEC on **March 10, 2023**; **March 6, 2024**.

Risks Related to the Company

****We are a clinical-stage company, we have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future and may never become profitable.***

We are a clinical-stage biopharmaceutical company. Since our incorporation, we have focused primarily on the development and acquisition of clinical-stage therapeutic candidates. All of our therapeutic candidates are in the clinical development stage and none of our pipeline therapeutic candidates have been approved for marketing or are being marketed or commercialized.

As a result, we have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the biopharmaceutical industry. We also have generated minimal revenues from collaboration and licensing agreements and no revenues from product sales to date and continue to incur significant research and development and other expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. We have incurred an accumulated deficit of **\$247.2 million** **\$255.3 million** from our inception through **September 30, 2023** **March 31, 2024**.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our drug development activities, seek partnering and/or regulatory approvals for our product candidates and begin to commercialize them if they are approved by the FDA, the EMA, or comparable foreign authorities. Even if we succeed in developing and commercializing one or more product candidates, we may never become profitable.

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****We are dependent on the success of one or more of our current product candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.***

We have spent significant time, money and effort on the licensing and development of our core assets, SLS-002 and SLS-005, and our other earlier-stage assets, SLS-004, SLS-006, SLS-007, SLS-008, SLS-009, SLS-010 and SLS-012. To date, no pivotal clinical trials

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designed to provide clinically and statistically significant proof of efficacy, or to provide sufficient evidence of safety to justify approval, have been completed with any of our pipeline product candidates. All of our product candidates will require additional development, including clinical trials as well as further preclinical studies to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our product candidates may fail to be safe and effective or because we have inadequate financial or other resources to advance our product candidates through the clinical development and approval processes. See the risk factor titled "We may expend our limited resources to pursue a particular

product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success" below. If any of our product candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the product candidate.

We do not anticipate that any of our current product candidates will be eligible to receive regulatory approval from the FDA, the EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these product candidates, we, or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of manufacturing the product on a commercial scale and competition with other drugs. The success of our product candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current product candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition and stock price may decline.

If development of our product candidates does not produce favorable results, or encounters challenges, we, and our collaborators, if any, may be unable to commercialize these products.

To receive regulatory approval for the commercialization of our core assets, SLS-002 and SLS-005, and our earlier-stage assets, SLS-004, SLS-006, SLS-007, SLS-008, SLS-009, SLS-010 and SLS-012, or any other product candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase III clinical trials, which our current product candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent commercialization of our current or future product candidates, including the following:

- clinical trials may produce negative or inconclusive results;
- preclinical studies conducted with product candidates during clinical development to, among other things, evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation may produce unfavorable results;
- we or our contract manufacturers may encounter manufacturing challenges, or the FDA may raise concerns regarding Chemistry, Manufacturing, and Controls (CMC) data or GMP compliance, or biocompatibility or drug-device interaction concerns for our combination product candidates;
- patient recruitment and enrollment in clinical trials may be slower than we anticipate;
- costs of development may be greater than we anticipate;
- our product candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- collaborators who may be responsible for the development of our product candidates may not devote sufficient resources to these clinical trials or other preclinical studies of these candidates or conduct them in a timely manner; or
- we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Success in early development does not mean that later development will be successful because, for example, product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

We have licensed or acquired all of the intellectual property related to our product candidates from third parties. All clinical trials, preclinical studies and other analyses performed to date with respect to our product candidates have been conducted by their original owners. Therefore, as a company, we have limited experience in conducting clinical trials for our product candidates. Since our experience with our product candidates is limited, we will need to train our existing personnel and hire additional personnel in order to

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successfully administer and manage our clinical trials and other studies as planned, which may result in delays in completing such planned clinical trials and preclinical studies. Moreover, to date our product candidates have been tested in less than the number of patients that will likely need to be studied to obtain regulatory approval. The data collected from clinical trials with larger patient populations may not demonstrate sufficient safety and efficacy to support regulatory approval of these product candidates.

We currently do not have strategic collaborations in place for clinical development of any of our current product candidates, except for our collaborative agreement with Team Sanfilippo Foundation ("TSF"), which we assumed in connection with the asset purchase agreement with Bioblast Pharma Ltd. for IV Trehalose, which is now known as SLS-005. Therefore, in the future, we or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our product candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our product candidates are promising, such data may not be sufficient to support marketing approval by the FDA, the EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than us or our collaborators. Our failure to adequately demonstrate the safety and efficacy of our product candidates would prevent our receipt of regulatory approval, and ultimately the potential commercialization of these product candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize our product candidates or any other product candidates that we may develop, we may seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these assets as a component of our strategic plan. However, our discussions with potential collaborators may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition, and results of operations.

****We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. For example, on March 29, 2023, we announced that we plan to focus the majority of our resources on the Phase II study of SLS-002 for the potential treatment of acute suicidal ideation and behavior ("ASIB") in patients with major depressive disorder ("MDD") and the fully enrolled Phase II/III study of SLS-005 in Amyotrophic Lateral Sclerosis ("ALS"). We further announced that we have temporarily paused additional enrollment of patients in the SLS-005-302 study in Spinocerebellar Ataxia ("SCA"). Patients already enrolled will continue

in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. We also announced that we are pausing all non-essential preclinical work. Further, on April 29, 2024, we announced our strategic focus on mental health initiatives related to, among other things, our ketamine expertise with SLS-002 in suicidality. Our resource allocation decisions may cause us to fail to capitalize on viable commercial medicines or profitable market opportunities. Our projections of both the number of people who have these disorders, as well as the subset of people with these disorders who have the potential to benefit from treatment with our product candidates, are based on estimates. If any of our estimates are inaccurate, the market opportunities for any of our product candidates could be significantly diminished and have an adverse material impact on our business. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations and prospects.

****We expect to continue to incur significant research and development expenses, which may make it difficult for us to attain profitability.***

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials of our product candidates, and to manufacture and market any product candidates in the event they are approved for commercial sale. We also may

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need additional funding to develop or acquire complementary companies, technologies, and assets, as well as for working capital requirements and other operating and general corporate purposes. Moreover, our planned increases in staffing will dramatically increase our costs in the near and long-term.

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However, our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Due to our limited financial and managerial resources, we must focus on a limited number of research programs and product candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

For example, as of March 2023, in order to focus the majority of our resources on the Phase II study of SLS-002 (intranasal racemic ketamine) for ASIB in patients with MDD and the fully enrolled Phase II/III study of SLS-005 in ALS, we are temporarily pausing additional enrollment of patients in the SLS-005-302 study in SCA. Patients already enrolled will continue in the study and data will continue to be collected in order to make decisions for resuming enrollment in the future. This temporary pause has been implemented as a business decision due to financial considerations and is not based on any data related to safety or therapeutic effects. **Further, on April 29, 2024, we announced our strategic focus on mental health initiatives related to, among other things, our ketamine expertise with SLS-002 in suicidality.** Our focus on these studies may cause us to fail to capitalize on other opportunities.

Because the successful development of our product candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our product candidates, to become profitable.

***Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable.**

On November 23, 2021, we issued and sold to Lind Global Asset Management V, LLC ("Lind") a convertible promissory note in an initial aggregate principal amount of \$22.0 million for an aggregate purchase price of \$20.0 million **as amended to date,** (the "Convertible Promissory Note"). The Convertible Promissory Note contains certain restrictive covenants and event of default provisions, including restrictions on certain sales or other dispositions of company assets, restrictions on entering into certain variable-rate transactions and a covenant requiring us to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the Convertible Promissory Note or more in cash and cash equivalents commencing on **March 28, 2024** **May 31, 2024.** As of **September 30, 2023** **May 8, 2024**, the outstanding principal amount of the Convertible Promissory Note was **\$16.8 million** approximately **\$12.6 million** and our cash and cash equivalents as of March 31, 2024 were approximately **\$0.5 million**. Based on our current operating plan and our cash balance as of **September 30, 2023** **March 31, 2024**, we do not expect to be able to maintain the minimum cash balance required to satisfy this covenant if we do not raise additional financing by **March 28, 2024** **May 31, 2024.** In the event we fail to meet the minimum cash balance as required under the Convertible Promissory Note, and if we are unable to cure such default within fifteen **business** days from its occurrence or otherwise obtain a waiver from Lind or amend the terms of the Convertible Promissory Note, we would trigger a default under the Convertible Promissory Note. Moreover, under Nasdaq rules, we are limited in the aggregate number of shares we can issue to Lind to satisfy principal and interest payments under terms of the Convertible Promissory Note unless we obtain stockholder approval to issue additional shares to Lind under the Convertible Promissory Note. As of September 30, 2023, we had 13,469,397 shares of our common stock remaining available for issuance to Lind under the Convertible Promissory Note. Under the terms of the Convertible Promissory Note if we would otherwise be required to issue shares to Lind but are unable to do so due to the limitation under Nasdaq rules, Lind may elect to require us to pay it cash in an amount that is equal to the number of shares we are unable to issue as a result of the limitation multiplied by the volume weighted average price of our common stock on the applicable payment date. If we are not able to comply or regain compliance with any of the covenants in, or otherwise fail to make cash payments or trigger a default under, the Convertible Promissory Note, Lind could declare the Convertible Promissory Note immediately due and payable, which would require us to pay 120% of the outstanding principal amount of the Convertible Promissory Note and would have a material adverse effect on our liquidity, financial condition, operating results, business and prospects, and could cause the price of our common stock to decline. In addition, since the borrowings under the Convertible Promissory Note are secured by a first priority lien on our assets, Lind would be able to foreclose on our assets if we do not cure any default or pay any amounts due and payable under the Convertible Promissory Note. In addition, upon an Event of Default (as defined in the Convertible Promissory Note), Lind shall have the right to convert the then outstanding principal amount of the Convertible Promissory Note into shares of our common stock at the lower of (x) the then-current conversion price (which is currently **\$6.00** **\$180.00** per share, subject to adjustment in certain circumstances as described in the Convertible Promissory Note) and (y) 85% of the average of the five lowest daily volume weighted average price of our common stock during the 20 trading days prior to the delivery by Lind of a notice of conversion.

