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, 2026

OR

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

For the transition period from to

Commission File Number: 001-41351

Semnur Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**98-1659463**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
960 San Antonio Road	
Palo Alto, CA	**94303**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 422-7515

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	SMNR	*
Warrants to purchase one share of common stock, each at an exercise price of $11.50 per share	SMNRW	*

* On April 16, 2025, the registrant's securities were suspended from trading on The Nasdaq Capital Market. On April 17, 2025, the registrant's securities began trading on the OTCQB marketplace maintained by the OTC Markets Group, Inc. under the symbols "DNQAF," "DNQWF" and "DNQUF." In connection with the domestication and business combination discussed herein, on September 23, 2025, the registrant's securities began trading on the OTCQB marketplace maintained by the OTC Markets Group, Inc. under the symbols "SMNR" and "SMNRW."

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 4, 2026, the registrant had 217,709,142 shares of common stock outstanding.

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SEMNUR PHARMACEUTICALS, INC.

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SEMNUR PHARMACEUTICALS, INC.

In this Quarterly Report on Form 10-Q, unless the context requires otherwise, references to the "Company", "Semnur", "we", "us", "our", and similar terms refer to Semnur Pharmaceuticals, Inc., a Delaware corporation formerly known as Denali Capital Acquisition Corp. ("Denali"), and its consolidated subsidiaries. References to "Legacy Semnur" refer to the private Delaware corporation that is now our wholly owned subsidiary and named Semnur, Inc. (formerly known as "Semnur Pharmaceuticals, Inc.").

On September 22, 2025, we consummated a business combination pursuant to an agreement and plan of merger, dated as of August 30, 2024 (the "Initial Merger Agreement," as amended by Amendment No. 1 to Agreement and Plan of Merger, dated April 16, 2025, "Amendment No. 1 to the Initial Merger Agreement" and Amendment No. 2 to Agreement and Plan of Merger, dated July 22, 2025, "Amendment No. 2 to the Initial Merger Agreement" and collectively, the "Merger Agreement"), by and among Denali, Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali ("Merger Sub"), and Legacy Semnur. Pursuant to the terms of the Merger Agreement, the business combination (herein referred to as the "Business Combination" or "reverse recapitalization" for accounting purposes) between Denali and Legacy Semnur was effected through the merger of Merger Sub with and into Legacy Semnur with Legacy Semnur surviving as Denali's wholly owned subsidiary. In connection with the Business Combination, Denali changed its name from Denali Capital Acquisition Corp. to Semnur Pharmaceuticals, Inc.

Unless otherwise noted or the context requires otherwise, references to our "Common Stock" refer to our common stock, par value $0.0001 per share.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Quarterly Report on Form 10-Q may constitute "forward-looking statements" for purposes of federal securities laws. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. Forward-looking statements appear in a number of places in this Quarterly Report on Form 10-Q including, without limitation, in the section titled "*Management's Discussion and Analysis of Financial Condition and Results of Operations*." In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Forward-looking statements are typically identified by words such as "plan," "believe," "expect," "anticipate," "contemplate," "intend," "outlook," "estimate," "forecast," "project," "continue," "could," "may," "might," "possible," "potential," "predict," "should," "will," "would" and other similar words and expressions (including the negative of any of the foregoing), but the absence of these words does not mean that a statement is not forward-looking.

These forward-looking statements are based on information available as of the date of this Quarterly Report on Form 10-Q and our management's current expectations, forecasts and assumptions, and involve a number of judgments, known and unknown risks and uncertainties and other factors, many of which are outside the control of the Company and our directors, officers and affiliates.

These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, those factors described in the section of this Quarterly Report on Form 10-Q titled "*Risk Factors*." There can be no assurance that future developments will be those that have been anticipated. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date.

Forward-looking statements in this Quarterly Report on Form 10-Q may include, but are not limited to, statements about:

- the ability to obtain the listing of our Common Stock on Nasdaq;
- our public securities' liquidity and trading;
- our ability to raise financing in the future;
- our expected use of proceeds from future issuances of equity or convertible debt securities;
- our future financial performance, including our revenue, costs of revenue and operating expenses;
- our future use of equity or debt financings to execute our business strategy;
- our ability to use cash on hand to meet current and future financial obligations, including funding our operations, debt service requirements and capital expenditures;
- the outcome of any legal proceedings that may be instituted against us;
- our ability to attract and retain qualified directors, officers, employees and key personnel;
- our ability to compete effectively in a highly competitive market;
- the competition from larger biotechnology companies that have greater resources, technology, relationships and/or expertise;

- the ability to protect and enhance our corporate reputation and brand;
- the impact from future regulatory, judicial and legislative changes in our industry;
- anticipated regulatory and legal developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;
- our ability to obtain and maintain regulatory approval of any of our products and product candidates;
- our ability to research, discover and develop additional product candidates;
- our ability to grow and manage growth profitably;
- our ability to obtain and maintain intellectual property protection and not infringe on the rights of others;
- our ability to execute our business plans and strategy;
- our ability to prevent, respond to, and recover from a cybersecurity incident;
- the effect of any geopolitical conflicts or new or increased international tariffs, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our clinical studies and clinical trials;
- the effect of global economic and political developments, including the conflicts in Ukraine and the Middle East (including Iran);
- regulatory developments related to crypto assets and crypto asset markets;
- a determination that we are an investment company under the Investment Company Act of 1940;
- our ability to successfully adopt and execute on our new cryptocurrency treasury strategy; and
- other factors detailed under the section of this Quarterly Report on Form 10-Q titled "*Risk Factors.*"

Should one or more of these risks or uncertainties materialize or should any of the assumptions made by our management prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. There may be additional risks that we consider immaterial or which are unknown. It is not possible to predict or identify all such risks. We do not undertake any obligation to update, add or otherwise correct any forward-looking statements contained herein to reflect events or circumstances after the date they were made, whether as a result of new information, future events, inaccuracies that become apparent after the date hereof or otherwise, except as may be required under applicable securities laws.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements.