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***Given our lack of current cash flow, we will need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution, or place significant restrictions on our ability to operate our business. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates or continue our development programs.**

As of **September 30, 2023** **March 31, 2024**, we had a cash balance of approximately **\$2.6 million** **\$0.5 million**. Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

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As a result of our recurring losses from operations, in addition to the risk of noncompliance with the minimum cash balance requirements under the Convertible Promissory Note as discussed above under the heading risk factor titled "Our debt agreement contains restrictive and financial covenants that may limit our operating flexibility and the failure to comply with such covenants could cause our outstanding debt to become immediately payable", there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern. If we are unsuccessful in our efforts to raise outside financing, we may be required to significantly reduce or cease operations. The report of our independent registered public accounting firm on our audited financial statements for the year ended **December 31, 2022** **December 31, 2023** included a "going concern" explanatory paragraph indicating that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern.

We currently have an effective shelf registration statement on Form S-3 filed with the **SEC** **SEC** (the "Shelf Registration Statement"). We may use the shelf registration statement on Form S-3 **Shelf Registration Statement** to offer from time to time up to \$246.0 million of any combination of debt securities, common and preferred stock and warrants. Moreover, However, for so long as our public float remains less than \$75 million, in no event will we have sell securities pursuant to shelf registration statements, including pursuant to the ability to sell up to \$50.0 million **Shelf Registration Statement**, with a value of additional shares more than one-third of the aggregate market value of our common stock to the public through an "at the market" offering pursuant to the Open Market Sale Agreements we entered into with Jefferies, LLC on May 12, 2022 (the "Sale Agreement"). As of September 30, 2023, a total of \$59.4 million of securities remains available for issuance pursuant to the shelf registration statement (inclusive of the \$49.5 million that remained allocated to sales of shares pursuant to the Sale Agreement as of such date). However, held by non-affiliates in any 12-month period. In addition, we agreed in a securities purchase agreement entered into in connection with our March 2023 registered direct offering (the "March 2023 RDO") that we would not, subject to certain exceptions, (including in relation to the satisfaction of the May Through September Payments), effect or enter into an agreement to effect any issuance of shares of common stock or common stock equivalents involving a variable rate transaction, which includes the Sale Agreement,

until the earlier of: (a) such time as no investor holds any warrants issued in the March 2023 RDO, and (b) September 21, 2026 (or, in the case of an at-the-market offering, September 21, 2024). Additionally, we agreed in a securities purchase agreement entered into in connection with our September 2023 registered direct offering (the "September 2023 RDO") that, until March 25, 2024, we will not effect or enter into an agreement to effect any issuance of shares of common stock or common stock equivalents involving an at-the-market offering or variable rate transaction, which includes the Sale Agreement. **We also agreed in a securities purchase agreement entered into in connection with our January 2024 registered direct offering that, until July 30, 2024, we will not, subject to certain exceptions, effect any issuance of shares of common Stock or common stock equivalents involving an at-the-market offering or variable rate transaction.**

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit, or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. In addition, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, preclinical studies, and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates;
- the cost of commercialization activities if any of our current or future product candidates are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;

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- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences, and privileges senior to those of our common stock. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our stockholders.

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In addition, debt financing may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends and may be secured by all or a portion of our assets. For example, we granted to Lind, as the holder of the Convertible Promissory Note, a first priority lien on our assets and properties and the Convertible Promissory Note includes restrictive covenants and event of default provisions, including restrictions on certain sales or other dispositions of company assets, restrictions on entering into certain variable-rate transactions and a covenant requiring us to maintain an aggregate minimum balance equal to 50% of the then outstanding principal amount under the Convertible Promissory Note or more in cash and cash equivalents commencing on **March 28, 2024** **May 31, 2024**. Our inability to raise capital when needed may harm our business, financial condition, and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition, and results of operations.

Undesirable side effects observed in clinical trials or in supportive preclinical studies with our product candidates could interrupt, delay, or halt their development and could result in the denial of regulatory approval by the FDA, the EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any such product candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our product candidates.

Our product candidates may exhibit adverse effects in preclinical toxicology studies and adverse interactions with other drugs. There are also risks associated with additional requirements the FDA, the EMA or comparable foreign authorities may impose for marketing approval with regard to a particular disease.

Our product candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study, and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug or could be limited to a more restricted patient population. Any risk management program required for approval of our product candidates could potentially have an adverse effect on our business, financial condition, and results of operations.

Undesirable side effects involving our product candidates may have other significant adverse implications on our business, financial condition, and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;
- our collaborators may terminate any development agreements covering these product candidates;
- if any development agreements are terminated, we may determine not to further develop the affected product candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these product candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;
- we may be subject to product liability or stockholder litigation; and
- we may be unable to attract and retain key employees.

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In addition, if any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the product, or we or our partners may decide to cease marketing and sale of the product voluntarily;
- we may be required to change the way the product is administered, conduct additional clinical trials or preclinical studies regarding the product, change the labeling of the product, or change the product's manufacturing facilities; and
- our reputation may suffer.

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Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

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

From time to time, we may publish interim data, including interim top-line results or preliminary results from our clinical trials. Any interim data and other results from our clinical trials may materially change as more patient data become available. Preliminary or top-line results also remain subject to audit, validation and verification procedures that may result in the final data being materially different from the interim and preliminary data we previously published. As a result, interim and preliminary data may not be predictive of final results and should be viewed with caution until the final data are available. We may also arrive at different conclusions, or considerations may qualify such results once we have received and fully evaluated additional data. Differences between preliminary or interim data and final data could adversely affect our business.

Our efforts to discover product candidates beyond our current product candidates may not succeed, and any product candidates we recommend for clinical development may not actually begin clinical trials.

We intend to use our technology, including our licensed technology, knowledge, and expertise to develop novel drugs to address some of the world's most widespread and costly central nervous system, respiratory and other disorders, including orphan indications. We intend to expand our existing pipeline of core assets by advancing drug compounds from current ongoing discovery programs into clinical development. However, the process of researching and discovering drug compounds is expensive, time-consuming, and unpredictable. Data from our current preclinical programs may not support the clinical development of our lead compounds or other compounds from these programs, and we may not identify any additional drug compounds suitable for recommendation for clinical development. Moreover, any drug compounds we recommend for clinical development may not demonstrate, through preclinical studies, indications of safety and potential efficacy that would support advancement into clinical trials. Such findings would potentially impede our ability to maintain or expand our clinical development pipeline. Our ability to

identify new drug compounds and advance them into clinical development also depends upon our ability to fund our research and development operations, and we cannot be certain that additional funding will be available on acceptable terms, or at all.

Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations ("CROs") and clinical trial sites;
- manufacturing sufficient quantities of a product candidate or other materials necessary to conduct clinical trials;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and

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- the failure of our collaborators to adequately resource our product candidates due to their focus on other programs or as a result of general market conditions.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards, or data safety monitoring boards charged with overseeing our clinical trials, the FDA, the EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, the EMA or comparable foreign authorities resulting in the imposition of a clinical hold;

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- unforeseen safety issues; or
- lack of adequate funding to continue the clinical trial.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to commence product sales and generate product revenues from any of our product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs and slow down our product candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to

obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Results of earlier clinical trials may not be predictive of the results of later-stage clinical trials.

The results of preclinical studies and early clinical trials of 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 results despite having progressed through preclinical studies and initial clinical trials. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

This product candidate development risk is heightened by any changes in the planned clinical trials compared to the completed clinical trials. As product candidates are developed through preclinical to early to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the product candidates for late-stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives. In addition, nonclinical studies may be requested or required even after clinical trials have been commenced or completed.

Any of these changes could make the results of our planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our product candidates, and/or jeopardize our ability to commence product sales and generate revenues.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

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If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability

to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business, financial condition and results of operations could be substantially harmed.

We intend to rely upon third-party CROs, medical institutions, clinical investigators, and contract laboratories to monitor and manage data for our ongoing preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with current requirements on good manufacturing practices ("cGMP") good clinical practices ("GCP") and good laboratory practice ("GLP"), which are a collection of laws and regulations enforced by the FDA, the EMA and comparable foreign authorities for all of our product candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval processes.

We may not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs will not be our employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our product candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition, or results of operations.

Our product candidates are subject to extensive regulation under the FDA, the EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing, and distribution of our product candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, the EMA or comparable authorities in foreign markets. In the U.S., neither we nor our collaborators are permitted to market our product candidates until we or our collaborators receive approval of a new drug application ("NDA") from the FDA or receive similar

approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at

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all. Any guidance that may result from recent FDA advisory panel discussions may make it more expensive to develop and commercialize such product candidates. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our product candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, the EMA or comparable foreign authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- a product candidate may not be deemed safe or effective;
- agency officials of the FDA, the EMA or comparable foreign authorities may not find the data from non-clinical or preclinical studies and clinical trials generated during development to be sufficient;
- the FDA, the EMA or comparable foreign authorities may not approve our third-party manufacturers' processes or facilities;
- the FDA, the EMA or a comparable foreign authority may change its approval policies or adopt new regulations; or
- our inability to obtain these approvals would prevent us from commercializing our product candidates.

We are pursuing the FDA 505(b)(2) NDA pathway for our lead product candidate, SLS-002, which presents certain additional development and commercialization risks as compared to a conventional 505(b)(1) NDA for an innovator product candidate. We may pursue this pathway for other product candidates as well.

For our lead product candidate (SLS-002) we are pursuing development in order to seek potential FDA approval under an abbreviated regulatory pathway called a 505(b)(2) NDA, which permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. We may also pursue this pathway for other of our product candidates. Section 505(b)(2), if applicable to us for a particular product candidate, would allow an NDA we submit to the FDA to rely, in part, on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for a product candidate by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval.

Even if the FDA allows us to rely on the 505(b)(2) regulatory pathway, there is no assurance that such marketing approval will be obtained in a timely manner, or at all. The FDA may require us to perform additional nonclinical studies and clinical trials, and conduct other development work, to support any change from the reference listed drug (including with respect to the route of administration and drug delivery method and device), which presents uncertainty about the data that may ultimately be necessary and could be time-consuming and substantially delay our application for or potential receipt of marketing approval. Even if we are able to utilize the 505(b)(2) regulatory pathway, a drug approved via this pathway may be subject to the same post-approval

limitations, conditions and requirements as any other drug, including, for example a Risk Evaluation and Mitigation Strategy (“REMS”), which we anticipate will be required for our lead product candidate.

Also, as has been the experience of others in our industry, our competitors may file citizens’ petitions with the FDA to contest approval of our NDA, which may delay or even prevent the FDA from approving any NDA that we submit under the 505(b)(2) regulatory pathway. If an FDA decision or action relative to our product candidate, or the FDA’s interpretation of Section 505(b)(2) more generally, is successfully challenged, it could result in delays or even prevent the FDA from approving a 505(b)(2) application for such product candidate.