SEMNUR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	September 30, 2026 (unaudited)	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 54	$ 20
Prepaid expenses and other current assets	1,205	576
Digital assets	-	-
Total current assets	**1,259**	**596**
Non-current assets:		
Property and equipment, net	750	750
Total assets	**$ 2,009**	**$ 1,346**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,107	$ 5,912
Accrued expenses	1,886	739
Promissory notes	2,286	3,517
Total current liabilities	**11,279**	**10,168**
Non-current liabilities:		
Related party loan	24,036	11,928
Total liabilities	**35,315**	**22,096**
Commitments and contingencies (See Note 4)		
Stockholders' deficit:		
Preferred stock, $0.0001 par value, 45,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 5,423,606 shares issued and outstanding as of September 30, 2026 and December 31, 2025; liquidation preference of $54,236,060 as of September 30, 2026 and December 31, 2025	1	1
Common stock, $0.0001 par value, 740,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 230,209,142 shares issued and 217,709,142 shares outstanding as of September 30, 2026; and 230,209,142 shares issued and outstanding as of December 31, 2025	23	23
Treasury stock, at cost; 12,500,000 shares and nil shares as of September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	255,026	255,026
Accumulated deficit	(288,356)	(275,800)
Total stockholders' deficit	**(33,306)**	**(20,750)**
Total liabilities and stockholders' deficit	**$ 2,009**	**$ 1,346**

See accompanying notes to the unaudited condensed consolidated financial statements

SEMNUR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 1,443	$ 1,143	$ 3,958	$ 1,832
General and administrative	2,134	151,451	8,419	152,426
Total operating expenses	**3,577**	**152,594**	**12,377**	**154,258**
Loss from operations	**(3,577)**	**(152,594)**	**(12,377)**	**(154,258)**
Other expense:				
Interest expense	(56)	-	(179)	-
Total other expense	**(56)**	**-**	**(179)**	**-**
Net loss and comprehensive loss	**$ (3,633)**	**$ (152,594)**	**$ (12,556)**	**$ (154,258)**
Net loss per share, basic and diluted	**$ (0.02)**	**$ (0.76)**	**$ (0.06)**	**$ (0.77)**
Weighted average shares of common stock outstanding, basic and diluted	**224,230,881**	**201,686,617**	**228,194,489**	**200,568,383**

See accompanying notes to the unaudited condensed consolidated financial statements

SEMNUR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
(in thousands, except share amounts)
(unaudited)

	Preferred Stock		Legacy Common Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2025	5,423,606	$ 1	—	$ —	230,209,142	$ 23	—	$ —	$ 255,026	$ (275,800)	$ (20,750)
Net loss	—	—	—	—	—	—	—	—	—	(4,576)	(4,576)
Balance, March 31, 2026	**5,423,606**	**1**	**—**	**—**	**230,209,142**	**23**	**—**	**—**	**255,026**	**(280,376)**	**(25,326)**
Net loss	—	—	—	—	—	—	—	—	—	(4,347)	(4,347)
Balance, June 30, 2026	**5,423,606**	**$ 1**	**—**	**$ —**	**230,209,142**	**$ 23**	**—**	**$ -**	**$ 255,026**	**$ (284,723)**	**$ (29,673)**
Net loss	—	—	—	—	—	—	—	—	—	(3,633)	(3,633)
Return of retainer shares held in treasury stock	—	—	—	—	—	—	(12,500,000)	—	—	—	—
Balance, September 30, 2026	**5,423,606**	**$ 1**	**—**	**$ -**	**230,209,142**	**$ 23**	**(12,500,000)**	**$ -**	**$ 255,026**	**$ (288,356)**	**$ (33,306)**

	Preferred Stock		Legacy Common Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2024	—	$ —	160,000,000	$ 2	—	$ —	—	$ —	$ 72,598	$ (115,384)	$ (42,784)
Retroactive application of recapitalization	—	—	(160,000,000)	(2)	200,000,000	20	—	—	(18)	—	—
Adjusted balance, January 1, 2025	—	—	—	—	**200,000,000**	**20**	—	—	**72,580**	**(115,384)**	**(42,784)**
Net loss	—	—	—	—	—	—	—	—	—	(665)	(665)
Balance, March 31, 2025	—	—	—	—	**200,000,000**	**20**	—	—	**72,580**	**(116,049)**	**(43,449)**
Net loss	—	—	—	—	—	—	—	—	—	(999)	(999)
Balance, June 30, 2025	—	**$ —**	—	**$ —**	**200,000,000**	**$ 20**	—	**$ -**	**$ 72,580**	**$ (117,048)**	**$ (44,448)**
Issuance of preferred stock and common stock for Debt Exchange Agreement	5,423,606	1	—	—	542,361	—	—	—	54,235	—	54,236
Issuance of common stock for Business Combination	—	—	—	—	2,598,617	—	—	—	(12,788)	—	(12,788)
Issuance of common stock to consultants	—	—	—	—	26,500,000	3	—	—	139,998	—	140,001
Issuance of common stock to underwriters	—	—	—	—	100,000	—	—	—	1,000	—	1,000
Net loss	—	—	—	—	—	—	—	—	—	(152,594)	(152,594)
Balance, September 30, 2025	**5,423,606**	**$ 1**	**—**	**$ —**	**229,740,978**	**$ 23**	**—**	**$ -**	**$ 255,025**	**$ (269,642)**	**$ (14,593)**

See accompanying notes to the unaudited condensed consolidated financial statements

SEMNUR PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash Flows from Operating Activities:		
Net loss	$ (12,556)	$ (154,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,634	140,403
Interest accrued on promissory notes	179	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(629)	9,841
Accounts payable	1,195	521
Accrued expenses	1,147	1,231
Net cash used in operating activities	**$ (7,030)**	**$ (2,262)**
Cash Flows from Financing Activities:		
Business Combination	—	26
Repayment of promissory notes	(1,410)	-
Payment made on behalf of Scilex	(19,748)	-
Proceeds from related party loans	8,474	9,911
Funds received from Scilex as an agent	19,748	-
Payments of deferred offering costs	-	(7,602)
Net cash provided by financing activities	**$ 7,064**	**$ 2,335**
Net change in cash and cash equivalents	**34**	**73**
Cash and cash equivalents at beginning of period	20	12
Cash and cash equivalents at end of period	**$ 54**	**$ 85**
Supplemental disclosure of non-cash financing activities:		
Related party debt settled in preferred stock pursuant to Debt Exchange Agreement	$ -	$ 54,236

See accompanying notes to the unaudited condensed consolidated financial statements

SEMNUR PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Note 1. Nature of Operations

Organization and Principal Activities

Semnur Pharmaceuticals, Inc. ("Semnur" or the "Company") is the successor entity to Denali Capital Acquisition Corp. ("Denali"). The Company is a Delaware corporation and is headquartered in Palo Alto, California. As of September 30, 2026, the Company has two wholly owned subsidiaries, Semnur (BVI), Limited and Semnur, Inc.

Denali was formed on January 5, 2022 as a Cayman Islands exempted company for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses or entities. Denali's initial public offering (the "IPO") became effective on April 6, 2022.

Legacy Semnur (as defined below), now known as Semnur, Inc., was originally formed in 2013 and became a wholly owned subsidiary of Scilex Holding Company ("Scilex") in 2019.

The Company is a late-stage clinical biopharmaceutical company focused on developing and commercializing innovative non-opioid pain management products for the treatment of acute and chronic pain.

The Company's lead product candidate is SP-102 (13.2 mg, dexamethasone sodium phosphate, equivalent to 10 mg dexamethasone, viscous gel) ("SP-102" or "SEMDEXA"), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica, for which the Company has completed a pivotal Phase 3 study and initiated the second Phase 3 study in September 2025.

Business Combination

References to "Legacy Semnur" refer to the private Delaware corporation that is now the Company's wholly owned subsidiary and named Semnur, Inc. (formerly known as "Semnur Pharmaceuticals, Inc."). Unless otherwise noted or the context requires otherwise, references to "Common Stock" refer to the Company's common stock, par value $0.0001 per share.

On September 22, 2025 (the "Closing"), the Company consummated a business combination pursuant to an agreement and plan of merger, dated as of August 30, 2024, (the "Initial Merger Agreement," as amended by Amendment No. 1 to Agreement and Plan of Merger, dated April 16, 2025, "Amendment No. 1 to the Initial Merger Agreement" and Amendment No. 2 to Agreement and Plan of Merger, dated July 22, 2025, "Amendment No. 2 to the Initial Merger Agreement" and collectively, the "Merger Agreement"), by and among Denali, Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali ("Merger Sub"), and Legacy Semnur. Pursuant to the terms of the Merger Agreement, the business combination (herein referred to as the "Business Combination" or "reverse recapitalization" for accounting purposes) between Denali and Legacy Semnur was effected through the merger of Merger Sub with and into Legacy Semnur with Legacy Semnur surviving as Denali's wholly owned subsidiary. In connection with the Business Combination, Denali changed its name from Denali Capital Acquisition Corp. to Semnur Pharmaceuticals, Inc. Pursuant to the Merger Agreement, the Company acquired all of the issued and outstanding equity interests of Legacy Semnur.

The Company's Common Stock and warrants were listed on the OTC Markets Group, Inc. on September 23, 2025 under the new ticker symbols "SMNR" and "SMNRW," respectively.

In accordance with the terms and subject to the conditions of the Merger Agreement, at Closing, (i) each share of Legacy Semnur common stock outstanding immediately prior to Closing was automatically cancelled in exchange for the right to receive 1.25 shares (the "Exchange Ratio") of Common Stock, (ii) each share of Legacy Semnur preferred stock outstanding immediately prior to the Closing was cancelled in exchange for the right to receive (a) one share of Series A Preferred Stock (as defined in Note 6) and (b) one-tenth of one share of Common Stock, and (iii) each option to purchase shares of Legacy Semnur common stock outstanding as of immediately prior to the Closing was converted into the right to receive a comparable option to purchase shares of Common Stock.

As such, 160,000,000 shares of Legacy Semnur common stock held by Scilex and 40,000,000 Legacy Semnur stock options, respectively, were automatically cancelled in exchange for 200,000,000 shares of Common Stock and 50,000,000 options to purchase Common Stock, respectively, at the Exchange Ratio.

Pursuant to the terms of the Debt Exchange Agreement (as defined in Note 8), all existing related party indebtedness between the Company and Scilex, totaling $54.2 million, was converted into 5,423,606 shares of Legacy Semnur Series A preferred stock. At Closing, such shares were exchanged for 5,423,606 shares of Series A Preferred Stock and 542,361 shares of Common Stock.

Additionally, at Closing, (i) loans between Scilex and Denali of $0.1 million were converted to 12,488 shares of Common Stock, (ii) 500,000 ordinary shares of Denali held by Scilex (see SIPA below) were converted into 500,000 shares of Common Stock and (iii) 2,072,500 ordinary shares of Denali held by Sponsor (the "Sponsor Shares") were converted into 2,072,500 shares of Common Stock.

Simultaneously with the Closing, 26,500,000 shares of Common Stock were issued to consultants (see Note 6) and 100,000 shares of Common Stock were issued to Denali underwriters (see Note 5).

The following summarizes the Company's Common Stock immediately following the Business Combination:

Holders	**Shares**
Denali public shareholders	13,629
Sponsor	2,072,500
Scilex Holding Company	201,054,849
Consultants	26,500,000
Denali underwriters	100,000
Total	229,740,978

The Business Combination was accounted for as a reverse recapitalization. Because Scilex controlled the Company before the Business Combination and also controlled the Company following the Business Combination, Denali was treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination was treated as the equivalent of Legacy Semnur issuing stock for the net assets of Denali, accompanied by a recapitalization whereby the net assets of Denali were stated at historical cost and no goodwill or other intangible assets are recorded.

At Closing, the assets and liabilities of Denali recognized at historical cost included prepaid expenses of $12 thousand, accounts payable of $4.4 million, related party liabilities of $3.9 million and notes payable of $4.6 million.