In addition, we may face Hatch-Waxman litigation in relation to our NDAs submitted under the 505(b)(2) regulatory pathway, which may further delay or prevent the approval of our product candidate. The pharmaceutical industry is highly competitive, and 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a 505(b)(2) NDA. If the previously approved drugs referenced in an applicant’s 505(b)(2) NDA are protected by patent(s) listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations publication, or the Orange Book, the 505(b)(2) applicant is required to make a claim after filing its NDA that each such patent is invalid, unenforceable or will not be infringed. The patent holder may thereafter bring suit for patent infringement, which will trigger a mandatory 30-month delay (or the shorter of dismissal of the lawsuit or expiration of the patent(s)) in approval of the 505(b)(2) NDA application.

If the FDA determines that our 505(b)(2) regulatory pathway is not viable for SLS-002 or any other applicable product candidate for any reason, we would need to reconsider our plans and might not be able to commercialize any such product candidate in a cost-

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efficient manner, or at all. If we were to pursue approval under the 505(b)(1) NDA pathway, we would be subject to more extensive requirements and risks such as conducting additional clinical trials, providing additional data and information or meeting additional standards for marketing approval. As a result, the time and financial resources required to obtain marketing approval for our product candidates would likely increase substantially and further complications and risks associated with our product candidates may arise. Also, new competing products may reach the market faster than ours, which may materially and adversely affect our competitive position, business and prospects.

Even if our product candidates receive regulatory approval in the U.S., we may never receive approval or commercialize our products outside of the U.S.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our product candidates.

Even if any of our product candidates receive regulatory approval, our product candidates may still face future development and regulatory difficulties.

If any of our product candidates receive regulatory approval, the FDA, the EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the product candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a product, our manufacturer and the manufacturer's facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our product candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;
- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain products or require a product recall.

The FDA, the EMA and comparable foreign authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA, the EMA and comparable foreign authorities strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or comparable foreign authorities as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment that our products could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. Such enforcement has become more common in the industry. The FDA, the EMA or comparable foreign authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business, financial condition and results of operations.

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*** If our competitors have product candidates that are approved faster, marketed more effectively, are better tolerated, have a more favorable safety profile or are demonstrated to be more effective than ours, our commercial opportunity may be reduced or eliminated.**

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, clinical trials, regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any which we are developing, or that would render our product candidates obsolete and noncompetitive. Even if we obtain regulatory approval for any of our product candidates, our competitors may succeed in obtaining regulatory approvals for their products earlier than we do. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and patient registration for clinical trials, and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

The key competitive factors affecting the success of each of our product candidates, if approved, are likely to be its efficacy, safety, tolerability, frequency and route of administration, convenience and price, the level of branded and generic competition and the availability of coverage and reimbursement from government and other third-party payors.

The pharmaceutical market for the treatment of major depressive disorder includes selective serotonin reuptake inhibitors ("SSRIs"), serotonin and norepinephrine reuptake inhibitors ("SNRIs") and atypical antipsychotics. A number of these marketed antidepressants will be generic and would be key competitors to SLS-002. These products include Forest Laboratory's Lexapro/Cipralex (escitalopram) and Viibryd (vilazodone), Pfizer, Inc.'s Zoloft (sertraline), Effexor (venlafaxine) and Pristiq (desvenlafaxine), GlaxoSmithKline plc's Paxil/Seroxat (paroxetine), Eli Lilly and Company's Prozac (fluoxetine) and Cymbalta (duloxetine), AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), among others.

Patients with treatment-resistant depression often require treatment with several antidepressants, such as an SSRI or SNRI, combined with an "adjunct" therapy such as an antipsychotic compound, such as AstraZeneca plc's Seroquel (quetiapine) and Bristol-Myers Squibb Company's Abilify (aripiprazole), or mood stabilizers, such as Janssen Pharmaceutica's Topamax (topiramate). In addition, Janssen's Spravato (intranasal esketamine), which has been approved for treatment-resistant depression and for depressive systems in adults with major depressive disorder with suicidal thoughts or actions, targets the NMDA receptor and is expected to have a faster onset of therapeutic effect as compared to currently available therapies.

Current treatments for Parkinson's Disease ("PD") are intended to improve the symptoms of patients. The cornerstone of PD therapy is levodopa, as it is the most effective therapy for reducing symptoms of PD. There are other drug therapies in development that will target the disease, such as gene and stem cell therapy and A2A receptor agonists.

Further, despite the great need for an effective disease-modifying treatment for ALS and significant research efforts by the pharmaceutical industry to meet this need, there have been limited clinical successes and no curative therapies approved to date. In May 2022, the FDA approved an orally administered version of edaravone, which has been available since 2017 as an intravenous infusion for the treatment of ALS. In July 2022, the FDA accepted an NDA for tofersen, an investigational drug from Biogen Inc., for the treatment of superoxide dismutase 1 ALS. ~~The NDA has been~~ In April 2023, the FDA granted priority review with a Prescription Drug User Fee Act goal date ~~accelerated approval to tofersen, branded as QALSODY, for the treatment of~~ April 25, 2023, superoxide dismutase 1 ALS. Additionally, in September 2022, the FDA approved AMX0035, now branded as Relyvrio, a drug from Amylyx Pharmaceuticals, Inc., for the treatment of ALS. AMX0035 previously received a conditional approval by Health Canada in June 2022.

~~Table~~ In October 2023, the EMA Committee for Medicinal Products for Human Use (CHMP) confirmed a June 2023 recommendation to refuse a marketing authorization for AMX0035 for the treatment of ~~Contents~~ adults with ALS in the European Union. In January 2024, the European Commission confirmed the adoption of the CHMP's negative opinion.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the United States and Europe, obtaining orphan drug approval may allow us to obtain financial incentives, such as an extended period of exclusivity during which only we are allowed to market the orphan drug. While we have received orphan drug designation for SLS-005 in Sanfilippo Syndrome and in spinocerebellar ataxia type 3 and in oculopharyngeal muscular dystrophy and we plan to seek orphan drug designation from the FDA for SLS-008 for the treatment of a pediatric indication, we, or any future collaborators, may not be granted orphan drug designations for our product candidates in the U.S. or in other jurisdictions.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active chemical and pharmacological characteristics, or moiety, can be approved for the same condition. Specifically, the FDA's

regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

The active ingredient of our lead product candidate, SLS-002, ketamine hydrochloride, is recognized as having the potential for abuse, misuse and diversion and, as a result, is and will be subject to extensive federal and state laws and regulations governing controlled substances and the entities involved in their research, manufacturing, sale and distribution, and possession. In addition, we anticipate that if we obtain marketing approval for SLS-002 it will be the subject of an FDA Risk Evaluation and Mitigation Strategy (REMS).

Ketamine is listed by the Drug Enforcement Administration (“DEA”) as a Schedule III controlled substance under the Controlled Substances Act. The DEA classifies substances as Schedule I, II, III, IV or V controlled substances, with Schedule I controlled substances considered to present the highest risk of substance abuse and Schedule V controlled substances the lowest risk. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, distribution and physician prescription procedures. In addition to federal scheduling, some drugs may be subject to state-level controlled substance laws and regulations and in some cases more broadly applicable or more extensive requirements than those determined by the DEA and FDA. Federal and state-level controlled substance laws impose a broad range of registration and licensure requirements along with requirements for systems and controls intended to provide security and reduce the risk of diversion and misuse, and to identify suspicious activities.

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Compliance with these laws can be expensive and time consuming. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration and state-level licenses.

If SLS-002 receives marketing approval from the FDA or other regulatory authority, we may be required to implement REMS to address the potential for abuse and misuse of our product candidate. As a result, our product candidate may only be available through a restricted or limited distribution system to which only certain prescribing healthcare professionals may have access for their patients or healthcare professionals may be limited in their prescribing.

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Furthermore, product candidates containing controlled substances may generate public controversy. As a result, these products may be at risk of having their sale and distribution and marketing approvals further restricted or in extreme cases withdrawn in the event that regulators were to assess that the benefits of a product no longer outweigh emerging risks. Political pressures or adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the commercialization of our product or product candidates.

We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, public health crises, pandemics and epidemics, power failures and numerous other factors.

In addition, any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our product candidates. We also may need to take inventory write-offs and incur other charges and expenses for product candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies, and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete such clinical trial, any significant delay or discontinuity in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates, which could harm our business, financial condition and results of operations.

Product candidates that are considered combination products for FDA purposes, such as the SLS-002 drug-device combination product consisting of ketamine hydrochloride and a USP aqueous spray solution in a bi-dose nasal delivery device, may face additional challenges, risks and delays in the product development and regulatory approval process.

SLS-002 is delivered by an intranasal delivery device and considered a drug-device combination product (the device having been developed by a third party is subject to a license agreement). When evaluating products that utilize a specific drug delivery system or device, the FDA will evaluate the characteristics of that delivery system and its functionality, as well as the potential for undesirable

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interactions between the drug and the delivery system, including the potential to negatively impact the safety or effectiveness of the drug. The FDA review process can be more complicated for combination products, and may result in delays, particularly if novel delivery systems are involved. Additionally, quality or design concerns with the delivery system could delay or prevent regulatory approval and commercialization of our product candidates.

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We and our contract manufacturers are subject to significant regulation with respect to manufacturing our product candidates. The manufacturing facilities on which we rely may not continue to meet regulatory requirements.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application ("MAA") on a timely basis and must adhere to GLP and cGMP regulations enforced by the FDA, the EMA or comparable foreign authorities through their facilities inspection program. Some of our contract manufacturers may not have produced a commercially approved pharmaceutical product and therefore may not have obtained the requisite regulatory authority approvals to do so. The facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or any of our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we plan to oversee the contract manufacturers, we cannot control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the products may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business, financial condition and results of operations.

If we or any of our third-party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a product candidate, withdrawal of an approval or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our product candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue.

Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future product candidates.

We may seek collaboration arrangements with biopharmaceutical companies for the development or commercialization of our current and potential future product candidates. To the extent that we decide to enter into collaboration agreements, we will face significant

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competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. The success of our collaboration

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arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable product candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with biopharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect our business, financial condition and results of operations.

If we are unable to develop our own commercial organization or enter into agreements with third parties to sell and market our product candidates, we may be unable to generate significant revenues.