Sponsor Interest Purchase Agreement (the "SIPA")

In connection with the execution and delivery of the Merger Agreement, Denali Capital Global Investments LLC (the "Sponsor") and Scilex entered into the SIPA dated August 30, 2024. Pursuant to the SIPA, Scilex agreed to purchase 500,000 Class B ordinary shares, par value $0.0001 per share (the "Purchased Interests"), of the Company that were held by the Sponsor. The aggregate consideration for the purchase and sale of the Purchased Interests is as follows: (i) $2.0 million (the "Cash Consideration") and (ii) 300,000 shares of common stock, par value $0.0001 per share ("Scilex Common Stock"), of Scilex (the "Scilex Shares"). Pursuant to the SIPA, Scilex paid the Cash Consideration and agreed to issue the Scilex Shares to the Sponsor contingent upon and following the occurrence of the Business Combination. The Purchased Interests converted automatically, on a one-for-one basis, into one Common Stock share upon Closing pursuant to the terms of the Merger Agreement. On September 22, 2025, the requirement to deliver the Scilex Shares was discharged pursuant to that certain Satisfaction and Discharge Agreement by and among the Company, Sponsor and Scilex.

Securities Purchase Agreement (the "PIPE SPA")

On August 20, 2025, the Company and Legacy Semnur entered into the PIPE SPA with the investor named therein, pursuant to which the investor agreed to purchase 1,250,000 shares of Common Stock at a price of $16.00 per share, for an aggregate purchase price of $20.0 million following the consummation of the Business Combination. On September 22, 2025, the PIPE SPA was amended to provide that unless such agreement was terminated pursuant to its terms (or otherwise by mutual agreement of the parties thereto), the closing of the transactions contemplated thereby would occur not later than the 14th business day following the closing of the Business Combination, subject to the satisfaction or waiver of the closing conditions set forth therein.

Additionally, in connection with the PIPE SPA, the Company would have been obligated to pay a cash financing service fee of 7% of the received investment funds (see Note 6 section *Consulting Services Agreement with JW Investment Management Company Limited*).

On April 20, 2026, the Company and Semnur, Inc. delivered written notice to the investor under the PIPE SPA terminating such agreement pursuant to Section 8 thereof. As a result of such termination, the PIPE SPA is no longer in effect and the transactions contemplated thereby will not be consummated.

Bitcoin Securities Purchase Agreement (the "Semnur/Biconomy SPA")

On September 23, 2025, the Company entered into the Semnur/Biconomy SPA with Biconomy Pte.Ltd ("Biconomy"). Pursuant to the Semnur/Biconomy SPA, the Company agreed to issue and sell, and Biconomy agreed to purchase, 6,250,000 shares of Common Stock, at a purchase price of $16.00 per share, for an aggregate purchase price of $100.0 million, payable in Bitcoin ("Bitcoin"), with such amount of Bitcoin equal to the quotient of (A) the buyer's respective aggregate purchase price divided by (B) the spot exchange rate for Bitcoin as published by Coinbase.com at 8:00 p.m. (New York City time) on the trading day immediately prior to the closing date of the purchase. In the event the transaction did not close on or before December 31, 2025, the nonbreaching party had an option to terminate the Semnur/Biconomy SPA without liability.

On April 20, 2026, the Company delivered written notice to Biconomy terminating the Semnur/Biconomy SPA pursuant to Section 8 thereof. Accordingly, the Semnur/Biconomy SPA was terminated effective April 20, 2026, and the transactions contemplated thereby will not be consummated.

Public Warrants and Private Placement Warrants

Upon completion of the Business Combination, public and private placement warrants that were issued by Denali in connection with its IPO ("Public Warrants" and "Private Warrants," respectively, and together, the "Warrants") remained outstanding and pursuant to the terms thereof holders of such warrants are entitled to acquire shares of Common Stock at an exercise price of $11.50. The Warrants expire in September 2027.

In December 2025, 1,327,878 Warrants were exercised on a cashless basis for 468,164 shares of Common Stock. As of September 30, 2026 and December 31, 2025, there were 7,432,122 Warrants outstanding which are exercisable for 7,432,122 shares of Common Stock.

The Company may redeem any unexpired Warrants prior to their exercise at a price of $0.01 per Warrant, provided that the closing price of Common Stock equals or exceeds $16.50 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on each of 20 trading days within any 30-trading-day period commencing after the Warrants became exercisable and ending on the third trading day prior to the date on which notice of redemption is given. If and when the Warrants become redeemable, the Company may exercise its redemption right even if they are unable to register or qualify the underlying securities for sale under all applicable state securities laws. In addition, the Company may redeem the Warrants at any time after they become exercisable and prior to their expiration for a number of shares of Common Stock determined based on the fair market value of Common Stock.

Liquidity and Going Concern

The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Management has assessed the Company's ability to continue as a going concern for at least one year after the issuance date of the accompanying unaudited condensed consolidated financial statements.

As of September 30, 2026, the Company had cash and cash equivalents of $54.0 thousand and accumulated deficit of $288.4 million. During the nine months ended September 30, 2026, the Company had operating losses of $12.4 million and negative cash flows from operations of $7.0 million. The Company is dependent upon Scilex to provide services and funding to support the operations of the Company until, at least, such time as external financing is obtained. The Company expects to incur significant expenses and operating losses for the foreseeable future as it continues its efforts to develop and seek regulatory approval for SP-102.

The Company will need additional financing to fund its ongoing activities. The Company may obtain additional funding through a combination of equity offerings, debt financings, collaborations, government contracts or other capital sources, including potential collaborations with other companies or other strategic transactions. The Company's plans are also dependent upon the success of future development and regulatory approval of SP-102.

Although the Company believes such plans, if executed, should provide the Company with financing to meet its needs, successful completion of such plans is dependent on factors outside the Company's control. As a result, management has concluded that the aforementioned conditions, among other things, raise substantial doubt about the Company's ability to continue as a going concern for one year after the date the condensed consolidated financial statements are

issued. These unaudited condensed consolidated financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). The Company may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in the Company's periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. The Company has elected not to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that the Company (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these condensed consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") regarding interim financial reporting. All intercompany balances and transactions have been eliminated in consolidation.

These interim condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, include all adjustments of a normal recurring nature necessary to present fairly, in all material respects, the Company's financial position, results of operations and cash flows. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP were condensed or omitted pursuant to such rules and regulations. These interim condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2025. Operating results for the nine-month periods presented are not necessarily indicative of the results that may be expected for the Company's 2026 fiscal year, or any subsequent period.

Carve-Out Method

Since 2019, the Company has operated as a wholly owned subsidiary of Scilex and the Company's financial results have been historically included in Scilex's consolidated financial results.

The accompanying condensed consolidated financial statements reflect assets, liabilities, and expenses that are directly attributable to the Company, including the assets, liabilities, and expenses of the SP-102 development program. The assets and liabilities excluded from the accompanying condensed consolidated financial statements consist of:

- Cash held by Scilex to fund the Company's operations. Scilex uses a centralized approach to cash management and financing of its operations and those of its subsidiaries. Accordingly, only the cash and cash equivalents residing in the Company's bank accounts and legally owned by the Company have been reflected in these condensed consolidated financial statements.
- Other assets and liabilities at Scilex which are not directly related to, or are not specifically owned by, or are not commitments, of the Company, including certain fixed assets, intangible assets, and leases shared by the Company with other business operations of Scilex.
- Third-party debt held by Scilex and the related interest expense have not been allocated to the Company's condensed consolidated financial statements as the Company was not the legal obligor of the third-party

debt and Scilex's borrowings were not directly attributable to the Company. To fund the Company's operating cash flow needs, Scilex made payments on behalf of the Company directly to vendors and allocated non-cash stock-based compensation expenses during the nine months ended September 30, 2026 and 2025. See Note 8 for additional details.

The Company's operating expenses consisted of both research and development ("R&D") and general and administrative ("G&A") expenses. R&D expenses directly related to the Company, including third-party costs of conducting studies and clinical trials for the SP-102 product candidate, were entirely attributed to the Company in the accompanying condensed consolidated financial statements. R&D salaries, wages, benefits, and stock-based compensation related to Scilex's equity incentive plans were allocated to the Company based on the estimated percentage of time certain Scilex R&D employees spent on the SP-102 program during the reporting period.

The Company also received services and support from other functions of Scilex. The Company's operations are dependent upon the ability of these other functions to provide these services and support. The costs associated with these services and support were allocated to the Company based on the estimated percentage of time certain Scilex employees spent supporting the SP-102 program. These allocated costs were primarily related to corporate administrative expenses, G&A employee related costs, including salaries, stock-based compensation related to Scilex's equity incentive plans, and other benefits for corporate employees, as well as other expenses for shared assets for the following functional groups: information technology, legal, accounting and finance, facilities, and other corporate and infrastructural services. These allocated costs were recorded as R&D expenses and G&A expenses in the statements of operations and comprehensive loss.

The Company believes the assumptions and allocations underlying the accompanying condensed consolidated financial statements were reasonable and appropriate under the circumstances. Nevertheless, the Company's condensed consolidated financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented and may not reflect the results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure. The Company also may have incurred additional costs associated with being a standalone, publicly listed company that were not included in the expense allocations and, therefore, would result in additional costs that are not reflected in its historical results of operations, financial position and cash flows.

Use of Estimates

The preparation of these condensed consolidated financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of operating expenses during the reporting period. These estimates include, but are not limited to, fair value of financial instruments, useful lives of property and equipment, certain assumptions used to calculate the fair value of Scilex stock option awards, as well as the percentage of time certain Scilex employees spent supporting the Company's SP-102 program, which is used to calculate the amount of operating expenses allocated from Scilex as discussed in the *"Carve-Out Method"* section above.

Risks and Uncertainties

Any product candidates developed by the Company will require approvals from the U.S. Food and Drug Administration (the "FDA") or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company's current and future product candidates will meet desired efficacy and safety requirements to obtain the necessary approvals. If approval is denied or delayed, it may have a material adverse impact on the Company's business and its condensed consolidated financial statements.

The Company is subject to a number of risks similar to other late-stage pharmaceutical companies including, but not limited to, dependency on the clinical success of the Company's product candidates, ability to obtain regulatory approval of its product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, significant competition, untested manufacturing capabilities, and dependence on key individuals and sole source manufacturers and suppliers.

Global economic and business activities continue to face widespread macroeconomic and geopolitical uncertainties, including global trade disputes, labor shortages, declines in consumer confidence, inflation and monetary supply shifts, recession risks, potential disruptions from the ongoing wars in Ukraine and the Middle East and related sanctions, declines in economic growth, tariffs, U.S. government shutdowns and uncertainty about economic stability. The

Company continues to actively monitor the impact of these macroeconomic and geopolitical factors on its financial condition, liquidity, operations, and workforce. The extent of the impact of these factors on the Company's operational and financial performance, including its ability to execute its business strategies and initiatives in the expected time frame, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact the Company's business.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution, which, at times, may exceed the federal deposit insurance coverage limit of $250,000. The Company has not experienced losses on this account.

Concentration of Supply Risk

The Company contracts with third parties for the manufacture, assembly, testing, packaging and storage of its product candidate. The Company's contract manufacturing organizations ("CMOs") comply with Current Good Manufacturing Practice and regulatory requirements. The CMOs are selected for specific competencies having met the Company's development, manufacturing, quality and the FDA regulatory requirements. These CMOs manufacture the Company's clinical supplies and commercial batches. The Company currently has no plans to build its own manufacturing or distribution infrastructure. As clinical trial development progresses forward, the Company will continue to explore both internal capabilities as well as deepening and expanding external relationships to ensure it is able to meet manufacturing requirements.

Lifecore Master Services Agreement

On January 27, 2017, the Company entered into a Master Services Agreement (as amended, the "Lifecore Master Services Agreement"), with Lifecore Biomedical, LLC ("Lifecore"). Pursuant to the Lifecore Master Services Agreement, Lifecore is responsible for clinical trial material manufacturing and development services for SP-102 as set forth in each separate statement of work. For the purposes of Lifecore's development and clinical trial material manufacturing obligations, the Company granted Lifecore a nonexclusive, worldwide and royalty-free license under the Company's owned or controlled intellectual property rights necessary to manufacture SP-102, without additional right, title or interest in the Company's intellectual property.