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our product candidates are approved for commercialization, we may be required to develop our sales, marketing and distribution capabilities, or make arrangements with a third party to perform sales and marketing services. Developing a sales force for any resulting product or any product resulting from any of our other product candidates is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our product candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our product revenues are likely to be lower than if we marketed and sold our product candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

The commercial success of our product candidates depends upon their market acceptance among physicians, patients, healthcare payors and the medical community.

Even if our product candidates obtain regulatory approval, our products, if any, may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the effectiveness of our approved product candidates as compared to currently available products;
- patient willingness to adopt our approved product candidates in place of current therapies;
- our ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- restrictions on use in combination with other products;
- availability of alternative treatments;
- pricing and cost-effectiveness assuming either competitive or potential premium pricing requirements, based on the profile of our product candidates and target markets;
- effectiveness of us or our partners' sales and marketing strategy;
- our ability to obtain sufficient third-party coverage or reimbursement; and
- potential product liability claims.

In addition, the potential market opportunity for our product candidates is difficult to precisely estimate. Our estimates of the potential market opportunity for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research reports and other surveys. Independent sources have not verified all of our assumptions. If any of these assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, our product revenue may be limited, it may be harder than expected to raise funds and it may be more difficult for us to achieve or maintain profitability. If we fail

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to achieve market acceptance of our product candidates in the U.S. and abroad, our revenue will be limited and it will be more difficult to achieve profitability.

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If we fail to obtain and sustain an adequate level of reimbursement for our potential products by third-party payors, potential future sales would be materially adversely affected.

There will be no viable commercial market for our product candidates, if approved, without reimbursement from third-party payors. Reimbursement policies may be affected by future healthcare reform measures. We cannot be certain that reimbursement will be available for our current product candidates or any other product candidate we may develop. Additionally, even if there is a viable commercial market, if the level of reimbursement is below our expectations, our anticipated revenue and gross margins will be adversely affected.

Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question and challenge the coverage of and the prices charged for drugs. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Reimbursement rates may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. There is a current trend in the U.S. healthcare industry toward cost containment.

Large public and private payors, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Such third-party payors, including Medicare, may question the coverage of, and challenge the prices charged for, medical products and services, and many third-party payors limit coverage of or reimbursement for newly approved healthcare products. In particular, third-party payors may limit the covered indications. Cost-control initiatives could decrease the price we might establish for products, which could result in product revenues being lower than anticipated. We believe our drugs will be priced significantly higher than existing generic drugs and consistent with current branded drugs. If we are unable to show a significant benefit relative to existing generic drugs, Medicare, Medicaid and private payors may not be willing to provide reimbursement for our drugs, which would significantly reduce the likelihood of our products gaining market acceptance.

We expect that private insurers will consider the efficacy, cost-effectiveness, safety and tolerability of our potential products in determining whether to approve reimbursement for such products and at what level. Obtaining these approvals can be a time consuming and expensive process. Our business, financial condition and results of operations would be materially adversely affected if we do not receive approval for reimbursement of our potential products from private insurers on a timely or satisfactory basis. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Medicare Part D, which provides a pharmacy benefit to Medicare patients as discussed below, does not require participating prescription drug plans to cover all drugs within a class of products. Our business, financial condition and results of operations could be materially adversely affected if Part D prescription drug plans were to limit access to, or deny or limit reimbursement of, our product candidates or other potential products.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. In many countries, the product cannot be commercially launched until reimbursement is approved. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. The negotiation process in some countries can exceed 12 months. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products to other available therapies.

If the prices for our potential products are reduced or if governmental and other third-party payors do not provide adequate coverage and reimbursement of our drugs, our future revenue, cash flows and prospects for profitability will suffer.

Current and future legislation may increase the difficulty and cost of commercializing our product candidates and may affect the prices we may obtain if our product candidates are approved for commercialization.

In the U.S. and some foreign jurisdictions, there have been a number of adopted and proposed legislative and regulatory changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-marketing activities and affect our ability to profitably sell any of our product candidates for which we obtain regulatory approval.

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In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit the coverage and reimbursement rate that we receive for any of our approved products. While the MMA only applies to drug benefits for Medicare

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beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the "PPACA"), was enacted. The PPACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The PPACA increased manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate amount for both branded and generic drugs and revised the definition of "average manufacturer

price", which may also increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also expanded Medicaid drug rebates and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the rebates due on those drugs. The Centers for Medicare & Medicaid Services, which administers the Medicaid Drug Rebate Program, also has proposed to expand Medicaid rebates to the utilization that occurs in the territories of the U.S., such as Puerto Rico and the Virgin Islands. Further, beginning in 2011, the PPACA imposed a significant annual fee on companies that manufacture or import branded prescription drug products and required manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." Legislative and regulatory proposals have been introduced at both the state and federal level to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

There have been public announcements by members of the U.S. Congress regarding plans to repeal and replace or amend and expand the PPACA and Medicare. For example, on December 22, 2017 the Tax Cuts and Jobs Act of 2017 was signed into law, which, among other things, eliminated the individual mandate requiring most Americans (other than those who qualify for a hardship exemption) to carry a minimum level of health coverage, effective January 1, 2019. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing approval testing and other requirements.

In addition to the PPACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third-party payers. While in general it is difficult to predict specifically what effects the PPACA or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

In Europe, the United Kingdom withdrew from the European Union on January 31, 2020 and began a transition period that ended on December 31, 2020. Although the ultimate effects of Brexit have yet to be seen, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for companies and increased restrictions on imports and exports throughout Europe, which could adversely affect our ability to conduct and expand our operations in Europe and which may have an adverse effect on our business, financial condition and results of operations. Additionally, Brexit may increase the possibility that other countries may decide to leave the EU in the future.

In addition, on August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which ~~shall take~~ took effect in 2023. Under the Inflation Reduction Act, Congress authorized Medicare beginning in 2026 to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars. This provision is limited in terms of the number of pharmaceuticals whose prices can be negotiated in any given year, and it only applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition are categorically excluded from price negotiation. Further, the new legislation provides that if pharmaceutical companies raise prices in Medicare faster than the rate of inflation, they must pay rebates back to the

government for the difference. The new law also caps Medicare out-of-pocket drug costs at an estimated \$4,000 a year in 2024 and, thereafter beginning in 2025, at \$2,000 a year.

Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our product candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

In December 2016, the 21st Century Cures Act was signed into law. This new legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform their respective roles; including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations.

We are subject to “fraud and abuse” and similar laws and regulations, and a failure to comply with such regulations or prevail in any litigation related to noncompliance could harm our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state healthcare “fraud and abuse” laws, including anti-kickback laws, false claims laws and other laws intended, among other things, to reduce fraud and abuse in federal and state healthcare programs. The federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer, or a party acting on its behalf, to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug, or other good or service for which payment in whole or in part may be made under a federal healthcare program, such as Medicare or Medicaid. Although we seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the federal Anti-Kickback Statute.

The federal False Claims Act prohibits anyone from, among other things, knowingly presenting or causing to be presented for payment to the government, including the federal healthcare programs, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Under the Health Insurance Portability and Accountability Act of 1996, we are prohibited from knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services to obtain money or property of any healthcare benefit program. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under the false claims laws of several states.

Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

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Neither the government nor the courts have provided definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare

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laws and regulations will involve substantial costs. If we are found in violation of one of these laws, we could be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from governmental funded federal or state healthcare programs and the curtailment or restructuring of our operations. If this occurs, our business, financial condition and results of operations may be materially adversely affected.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our product candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our product candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from product sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

***If we fail to retain current members of our senior management and scientific personnel, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our product candidates.**

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of **September 30, 2023** **May 8, 2024**, we have **1610** employees. Our organization will rely primarily on outsourcing research, development and clinical trial activities, and manufacturing operations, as well as other functions critical to our business. We believe this approach enhances our ability to focus on our core product opportunities, allocate resources efficiently to different projects and allocate internal resources more effectively. **We have filled several key open positions and are currently recruiting for a few remaining positions.** However, competition for qualified personnel is intense. In addition, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete agreements with employees and require employers to rescind existing non-compete agreements, may lead to increased uncertainty in hiring and competition for talent. We may not be successful in attracting qualified personnel to fulfill our current or future needs and there is no guarantee that any of these individuals will join us on a full-time employment basis, or at all. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. **In addition, we may experience employee turnover as a result of the ongoing "great resignation" occurring throughout the U.S. economy, which has impacted job market dynamics.** New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our product candidates, and may have difficulty in meeting our obligations as a public company. We do not maintain "key person" insurance on any of our employees.

In addition, competitors and others are likely in the future to attempt to recruit our employees. The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. Moreover, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete with employees and require employers to rescind existing non-compete, may lead to increased uncertainty in hiring and competition for talent. In addition, the replacement of key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

On April 30, 2024, we announced a reduction in our workforce that affected approximately 33% of our current employees, along with a reduction in working hours and related compensation for all of our remaining employees. Our cost reduction plan may be disruptive to our operations, and our workforce reductions could yield unanticipated consequences, such as attrition beyond planned workforce reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in the need for contract support at

unplanned additional expense or harm our productivity. Our workforce reductions could also harm our ability to attract and retain qualified personnel. In addition, we

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may not realize the anticipated benefits, savings and improvements from our cost reduction efforts due to unforeseen difficulties, delays or unexpected costs.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

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We will need to increase the size of our organization and may not successfully manage our growth.

We are a clinical-stage biopharmaceutical company with a small number of planned employees, and our management system currently in place is not likely to be adequate to support our future growth plans. Our ability to grow and to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. Hiring a significant number of additional employees, particularly those at the management level, would increase our expenses significantly. Moreover, if we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations.

Our management's limited public company experience could put us at greater risk of incurring fines or regulatory actions for failure to comply with federal securities laws and could put us at a competitive disadvantage and could require our management to devote additional time and resources to ensure compliance with applicable corporate governance requirements.

Our executive officers have limited prior experience as executive officers in managing and operating a public company, which could have an adverse effect on their ability to quickly respond to problems or adequately address issues and matters applicable to public companies. Any failure to comply with federal securities laws, rules or regulations could subject us to fines or regulatory actions, which may materially adversely affect our business, financial condition and results of operations. Further, since our executive

officers have limited prior experience as executive officers managing and operating a public company, we may need to dedicate additional time and resources to comply with legally mandated corporate governance policies relative to our competitors whose management teams have more public company experience.

We are exposed to product liability, non-clinical and clinical liability risks which could place a substantial financial burden upon us, should lawsuits be filed against us.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. In addition, the use in our clinical trials of pharmaceutical products and the subsequent sale of these products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently carry product liability insurance for our clinical development activities. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Our research and development activities involve the use of hazardous materials, which subject us to regulation, related costs and delays and potential liabilities.