The Lifecore Master Services Agreement expires on December 31, 2028, unless terminated earlier in accordance with the terms of such agreement, or unless renewed further by the parties. Either party may terminate the Lifecore Master Services Agreement (1) if the other party is in material breach of the agreement and fails to cure such breach within 30 days of written notice, subject to certain exceptions; or (2) immediately upon written notice to the other party if the other party (a) becomes insolvent, (b) ceases to function as a going concern, (c) is convicted of or pleads guilty to a charge of violating any law relating to either party's business, or (d) engages in any act which materially impairs goodwill associated with SEMDEXA or materially impairs the terminating party's trademark or trade name. In addition, Lifecore may terminate the agreement if (i) Semnur fails to pay past due invoices upon 30 days' written notice, or (ii) Semnur rejects or fails to respond to a major change or minor change proposed by Lifecore that does not change SEMDEXA's written and approved acceptance criteria.

The Lifecore Master Services Agreement contains customary reciprocal indemnification obligations for Lifecore and Semnur.

During the three and nine months ended September 30, 2026, the Company incurred expenses of $0.07 million and $0.15 million, respectively, related to the Lifecore Master Services Agreement.

Segments

Operating segments are identified as components of an entity where separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions on how to allocate resources and assess performance. The Company has determined that its chief operating decision maker ("CODM") is its Chief Executive Officer, as he is responsible for making decisions regarding the allocation of resources and assessing performance as well as for strategic operational decisions. Since inception, the Company has devoted all of its efforts to the development of SP-102. Accordingly, the Company has determined that it operates its business as a single operating segment and has one reportable segment. The CODM assesses performance and decides how to allocate resources based on net loss. Net loss is used to monitor budget versus actual results. The measure of segment net loss and segment expenses is reported on the condensed consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the condensed consolidated balance sheets as total assets. All long-lived

assets are maintained in the United States of America and Switzerland.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents, such as money market accounts. The Company minimizes its credit risk associated with cash and cash equivalents by periodically evaluating the credit quality of its primary financial institution.

Fair Value of Financial Instruments

The Company follows accounting guidance on fair value measurements for financial instruments measured on a recurring basis, as well as for certain assets and liabilities that are initially recorded at their estimated fair values. Fair value is defined as the exit price, or the amount that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company uses the following three-level hierarchy that maximizes the use of observable inputs and minimizes the use of unobservable inputs to value its financial instruments:

Level 1 —Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 —Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable inputs for similar assets or liabilities. These include quoted prices for identical or similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active; and

Level 3 —Significant 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.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires it to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed or initial amounts recorded may not be indicative of the amount that the Company or holders of the instruments could realize in a current market exchange.

The Company's financial assets carried at fair value are comprised of cash, cash equivalents and digital assets. Cash and cash equivalents consist of money market accounts and bank deposits which are highly liquid and readily tradable. These assets are Level 1 assets as they are valued using inputs observable in active markets for identical securities.

Digital Assets

The Company holds digital assets, including stablecoins, and other digital tokens received in connection with corporate transactions, which are presented as a separate line item within the condensed consolidated balance sheets. In accordance with ASU 2023-08, Intangibles—Goodwill and Other—Crypto Assets (Subtopic 350-60), digital assets within the scope of this guidance are measured at fair value each reporting period, with changes in fair value recognized in unrealized gains and losses within other expense, net, in the condensed consolidated statements of operations and comprehensive loss. Fair value is determined using the quoted price of each digital asset on its principal market (or most advantageous market, if no principal market exists) as of the balance sheet date, without regard to contractual sale restrictions, consistent with Level 1 of the fair value hierarchy. Upon sale, the Company recognizes a realized gain or loss for the difference between sale proceeds and the carrying value immediately prior to sale, using the specific identification method to determine the cost basis of units sold. Digital assets are classified as long-term assets unless management intends to sell or utilize a specific holding within twelve months of the balance sheet date. Digital assets not meeting the scope of ASC 350-60 are accounted for as general intangible assets.

During the three and nine months ended September 30, 2026, at the written direction of Scilex, the Company's parent, the Company purchased stablecoins (USDT) and subsequently transferred the USDT stablecoins to a third-party vendor of Scilex in settlement of an amount owed by Scilex to that vendor. In exchange, Scilex reduced the principal of the Company's related party loan payable to Scilex by an equivalent amount. The Company acquired the stablecoins solely to make this payment and did not hold it for investment purposes.

The table below summarizes the amounts shown on our unaudited condensed consolidated balance sheets as of September 30, 2026 (in thousands except units of digital assets):

	September 30, 2026		
	Units	Cost Basis	Fair Value
Stablecoins	301	—	—
Total Digital assets	301	$ —	$ —

The following table summarizes the activity in the Company's digital assets (in thousands) for the period indicated:

	September 30, 2026
Beginning digital assets balance at fair value December 31, 2025	$ —
Additions (Funds received from Scilex as an agent)	19,748
Disposals (Payment made on behalf of Scilex)	(19,748)
Ending balance at fair value September 30, 2026	$ —

Property and Equipment

Property and equipment are carried at cost less accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the assets, which are generally five to seven years. The cost of repairs and maintenance is expensed as incurred. Costs for property and equipment not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. There was no impairment of long-lived assets during the three and nine months ended September 30, 2026 and 2025.

Promissory Notes and Related Party Loan

The Company accounts for its promissory notes and related party loan in accordance with ASC 470, *Debt*, and related guidance. Debt is recognized at the issuance date fair value, net of any debt discounts or issuance costs. Debt is subsequently carried at amortized cost, with any applicable interest expense recognized using the effective interest method over the contractual term.

If the debt is amended or exchanged, the Company evaluates whether the modification is considered a troubled debt restructuring or an extinguishment under ASC 470-50. When extinguishment accounting applies, the old debt is derecognized and any difference between the reacquisition price and the carrying amount of the extinguished debt is recognized in earnings.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, *Distinguishing Liabilities from Equity*, and ASC 815, *Derivatives and Hedging*. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own ordinary shares and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment

is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in-capital at the time of issuance. For issued or modified warrants that do not meet all of the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. As of September 30, 2026 and December 31, 2025, the Company has accounted for the Public Warrants and Private Warrants as equity-classified instruments.