Our research and development activities involve the controlled use of hazardous materials and chemicals, and we will need to develop additional safety procedures for the handling and disposing of hazardous materials. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

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We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our drug development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of drug development or clinical trial data could result in

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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 our development programs and the development of our product candidates could be delayed.

Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee and consultant misconduct also could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such 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 or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

We and our suppliers may experience a disruption in our and their business as a result of natural disasters. A significant natural or man-made disaster, such as an earthquake, power outages, hurricane, flood or fire, droughts and other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the greater New York, New York region, as well as the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia and the Israel-Hamas war, could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may

increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;

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- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;

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- impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and could have a material adverse effect on our business, financial condition and results of operations.

****Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition, or results of operations.***

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation (the "GDPR"), which took effect across all member states of the European Economic Area (the "EEA") in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on

companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to 4% of global revenues or €20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the “CCPA”), which went into effect on January 1, 2020, and the California Privacy Rights Act (the “CPRA”), effective January 1, 2023, secure new privacy rights for consumers and impose new obligations on us. Many other states have implemented or are considering similar legislation which will change the privacy law landscape in the United States. For example, Virginia, Colorado, Utah, and Connecticut, which took effect in 2023. Additionally, Delaware, Indiana, Iowa, Indiana, Montana, Oregon, Tennessee and Montana Texas have all adopted privacy laws, which take effect from January 1, 2023 (in Virginia) and July 1, 2024 through 2026. Further, Washington’s My Health My Data Act, taking effect July 1, 2024, imposes similar requirements specific to consumer health data. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data. This is particularly true with respect to data security incidents, and sensitive personal information, including health and biometric data. Even if we are not determined to have violated these laws, government

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investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and business.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our

business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or

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results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. If we fail to comply with these laws, we could be subject to civil or criminal liabilities, other remedial measures and legal expenses, be precluded from developing, manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (the "FCPA"), the U.K. Bribery Act 2010 (the "Bribery Act") and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, the Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, the Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States, the United Kingdom and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively referred to as "Trade Control Laws"). In addition, 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.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control Laws. If we are not in compliance with the FCPA, the Bribery Act and other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations

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of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control Laws by U.S., United Kingdom or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

In some countries, particularly member states 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 reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced

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member states, can further reduce prices. In some countries, we, or our future collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

*** Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.**

There is an increasing focus from certain investors, employees, regulators, and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, certain investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our board of directors accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate.

We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third-party rating services. A low ESG or sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead. Ongoing focus on corporate responsibility matters by investors and other parties as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share price, financial condition, or results of operations, including the sustainability of our business over time.

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In addition, on March 6, 2024 the SEC has announced proposed finalized new rules for public companies that will require extensive climate-related disclosures and significant analysis of the impact of climate-related issues on our business, strategy, results of operations, and financial condition (the "SEC Climate Disclosure Rules"), and extensive attestation requirements. The new rules require disclosure of, among other matters, will establish a framework for reporting of climate-related risks. To things and to the extent material, climate-related risks and opportunities, greenhouse gas emissions inventory, climate-related targets and goals, and financial impacts of physical and transition risks. Subsequently, in April 2024, the proposed rules impose additional reporting obligations, SEC issued an order staying implementation of the SEC Climate Disclosure Rules pending the resolution of certain challenges. Nonetheless, our legal, accounting, and other compliance expenses may increase significantly, and compliance efforts may divert management time and attention as we could face increased costs, prepare for the potential implementation of the SEC Climate Disclosure Rules, and such expenses, efforts and diversions of management time and attention may be even greater if the SEC Climate Disclosure Rules ultimately go into effect. We may also be exposed to legal or regulatory action or claims as a result of these new regulations. Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures

in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient. All of these risks could have a material adverse effect on our business, financial position, and/or stock price.

***We face risks arising from our recent workforce reductions, including adverse effects on employee morale and uncertainty around our ability to achieve anticipated cost savings from the workforce reductions.**

On April 30, 2024, we announced a reduction in our workforce that affected approximately 33% of our current employees (the "RIF"), along with a reduction in working hours and related compensation for all of our remaining employees. This decision relates to our recent announcement of our strategic focus on our mental health initiatives and serves to reduce ongoing operating expenses not related to such initiatives and extend our cash runway. Total annualized cost savings from the RIF are estimated at approximately \$0.8 million and total annualized cost savings from the reduction in working hours are estimated at approximately \$1.6 million. The RIF was substantially completed on April 30, 2024. We expect to recognize approximately \$50,000 in total charges for related benefits for employees whose employment was terminated pursuant to the RIF. These are one-time termination benefits and are cash charges. The estimates of costs and expenses that we expect to incur in connection with the RIF are subject to a number of assumptions and actual results may differ materially from those estimates. We may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the RIF.

These workforce reductions may result in unintended consequences, such as unwelcome attrition and reduced employee morale, which may cause our employees who were not affected by the reduction in workforce to seek alternative employment. Employees whose positions were eliminated or those who determine to seek alternative employment may seek employment with our competitors.

We cannot provide assurance that we will not undertake additional workforce reductions or that we will be able to realize the cost savings and other anticipated benefits from our previous or any future workforce reduction. In addition, our previous and any future workforce reductions, may adversely affect our ability to respond rapidly to any new product, growth, or revenue opportunities, and otherwise to execute on our business plans. Additionally, reductions in workforce may make it more difficult to recruit and retain new employees. If we need to increase the size of our workforce in the future, we may encounter a competitive hiring market due to labor shortages, increased employee turnover, changes in the availability of workers, and increased wage costs.

Risks Related to Our Intellectual Property

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because several of our programs require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to maintain and exploit these proprietary rights. In addition, we may need to acquire or in-license additional intellectual property in the future. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our product candidates. We face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

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We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical product candidates. Typically, these agreements include an option for the company to negotiate a license to the institution's intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating

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institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, including if our patent applications do not result in the issuance of patents, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.

Our license agreement with Ligand Pharmaceuticals Incorporated, Neurogen Corporation and CyDex Pharmaceuticals, Inc. (the "Ligand License Agreement"), our license agreement with the Regents of the University of California (the "UC Regents License Agreement"), our license agreement with Duke University (the "Duke License Agreement") and our license agreement with iX Biopharma Ltd. (the "iX License Agreement", together with the Ligand License Agreement, the UC Regents License Agreement, and the Duke License Agreement, the "License Agreements") are important to our business and we expect to enter into additional license agreements in the future. The License Agreements impose, and we expect that future license agreements will impose, various milestone payments, royalties and other obligations on us. If we fail to comply with our obligations under these agreements, or if we file for bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

Pursuant to the terms of the Ligand License Agreement, the licensors each have the right to terminate the Ligand License Agreement with respect to the programs licensed by such licensor under certain circumstances, including, but not limited to: (i) if we do not pay an amount that is not disputed in good faith, (ii) if we willfully breach the Ligand License Agreement in a manner for which legal remedies would not be expected to make such licensor whole, or (iii) if we file or have filed against us a petition in bankruptcy or make an assignment for the benefit of creditors. In the event the Ligand License Agreement is terminated by a licensor, all licenses granted to us by such licensor will terminate immediately. Further, pursuant to the terms of the UC Regents License Agreement, the licensor has the right to terminate the UC Regents License Agreement or reduce our license to a nonexclusive license if we fail to achieve certain milestones within a specified timeframe. Similarly, pursuant to the terms of the

Duke License Agreement and the iX License Agreement, each licensor has the right to terminate the Duke License Agreement or the iX License Agreement, as applicable, if we fail to achieve certain milestones within a specified timeframe.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in-license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us, our licensors and our collaborators; and
- the priority of invention of patented technology.

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If disputes over intellectual property and other rights that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate its licenses to us, in which case

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we would not be able to market products covered by these licenses. The loss of our licenses would have a material adverse effect on our business.

We are required to make certain cash payments and may be required to pay milestones and royalties pursuant to certain commercial agreements, which could adversely affect the overall profitability for us of any products that we may seek to commercialize.

Under the terms of the Ligand License Agreement, we may be obligated to pay the licensor under the Ligand License Agreement up to an aggregate of approximately \$126.7 million in development, regulatory and sales milestones. Similarly, under the terms of the iX License Agreement, we may be obligated to pay the licensor under the iX License Agreement up to an aggregate of approximately \$239 million in development, regulatory and sales milestones. We will also be required to pay royalties on future worldwide net product sales. We will also be required to pay up to an aggregate of approximately \$17 million in development and regulatory milestones and royalties on any net sales of SLS-005 pursuant to our asset purchase agreement with Bioblast Pharma Ltd. These cash, milestone and royalty payments could adversely affect the overall profitability for us of any products that we may seek to commercialize.

We may not be able to protect our proprietary or licensed technology in the marketplace.

We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing, and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any licensor's or licensee's ability to obtain and maintain patent protection in the U.S. and other countries with respect to our proprietary or licensed technology and products. We currently in-license some of our intellectual property rights to develop our product candidates and may in-license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by our current or future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that our current or future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition, and results of operations.

Although we believe we will be able to obtain, through prosecution of patent applications covering our owned technology and technology licensed from others, adequate patent protection for our proprietary drug technology, including those related to our in-licensed intellectual property, if we are compelled to spend significant time and money protecting or enforcing our licensed patents and future patents we may own, designing around patents held by others or licensing or acquiring, potentially for large fees, patents or other proprietary rights held by others, our business, financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or in-license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our products.

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 for licensed patents, pending patent applications and potential future patent applications and patents 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/or patent applications will be due to be paid to the U.S. Patent and Trademark Office ("USPTO") and various governmental patent agencies outside of the U.S. in several stages over the lifetime of the applicable patent and/or patent application. 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. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or

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patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our in-licensed patents or patent applications we may file in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

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The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the U.S. and many jurisdictions outside of the U.S. is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current product candidates and potential products may prevent us from obtaining or enforcing patents relating to these product candidates and potential products, including without limitation composition-of-matter patents, which are generally believed to offer the strongest patent protection.

Patents that we currently license and patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our product candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our product candidates;
- we, or third parties from whom we in-license or may license patents, may be required to disclaim part of the term of one or more patents;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent our licensed patents or future patents we may own by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our licensed patents or any future patents we may own, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our licensed patents or any future patents we may own invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate 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

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technology and products, or limit the duration of the patent protection of our technology and potential products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

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We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe.

Moreover, patent applications are in some cases maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and patent applications were filed. Because patents can take many years to issue, there may be currently pending applications of which we are unaware that may later result in issued patents that our product candidates or potential products infringe. For example, pending applications may exist that claim or can be amended to claim subject matter that our product candidates or potential products infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional, or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., 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 have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire.

We may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, 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 materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.

We may be required to initiate litigation to enforce or defend our licensed and owned intellectual property. Lawsuits to protect our intellectual property rights can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the biopharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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. Moreover, there can be no assurance that we will have

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sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or

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proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our licensed patents and patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention.

****Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming, and inherently uncertain. For example, the U.S. previously enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws

and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect (a "Unitary Patent"). Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court ("UPC"). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

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

Filing, prosecuting, and defending patents on product candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop

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the infringement of our licensed patents and future patents we may own, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the

same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the U.S. and abroad. For example, China currently affords less protection to a company's intellectual property than some other jurisdictions. As such, the lack of strong patent and other intellectual property protection in China may significantly increase our vulnerability regarding unauthorized disclosure or use of our intellectual property and undermine our competitive position. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary and licensed technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

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

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented, or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest, and it may be difficult and costly to register, maintain and/or protect our rights to these trademarks and trade names in jurisdictions in and outside of the United States. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We expect to employ individuals who were previously employed at other biopharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. To date, none of our employees have been subject to such claims.

We may be subject to claims challenging the inventorship of our licensed patents, any future patents we may own and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our licensed patents or our licensed or owned intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our licensed patents or other licensed or owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arising from conflicting obligations of consultants or others who are involved in developing our

product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any

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such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial

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condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application ("IND") (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

Risks Related to Owning Our Common Stock

***The market price of our common stock has been and will likely continue to be volatile.**

The trading price of our common stock has been and is likely to continue to be volatile. For example, in **2022** **2023** our closing stock price ranged from **\$0.51** **\$1.25** to **\$1.71** **\$49.20** per share, and during the quarter ended **September 30, 2023** **March 31, 2024**, our closing stock price ranged from **\$0.16** **\$0.49** to **\$1.64** **\$1.79** per share. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- results from, and any delays in, planned clinical trials for our product candidates, or any other future product candidates, and the results of trials of competitors or those of other companies in our market sector;
- any delay in filing an NDA for any of our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that NDA;
- significant lawsuits, including patent or stockholder litigation;
- inability to obtain additional funding;
- failure to successfully develop and commercialize our product candidates;
- changes in laws or regulations applicable to our product candidates;
- inability to obtain adequate product supply for our product candidates, or the inability to do so at acceptable prices;
- unanticipated serious safety concerns related to any of our product candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- failure to meet or exceed drug development or financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the biopharmaceutical industry by the public, legislatures, regulators, and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our licensed and owned technologies;
- additions or departures of key scientific or management personnel;

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- changes in the market valuations of similar companies;

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- general economic and market conditions and overall fluctuations in the U.S. equity market, including any potential recession or economic downturn;
- public health crises, pandemics, and epidemics, such as the COVID-19 pandemic;
- sales of our common stock by us or our stockholders in the future; and
- the trading volume of our common stock.

In addition, the stock market in general, and small biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause our stock price to decline rapidly and unexpectedly.

Moreover, in the past, stockholders have initiated class action and other lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock or periods of decreased stock price. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. For example, on October 10, 2023, Empery Asset Management, LP ("Empery") issued a press release disclosing that it transmitted a letter to our management and board of directors claiming that our Chief Executive Officer allegedly made material misrepresentations regarding the Phase II study of SLS - 002 (intranasal racemic ketamine) for ASIB in patients with MDD. Then, on March 22, 2024, Empery Asset Master Ltd. and other related entities commenced an action against us in the Supreme Court of the State of New York, County of New York, entitled *Empery Asset Master Ltd., et al. v. Seelos Therapeutics, Inc.* (case No. 651525/2024), asserting a claim of fraudulent inducement. The complaint alleges that we made material misrepresentations to the plaintiffs regarding the Phase II study of SLS-002 (intranasal racemic ketamine) for ASIB in patients with MDD. We intend to vigorously defend ourselves against the claims asserted against us. However, there can be no assurances that we will prevail in any adverse determination against us in these proceedings, or even the allegations contained in the claims, regardless of whether they are ultimately found to be without merit, may also result in settlements, injunctions or damages that could have a material adverse effect on our business, financial condition and results of operations.

***If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.**

We must continue to satisfy the Nasdaq Capital Market's continued listing requirements, including, among other things, a minimum closing bid price requirement of \$1.00 per share for 30 consecutive business days. If a company fails for 30 consecutive business days to meet the \$1.00 minimum closing bid price requirement, The Nasdaq Stock Market LLC ("Nasdaq") will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements.

A delisting of our common stock from the Nasdaq Capital Market could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors and employees.

On November 21, 2022 April 30, 2024, we received a written notice (the "Bid Notice") from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until May 22, 2023, to regain compliance. On May 23, 2023, Nasdaq provided a notice to us that we had not regained compliance with Rule 5550(a)(2) and were not eligible for a second 180 calendar day compliance period as we did not comply with the minimum \$5,000,000 stockholder's equity requirement for initial listing on the Nasdaq Capital Market. We timely submitted a hearing request before the Nasdaq Hearings Panel, and also provided the Nasdaq Hearings Panel with a plan to regain compliance, which plan included a commitment and intent to conduct a reverse stock split of our common stock to regain compliance with Rule 5550(a)(2). On June 26, 2023, we received a letter from Nasdaq granting us a temporary exception until October 31, 2023 to regain compliance with Rule 5550(a)(2) by evidencing a closing bid price of \$1.00 or more per share for a minimum of ten consecutive trading sessions. On July 24, 2023, we received a letter from Nasdaq notifying us that we regained

compliance with Rule 5550(a)(2), as required by the Nasdaq Hearings Panel and the Compliance Plan. This letter further noted that the Nasdaq Hearings Panel determined to continue the listing of our common stock.

On November 1, 2023, we received an additional written notice from Nasdaq indicating that, for the last thirty consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market under Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until April 29, 2024 October 28, 2024, to regain compliance. The Bid Notice states that the Nasdaq staff will provide written confirmation that we have the Company has achieved compliance with Rule 5550(a)(2) if at any time before April 29, 2024 October 28, 2024, the bid price of our the Company's common stock closes at \$1.00 per share or more for a minimum of ten consecutive business days. In addition, on

If we do not regain compliance with Rule 5550(a)(2) by October 28, 2024, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period, by effecting a

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reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities will be subject to delisting.

On November 2, 2023, we received an additional a written notice (the Initial Notice) from Nasdaq indicating that, for the last thirty-two consecutive business days, the market value of our listed securities has been below the minimum requirement of \$35 million for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2) ("Rule 5550(b)(2)"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have been were provided a period of 180 calendar days, or until April 30, 2024, to regain compliance. The Initial Notice stated that the Nasdaq staff will provide written notification that we have achieved compliance with Rule 5550(b)(2) if at any time before April 30, 2024, the market value of our common stock closes at \$35 million or more for a minimum of ten consecutive business days. We intend

On May 1, 2024, we received written notice (the "Delist Notice" and, together with the Bid Notice and Initial Notice, the "Notices") from Nasdaq indicating that, based upon our continued non-compliance with Rule 5550(b)(2), the Nasdaq staff has determined to monitor the bid price and market value of delist our common stock and consider available options if from the Nasdaq Capital market effective May 10, 2024 unless we timely request an appeal of this determination before the Nasdaq Hearings Panel (the "Panel") by May 8, 2024. We timely requested a hearing before the Panel, which had the effect of staying the suspension of the Company's common stock pending the Panel's final written decision. During the pendency of any requested hearing before the Panel, our common stock does not trade at a level likely will remain listed and trading on Nasdaq.

We are diligently working to result in our regaining evidence compliance with all applicable requirements for continued listing on the Nasdaq Capital Market's minimum bid price rule by April 29, 2024, or Market and we expect to submit a plan to that effect to the minimum market value Panel as part of listed securities rule by April 30, 2024, which may include, among other options, effectuating a reverse stock split. There the hearing process; however, there can be no assurances assurance the Panel will grant any request for continued listing or that we will be able to

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regain compliance with Nasdaq's minimum bid price rule or Nasdaq's minimum market value the applicable listing criteria within the period of listed securities rule or time that we will otherwise be in compliance with the other listing standards for the Nasdaq Capital Market. If we do not regain compliance with Rule 5550(a)(2) by April 29, 2024, we may be afforded a second 180 calendar day period to regain compliance. To qualify, we would be required to meet granted by the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, except for the minimum bid price requirement. In addition, we would be required to notify Nasdaq of our intent to cure the deficiency during the second compliance period, which may include, if necessary, implementing a reverse stock split. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq would notify us that our securities will be subject to delisting. Additionally, if we do not regain compliance with Rule 5550(b)(2) by April 30, 2024, we will receive written notification that our securities are subject to delisting. In the event we receive any such notification, we may appeal the Nasdaq staff's determination to delist our securities, but there can be no assurances that the Nasdaq staff would grant any request for continued listing. Panel.

In addition, we have previously received similar notices from Nasdaq that our bid price of our common stock had closed below the minimum \$1.00 per share requirement for continued listing on the Nasdaq Capital Market under Rule 5550(a)(2), and that the market value of our listed securities has been below the minimum requirements of \$35 million for continued listing on the Nasdaq Capital Market under Rule 5550(b)(2). Even though we previously regained compliance with the Nasdaq Capital Market's minimum closing bid price requirement, and minimum market value of listed securities requirement, there is no guarantee that we will remain in compliance with such listing requirements or other listing requirements in the future. Any failure to maintain compliance with continued listing requirements of the Nasdaq Capital Market could result in delisting of our common stock from the Nasdaq Capital Market and negatively impact our company and holders of our common stock, including by reducing the willingness of investors to hold our common stock because of the resulting decreased price, liquidity and trading of our common stock, limited availability of price quotations and reduced news and analyst coverage. Delisting may adversely impact the perception of our financial condition, cause reputational harm with investors, our employees and parties conducting business with us and limit our access to debt and equity financing.

We will incur significant costs as a result of operating as a public company and our management will be required to devote substantial time to new compliance initiatives.

The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "Dodd-Frank Act") as well as rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such insurance coverage.