Research and Development Costs

The Company expenses the cost of R&D as incurred. R&D expenses are comprised of costs incurred in performing R&D activities, including clinical trial costs, manufacturing costs for clinical materials, and the costs relating to other contracted services, license fees and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development.*

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC 718, *Compensation – Stock Compensation,* which establishes accounting for equity instruments exchanged for employee and consulting services. Stock-based compensation cost is measured at the grant date, based on the fair value of the award determined using the Black-Scholes option pricing model, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant) or non-employee's vesting period. The Company accounts for forfeitures as incurred.

For purposes of determining the inputs used in the calculation of stock-based compensation, the Company determines the expected life assumption for options issued using the simplified method, which is an average of the contractual term of the option and its ordinary vesting period since the Company does not have historic exercise behavior. The Company determines an estimate of option volatility based on an assessment of historical volatilities of comparable companies whose share prices are publicly available. The Company uses these estimates, in conjunction with the fair value of Scilex Common Stock, risk-free interest rate, and the expected dividend yield as inputs in the Black-Scholes option pricing model. Depending upon the number of stock options granted, any fluctuations in these calculations could have a material effect on the results presented in the Company's condensed consolidated statement of operations.

Stock-based compensation for Scilex employees who provide services and support activities related to the Company are allocated and attributed to the Company based on the estimated percentage of their time spent providing services attributable to the Company.

Income Taxes

The provisions of ASC 740, *Income Taxes*, address the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the financial statements. Under ASC 740-10, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by taxing authorities, based on the technical merits of the position. The Company has determined that it has uncertain tax positions.

The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates.

The Company has deferred tax assets, which are subject to periodic recoverability assessments. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount that more likely than not will be realized.

Comprehensive loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. There are no components of other comprehensive loss for the Company. Thus, comprehensive loss is the same as the net loss for the periods presented.

Net Loss per Share

Basic net loss per share is computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options and warrants. The treasury

stock method is used to calculate the potential dilutive effect of these common stock equivalents. Potentially dilutive shares are excluded from the computation of diluted net loss per share when their effect is anti-dilutive. In periods where a net loss is presented, all potentially dilutive securities are anti-dilutive and are excluded from the computation of diluted net loss per share.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which requires disaggregated information about certain income statement expense line items on an annual and interim basis. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted and can be applied prospectively or retrospectively. The Company is evaluating the impact of the adoption of this standard on the Company's consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements, which clarifies interim disclosure requirements and the applicability of Topic 270. The ASU also includes a disclosure principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The ASU is effective for all public business entities for interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is evaluating the impact of the adoption of this standard on the Company's consolidated financial statements and related disclosures.

Note 3. Balance Sheet Components

Prepaid expenses

Prepaid expenses consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Prepaid research & development	$ 1,101	$ 436
Prepaid insurance	104	140
Total prepaid expenses	$ 1,205	$ 576

Property and equipment, net

Property and equipment, net consists of the following (in thousands):

	September 30, 2026	December 31, 2025
Construction-in-progress	$ 750	$ 750
Furniture	17	17
Computers and equipment	8	8
Property and equipment, gross	775	775
Less: accumulated depreciation	(25)	(25)
Property and equipment, net	$ 750	$ 750

The Company recognized no depreciation expense for the three months ended September 30, 2026 and 2025 and the nine months ended September 30, 2026 and 2025. Costs for long-lived assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service.

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued compensation	$ 1,778	$ 469
Accrued research & development	72	30
Accrued professional fees	34	236
Accrued other	2	4
Total accrued expenses	$ 1,886	$ 739

Note 4. Commitments and Contingencies

In the normal course of business, the Company may from time to time be named as a party to various legal claims, actions and complaints, including matters involving employment, intellectual property, effects from the use of therapeutics utilizing its technology, or others. It is impossible to predict with certainty whether any resulting liability would have a material adverse effect on the Company's financial position, results of operations or cash flows. As of September 30, 2026 and December 31, 2025, the Company was not a party to any material legal proceedings with respect to itself or any of its material properties.

iHolding Term Sheet

On July 3, 2026, the Company entered into a binding term sheet with iHolding Group LLP ("iHolding"), which contemplates that iHolding will purchase $100.0 million of newly issued shares of Common Stock. The purchase price for such shares is expected to be $10.00 per share, which would represent approximately 10,000,000 shares. The term sheet has no fixed completion date. As of September 30, 2026, no definitive agreement has been executed.

Legacy Semnur Merger Agreement

On March 18, 2019, Legacy Semnur was acquired by Scilex pursuant to an Agreement and Plan of Merger with Semnur (as amended, the "Legacy Semnur Merger Agreement"), Sigma Merger Sub, Inc., a wholly owned subsidiary of Scilex ("Sigma Merger Sub"), Fortis Advisors LLC, solely as representative of the holders of Legacy Semnur's equity, and for limited purposes, Sorrento Therapeutics, Inc. Pursuant to the Legacy Semnur Merger Agreement, Sigma Merger Sub merged with and into Legacy Semnur, and Legacy Semnur survived as Scilex's wholly owned subsidiary.

Pursuant to the Legacy Semnur Merger Agreement, and upon the terms and subject to the conditions contained therein, Scilex agreed to pay the former holders of Legacy Semnur's capital stock up to $280.0 million in aggregate contingent cash consideration based on the achievement of certain milestones (which amount is expected to be charged back to Semnur through an intercompany arrangement), comprised of a $40.0 million payment that will be due upon obtaining the first approval of a new drug application of a Semnur product by the FDA and additional payments that will be due upon the achievement of certain amounts of net sales of Semnur products, as follows: (i) a $20.0 million payment upon the achievement of $100.0 million in cumulative net sales of a Semnur product, (ii) a $20.0 million payment upon the achievement of $250.0 million in cumulative net sales of a Semnur product, (iii) a $50.0 million payment upon the achievement of $500.0 million in cumulative net sales of a Semnur product, and (iv) a $150.0 million payment upon the achievement of $750.0 million in cumulative net sales of a Semnur product. To date, none of the foregoing payments have been triggered.

Shah Assignment Agreement

On August 6, 2013, Legacy Semnur entered into an Assignment Agreement (the "Shah Assignment Agreement") with Shah Investor LP ("Shah Investor"). Pursuant to the Shah Assignment Agreement, Shah Investor assigned to Legacy Semnur the patents, know-how and other intellectual property related to pharmaceutical compositions of corticosteroids.