As a publicly traded company, we will incur legal, accounting, and other expenses associated with the SEC reporting requirements applicable to a company whose securities are registered under the Exchange Act, as well as corporate governance requirements, including those under the Sarbanes-Oxley Act, the Dodd-Frank Act and other rules implemented by the SEC and Nasdaq. The expenses incurred by public companies generally to meet SEC reporting, finance and accounting and corporate governance

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requirements have been increasing in recent years as a result of changes in rules and regulations and the adoption of new rules and regulations applicable to public companies.

***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders, future issuances of our common stock or rights to purchase our common stock, could cause our stock price to fall.**

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock, and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of **September 30, 2023** **March 31, 2024**, we have outstanding warrants to purchase an aggregate of approximately **32,274,232** **8,667,469** shares of our common stock, which, if exercised, would further increase the number of shares of our common stock outstanding and the number of shares eligible for resale in the public market. As of **September 30, 2023** **March 31, 2024**, **24,558,828** **919,110** shares of our common stock were

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reserved for issuance under our equity incentive plans, of which **15,341,515** **789,902** shares of our common stock were subject to options outstanding at such date at a weighted-average exercise price of **\$1.60** **\$31.52** per share, **5,247,760** **18** shares of our common stock were reserved for future issuance pursuant to our Amended and Restated 2012 Stock Long Term Incentive Plan, **646,465** **21,756** shares of our common stock were reserved for future issuance pursuant to our 2019 Inducement Plan and **3,323,088** **107,434** shares of our common stock were reserved for issuance pursuant to our 2020 Employee Stock Purchase Plan. To the extent outstanding options are exercised, our existing stockholders may incur dilution. Furthermore, from time to time and before the maturity date of the Convertible Promissory Note, Lind currently has the option to convert any portion of the then-outstanding principal amount of the Convertible Promissory Note into shares of our common stock at a price per share of **\$6.00**, **\$180.00**, subject to adjustment for stock splits, reverse stock splits, stock dividends and similar transactions. We may also elect to make amortization and interest payments on the Convertible Promissory Note in the form of shares of our common stock, with the number of shares issuable calculated based on **ninety** **eighty-five** percent **(90%)** **(85%)** of the average of the five (5) lowest daily volume weighted average price of shares of our common stock during the twenty (20) trading days ending on the last trading

day prior to such payment date. Any issuances of shares of our common stock pursuant to the Convertible Promissory Note will result in dilution to our then-existing stockholders and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market could depress the market price of our common stock.

The Financing Warrants contain price-based adjustment provisions which, if triggered, may cause substantial additional dilution to our stockholders.

On October 16, 2018, we entered into a Securities Purchase Agreement with the investors listed on the Schedule of Buyers attached thereto, as amended, pursuant to which, among other things, we issued warrants to purchase shares of our common stock (the "Financing Warrants").

The outstanding Financing Warrants contain price-based adjustment provisions, pursuant to which the exercise price of the Financing Warrants may be adjusted downward in the event of certain dilutive issuances by us.

If the Financing Warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to our then-existing stockholders and increase the number of shares eligible for resale in the public market. As of September 30, 2023, the Financing Warrants were exercisable for approximately 0.3 million shares of our common stock at an exercise price of \$0.2734 per share of common stock. Sales of substantial numbers of such shares in the public market could depress the market price of our common stock.

Anti-takeover provisions in our governing documents and under Nevada law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our articles of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors and the ability of the board of directors to issue preferred stock without stockholder approval. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Certain provisions of Nevada corporate law deter hostile takeovers. Specifically, Nevada Revised Statutes ("NRS") 78.411 through 78.444 prohibit a publicly held Nevada corporation from engaging in a "combination" with an "interested stockholder" for a period of two years following the date the person first became an interested stockholder, unless (with certain exceptions) the "combination" or the transaction by which the person became an interested stockholder is approved in a prescribed manner. Generally, a "combination" includes a merger, asset or stock sale, or certain other transactions resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, beneficially owns or within two years prior to becoming an "interested stockholder" did own, 10% or more of a corporation's voting power. While these statutes permit a corporation to opt out of these protective provisions in its articles of incorporation, our articles of incorporation do not include any such opt-out provision.

Nevada's "acquisition of controlling interest" statutes, NRS 78.378 through 78.3793, contain provisions governing the acquisition of a controlling interest in certain Nevada corporations. These "control share" laws provide generally that any person that acquires a "controlling interest" in certain Nevada corporations may be denied voting rights, unless a majority of the disinterested stockholders

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of the corporation elects to restore such voting rights. These statutes provide that a person acquires a “controlling interest” whenever a person acquires shares of a subject corporation that, but for the application of these provisions of the NRS, would enable that person to exercise (1) one-fifth or more, but less than one-third, (2) one-third or more, but less than a majority or (3) a majority or more, of all of the voting power of the corporation in the election of directors. Once an acquirer crosses one of these thresholds, shares that it

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acquired in the transaction taking it over the threshold and within the 90 days immediately preceding the date when the acquiring person acquired or offered to acquire a controlling interest become “control shares” to which the voting restrictions described above apply. While these statutes permit a corporation to opt out of these protective provisions in its articles of incorporation or bylaws, our articles of incorporation and bylaws do not include any such opt-out provision.

Further, NRS 78.139 also provides that directors may resist a change or potential change in control of the corporation if the board of directors determines that the change or potential change is opposed to or not in the best interest of the corporation upon consideration of any relevant facts, circumstances, contingencies, or constituencies pursuant to NRS 78.138(4).

Our net operating loss carryforwards and certain other tax attributes may be subject to limitations. The net operating loss carryforwards and certain other tax attributes of us may also be subject to limitations as a result of certain prior ownership changes.

In general, a corporation that undergoes an “ownership change” as defined in Section 382 of the United States Internal Revenue Code of 1986, as amended, is subject to limitations on its ability to utilize its pre-change net operating loss carryforwards to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders, generally stockholders beneficially owning five percent or more of a corporation’s common stock, applying certain look-through and aggregation rules, increases by more than 50 percentage points over such stockholders’ lowest percentage ownership during the testing period, generally three years. We may have experienced ownership changes in the past and may experience ownership changes in the future. It is possible that our net operating loss carryforwards and certain other tax attributes may also be subject to limitation as a result of ownership changes in the past. Consequently, even if we achieve profitability, we may not be able to utilize a material portion of our net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

We are a “smaller reporting company” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company, as defined in Rule 12b-2 under the Exchange Act, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than \$100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than

\$700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are permitted to rely on exemptions from certain disclosure requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting, reduced disclosure obligations regarding executive compensation and not being required to provide disclosures regarding quantitative and qualitative disclosures about market risk in our Annual Reports on Form 10-K.

We have elected to take advantage of certain of these exemptions in the past and may continue to choose to take advantage of some, but not all, of them in the future. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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, which may result in additional stock price volatility.

We may never pay dividends on our common stock so any returns would be limited to the appreciation of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate we will declare or pay any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

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General Risk Factors

An active trading market for our common stock may not be sustained, and you may not be able to resell your common stock at a desired market price.

If no active trading market for our common stock is sustained, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by

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selling securities in the future or impair our ability to acquire or in-license other product candidates, businesses or technologies using our shares as consideration.

Our internal control over financial reporting may not meet the standards required by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, could have a material adverse effect on our business and share price.

Our management is required to report on the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies or material weaknesses that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and, when required, receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. Failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business, financial condition and results of operations and could limit our ability to report our financial results accurately and in a timely manner.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock 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. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

****The impact of the Russian invasion of Ukraine, and the Israel-Hamas war and the tensions between Israel and Iran on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations.***

The short and long-term implications of Russia's invasion of Ukraine, and the Israel-Hamas war and the tensions between Israel and Iran are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel-Hamas war and the tensions between Israel and Iran may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and other third parties with which we conduct business. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs, of raw materials. We will continue to monitor this fluid situation and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed herein, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation; disruptions to our technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; disruptions in global supply chains; and constraints, volatility, or disruption in the capital markets, any of which could negatively affect our business and financial condition.

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

Our business, financial condition and results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business,

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including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, service providers, manufacturers or other partners and there is a risk that one or more would not survive or be able to meet their commitments to us under such circumstances. As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years and especially in 2020, 2021 and 2022 due to the impacts of the COVID-19 pandemic, and, more recently, the ongoing conflict between Ukraine and Russia and the global impact of restrictions and sanctions imposed on Russia, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in

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economic growth, increases in unemployment rates and uncertainty about economic stability. Moreover, the global impacts of the Israel-Hamas war and the tensions between Israel and Iran are still unknown. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. For example, U.S. debt ceiling and budget deficit concerns have increased the possibility of additional credit-rating downgrades and economic slowdowns, or a recession in the United States. Although U.S. lawmakers passed legislation to raise the federal debt ceiling on multiple occasions, including a suspension of the federal debt ceiling in June 2023, ratings agencies have lowered or threatened to lower the long-term sovereign credit rating on the United States. The impact of this or any further downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions. Absent further quantitative easing by the Federal Reserve, these developments could cause interest rates and borrowing costs to rise, which may negatively impact our results of operations or financial condition. Moreover, disagreement over the federal budget has caused the U.S. federal government to shut down for periods of time. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non - performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non - performance, or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market - wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our lenders or

counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008 - 2010 financial crisis.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- loss of access to revolving existing credit facilities or other working capital sources and/or the
- inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements;
- potential or actual breach of financial covenants in our credit agreements or credit arrangements;
- potential or actual cross - defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

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Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our customers or suppliers, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are

described above as factors that could result in material adverse impacts on our company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer or supplier bankruptcy or insolvency, or the failure of any customer to make payments when due, or any breach or default by a customer or supplier, or the loss of any significant supplier relationships, could result in material losses to our company and may have material adverse impacts on our business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

During the quarter ended **September 30, 2023** **March 31, 2024**, we issued the following shares of common stock to Lind to satisfy principal and interest payments under the 2021 Note: (a) **395,919** **360,609** shares of common stock on **July 24, 2023** **January 12, 2024** to satisfy principal payments thereunder at a repayment share price of **\$1.051** **\$1.204** per share, (b) **61,205** **121,118** shares of common stock on **August 1, 2023** **January 12, 2024** to satisfy interest payments thereunder at a repayment share price of **\$1.092** **\$1.204** per share, (c) **403,208** **899,280** shares of common stock on **August 23, 2023** **February 15, 2024** to satisfy principal payments thereunder at a repayment share price of **\$1.032** **\$0.695** per share, and (d) **64,860** **673,076** shares of common stock on **August 31, 2023** **March 25, 2024** to satisfy interest payments thereunder at a repayment share price of **\$0.965** **\$0.468** per share ((a) through (d), collectively, the "Lind Shares"). The Lind Shares were issued to Lind in transactions exempt from registration under the Securities Act, in reliance on Section 4(a)(2) thereof and Rule 506(b) of Regulation D thereunder. Accordingly, the Lind Shares have not been registered under the Securities Act and the Lind Shares may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act and any applicable state securities laws.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable. During the fiscal quarter ended March 31, 2024, none of our directors or officers (as defined in Section 16 of the Securities Exchange Act of 1934, as amended) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1 (c) or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408 (a) of Regulation S-K.

Since March 31, 2024, we have issued the following shares of common stock to Lind to satisfy principal and interest payments under the 2021 Note: (a) 682,926 shares of common stock on April 10, 2024 to satisfy principal and interest payments thereunder at a repayment share price of \$0.451 per share, (b) 669,934 shares of common stock on April 23, 2024 to satisfy principal and interest payments thereunder at a repayment share price of \$0.306 per share, and (c) 775,510 shares of common stock on May 3, 2024 to satisfy principal and interest payments thereunder at a repayment share price of \$0.245 per share ((a) through (c), collectively, the "Additional Lind Shares"). The Additional Lind Shares were issued to Lind in transactions exempt from registration under the Securities Act, in reliance on Section 4(a)(2) thereof and Rule 506(b) of Regulation D thereunder. Accordingly, the Additional Lind Shares have not been registered under the Securities Act and the Additional Lind Shares may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act and any applicable state securities laws.

[Table of Contents](#)**ITEM 6. EXHIBITS****EXHIBITS****NO. DESCRIPTION**

2.1*	Agreement and Plan of Merger and Reorganization, dated July 30, 2018, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 30, 2018).
2.2	Amendment No. 1 Agreement and Plan of Merger and Reorganization, dated October 16, 2018, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 17, 2018).
2.3	Amendment No. 2 Agreement and Plan of Merger and Reorganization, dated December 14, 2018, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 14, 2018).
2.4	Amendment No. 3 Agreement and Plan of Merger and Reorganization, dated January 16, 2019, by and among the Company, Arch Merger Sub, Inc. and Seelos Therapeutics, Inc. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 16, 2019).
2.5*	Asset Purchase Agreement, dated February 15, 2019, by and between the Company and Bioblast Pharma Ltd. (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 19, 2019 February 19, 2019).
3.1	Amended and Restated Articles of Incorporation of the Company (incorporated herein by reference to Exhibit 2.1 to the Company's Registration Statement on Form 10-SB filed with the Securities and Exchange Commission on March 14, 1997).
3.2	Certificate of Amendment to Articles of Incorporation of the Company, dated June 22, 2000 (incorporated herein by reference to Exhibit 3.2 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2003).
3.3	Certificate of Amendment to Articles of Incorporation of the Company, dated June 14, 2005 (incorporated herein by reference to Exhibit 3.4 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2006).
3.4	Certificate of Amendment to Amended and Restated Articles of Incorporation of the Company, dated March 3, 2010 (incorporated herein by reference to Exhibit 3.6 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010).

3.5 [Certificate of Correction to Certificate of Amendment to Amended and Restated Articles of Incorporation of the Company, dated March 3, 2010 \(incorporated herein by reference to Exhibit 3.7 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2010\).](#)

3.6 [Certificate of Designation for Series D Junior-Participating Cumulative Preferred Stock \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-A12G filed with the Securities and Exchange Commission on March 24, 2011\).](#)

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3.7 [Certificate of Change filed with the Nevada Secretary of State \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2010\).](#)

3.8 [Certificate of Amendment to Amended and Restated Articles of Incorporation of the Company, dated September 10, 2010 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 10, 2010\).](#)

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3.9 [Certificate of Withdrawal of Series D Junior Participating Cumulative Preferred Stock, dated May 15, 2013 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 16, 2013\).](#)

3.10 [Certificate of Change filed with the Nevada Secretary of State \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 25, 2016\).](#)

3.11 [Certificate of Amendment filed with the Nevada Secretary of State \(incorporated herein by reference to Exhibit 3.10 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 2, 2017\).](#)

3.12 [Certificate of Amendment filed with the Nevada Secretary of State \(incorporated herein by reference to Exhibit 3.12 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2018\).](#)

3.13 [Certificate of Amendment related to the Share Increase Amendment, filed January 23, 2019 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 24, 2019 at 8:05 Eastern Time\).](#)

3.14 [Certificate of Amendment related to the Name Change, filed January 23, 2019 \(incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 24, 2019 at 8:05 Eastern Time\).](#)

3.15 [Amended and Restated Bylaws, dated March 23, 2023 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2023\).](#)

3.16 [Certificate of Correction to Certificate of Amended and Restated Articles of Incorporation of the Company, dated March 25, 2020 \(incorporated herein by reference to Exhibit 3.16 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2020\).](#)

3.17 [Certificate of Amendment to the Amended and Restated Articles of Incorporation of the Company, filed May 18, 2020 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2020\).](#)

3.18 [Certificate of Correction to Certificate of Amended and Restated Articles of Incorporation of the Company, filed May 20, 2020 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2020\).](#)

3.19 [Certificate of Amendment to the Amended and Restated Articles of Incorporation of the Company, filed May 21, 2021 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 21, 2021\).](#)

3.20 [Certificate of Amendment to the Amended and Restated Articles of Incorporation of the Company, filed May 18, 2023 \(incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2023\).](#)

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4.1 [Form of Common Stock Certificate \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 24, 2011\).](#)

4.2 [Form of Warrant issued to the lenders under the Loan and Security Agreement, dated as of October 17, 2014, by and among the Company, NexMed \(U.S.A.\), Inc., NexMed Holdings, Inc. and Apricus Pharmaceuticals USA, Inc., as borrowers, Oxford Finance LLC, as collateral agent, and the lenders party thereto from time to time including Oxford Finance LLC and Silicon Valley Bank \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 20, 2014\).](#)

4.3 [Form of Warrant \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 21, 2018\).](#)

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4.4 [Form of Wainwright Warrant \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 21, 2018\).](#)

4.5 [Form of Investor Warrants \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 17, 2018\).](#)

4.6 [Form of Series A Warrant, issued to investors on January 31, 2019 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 6, 2019\).](#)

4.7 [Form of Warrant, issued to investors on August 27, 2019 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 27, 2019\).](#)

4.8 [Form of Warrant, issued to investors on September 9, 2020 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 9, 2020\).](#)

4.9 [Form of Convertible Promissory Note due November 13, 2024 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission at 7:27 a.m. Eastern Time on November 24, 2021\).](#)

4.10 [Amendment to Convertible Promissory Note, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC, dated December 10, 2021 \(incorporated herein by reference to Exhibit 4.22 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2022\).](#)

4.11 [Amendment No. 2 to Convertible Promissory Note, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC, dated February 8, 2023 \(incorporated herein by reference to Exhibit 4.14 to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 2023\).](#)

4.12 [Amendment No. 3 to Convertible Promissory Note, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC, dated May 19, 2023 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2023\).](#)

4.13 [Form of Pre-Funded Warrant, dated March 14, 2023 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 14, 2023\).](#)

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4.14 [Form of Common Stock Warrant, dated March 14, 2023 \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 14, 2023\).](#)

4.15 [Form of Common Stock Warrant, dated May 19, 2023 \(incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2023\).](#)

4.16 [Form of Common Stock Warrant, dated September 25, 2023 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2023\).](#)

4.17 [Amendment No. 4 to Convertible Promissory Note and Amendment to Letter Agreement, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC, effective September 30, 2023 \(incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 2, 2023\).](#)

10.1† [Form of Amendment No. 1 to Securities Purchase Agreement, by and between Seelos Therapeutics, Inc. and each purchaser identified on the signature pages thereto, dated May 19, 2023 \(incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2023\).](#)

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10.2† [Form of Securities Purchase Agreement, by and between Seelos Therapeutics, Inc. and each purchaser identified on the signature page thereto, dated September 21, 2023 \(incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2023\).](#)

10.3	<u>Letter Agreement, dated September 21, 2023, by and between Seelos Therapeutics, Inc. and Lind Global Asset Management V, LLC (incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 25, 2023).</u>
31.1	<u>Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1 (1)	<u>Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2 (1)	<u>Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
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
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 and contained in Exhibit 101).

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(1) Furnished, not filed.

- * All schedules and exhibits to the agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
- † Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the Securities and Exchange Commission.

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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.

Seelos Therapeutics, Inc.

Date: November 14, 2023 May 14, 2024

/s/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

President, Chief Executive Officer and Chairman of the Board
(*Principal Executive Officer*)

Date: November 14, 2023 May 14, 2024

/s/ Michael Golembiewski

Michael Golembiewski

Chief Financial Officer

(*Principal Financial and Accounting Officer*)

Exhibit 31.1

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Raj Mehra, Ph.D., certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Seelos Therapeutics, Inc. (the "Registrant");

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

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

(4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and~~

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

- a. ~~all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and~~
- b. ~~any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls over financial reporting.~~

Dated: November 14, 2023

By: /s/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

Chief Executive Officer & President

(Principal Executive Officer)

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Golembiewski, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of Seelos Therapeutics, Inc. (the "Registrant");
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
- (4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
- (5) The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
 - a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

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

Dated: November 14, 2023 May 14, 2024

By: /s/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

Chief Executive Officer & President

(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael Golembiewski, certify that:

- (1) I have reviewed this Quarterly Report on Form 10-Q of Seelos Therapeutics, Inc. (the "Registrant");
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
- (4) The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

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

- a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
- b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal controls over financial reporting.

Dated: May 14, 2024

By: /s/ Michael Golembiewski

Michael Golembiewski
Chief Financial Officer
(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 Seelos Therapeutics, Inc. (the "Company") for the quarterly period ended **September 30, 2023** **March 31, 2024** as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Raj Mehra, Ph.D., Chief Executive Officer and President of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: November 14, 2023 | May 14, 2024

By: /s/ Raj Mehra, Ph.D.

Raj Mehra, Ph.D.

Chief Executive Officer and President

(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Seelos Therapeutics, Inc. (the "Company") for the quarterly period ended September 30, 2023 | March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael Golembiewski, Chief Financial Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company, as of, and for, the periods presented in the Report.

Dated: November 14, 2023 | May 14, 2024

By: /s/ Michael Golembiewski

Michael Golembiewski

Chief Financial Officer

(Principal Financial Officer)

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