In consideration of the license and rights granted by Shah Investor, Legacy Semnur agreed to pay royalties (i) at the rate of 1.5% of the Net Sales for Annual Net Sales (each as defined therein) up to $250.0 million and (ii) at the rate of 2.5% of the Net Sales for Annual Net Sales of $250.0 million and above, subject to certain adjustments as set out in the Shah Assignment Agreement. Such royalty payment for a given calendar quarter shall be due and payable on the date the royalty report for such quarter is due under the Shah Assignment Agreement. To date, none of the foregoing payments have been triggered.

The Shah Assignment Agreement continues in full force and effect on a country-by-country and product-by-product basis until royalties are no longer due on such product under the agreement. The Shah Assignment Agreement contains customary reciprocal indemnification obligations for Shah Investor and Semnur.

Subsidiary Guarantee to Scilex-Oramed Note

On September 21, 2023, Scilex entered into, and consummated the transactions contemplated by, a Securities Purchase Agreement (the "Scilex-Oramed SPA") with Oramed Pharmaceuticals Inc. ("Oramed") and the Agent (as defined below), pursuant to which, among other things, Scilex issued to Oramed a senior secured promissory note due 18 months from the date of issuance in the principal amount of $101.9 million (the "Scilex-Oramed Note"). In connection with the Scilex-Oramed SPA, Scilex and each of its subsidiaries, including Legacy Semnur, (collectively, the "Guarantors") entered into a subsidiary guarantee (as amended, the "Subsidiary Guarantee") with Oramed and Acquiom Agency Services LLC, as the collateral agent for the holders of the Scilex-Oramed Note (the "Agent"), pursuant to which, the Guarantors have agreed to guarantee and act as surety for payment of the Scilex-Oramed Note and any additional notes issued by Scilex in full or partial substitution of the Scilex-Oramed Note. Following the execution of the amended and restated security agreement with Oramed on October 8, 2024, and upon completion of the Business Combination, as of September 22, 2025, the Company was no longer a Guarantor under the Subsidiary Guarantee.

Note 5. Promissory Notes

Pursuant to the Business Combination, the Company assumed all liabilities of Denali including its existing promissory notes and its liability for its deferred underwriting costs associated with the IPO. Simultaneously upon Closing, the agreements for these existing liabilities were terminated and new promissory notes and discharge payment agreements were signed with the holders.

Immediately prior to the Closing, Denali, Sponsor and Legacy Semnur entered into a Satisfaction and Discharge of Indebtedness Agreement, pursuant to which the Sponsor received $1.1 million in cash and a promissory note for $0.8 million (the "Sponsor Note"). The Sponsor Note shall be payable in six monthly installments of $134 thousand beginning on October 1, 2025 and ending on March 1, 2026.

Immediately prior to the Closing, Denali and FutureTech Capital LLC ("FutureTech") entered into a Satisfaction and Discharge of Indebtedness Agreement, pursuant to which FutureTech received $340 thousand in cash and a promissory note for $1.0 million (the "FutureTech Note"). The FutureTech Note shall be payable in six monthly installments of $170 thousand beginning on October 1, 2025 and ending on March 1, 2026.

At Closing, Denali, the Denali underwriters and the Company entered into Satisfaction and Discharge of Indebtedness Agreements, pursuant to which the Denali underwriters received $350 thousand in cash and promissory notes for a total of $2.7 million (the "Denali Underwriter Notes"). The Denali Underwriter Notes shall be payable in nine monthly installments of $300 thousand beginning on October 1, 2025 and ending on June 1, 2026.

The following summarizes the new promissory notes as a result of the Business Combination:

			New Agreements	
Note	Original Issue Date	Existing Balance	Note	Discharge
Sponsor Note	4/11/2023, 7/10/2024	$ 1,807	$ 806	$ 1,144
FutureTech Note	7/11/2023	1,363	1,022	340
Denali Underwriter Notes	4/6/2022	2,888	2,650	350
Total promissory notes		$ 6,058	$ 4,478	$ 1,834

As of September 30, 2026 and December 31, 2025, the Company had total current promissory notes of $2.3 million and $3.5 million, respectively, all of which are due in less than a year.

Notwithstanding the payment schedules in the Sponsor Note, the FutureTech Note and the Denali Underwriter Notes, the balance due on any notes (less any payments previously made to the holder thereunder) shall be accelerated and become immediately due and payable in the event the Company receives gross proceeds from any equity or debt financing (including any private placement offering or registered offering), in an amount equal to or greater than the then-outstanding principal of such note plus any accrued but unpaid interest due thereon.

In addition, in the case of an event of default, the Sponsor Note, the FutureTech Note and the Denali Underwriter Notes shall bear interest at a rate of 10% per annum until such event of default is cured. The Sponsor Note, the FutureTech Note and the Denali Underwriter Notes shall become immediately due and payable (in accordance with the terms thereof), upon the Company's failure to make payments thereunder when due (subject to a 14-day cure period) or certain other actions related to voluntary or involuntary bankruptcy proceedings (as more fully described therein).

Out of the outstanding promissory notes, the Company did not make certain scheduled installment payments during the first quarter of 2026 on the Sponsor Note (monthly installments of $134 thousand), the Denali Underwriter Note for U.S. Tiger Securities, Inc. (monthly installments of $150 thousand) and the FutureTech Note (monthly installments of $170 thousand). As of September 30, 2026 and December 31, 2025, the Sponsor Note had an outstanding principal balance of $480 thousand and $806 thousand, respectively, and accrued interest of approximately $48 thousand and $20 thousand, respectively, at 10% per annum (calculated monthly).

As of September 30, 2026, the FutureTech Note and Denali Underwriter Notes had an outstanding principal balance of $356 thousand and $1,450 thousand, respectively. As of December 31, 2025, the FutureTech Note and Denali Underwriter Notes had an outstanding principal balance of $511 thousand and $2,200 thousand, respectively. Accrued interest related to the FutureTech Note and Denali Underwriter Notes was approximately $131 thousand as of September 30, 2026. The Company has not received a notice of default under the Sponsor Note, the FutureTech Note nor the Denali Underwriter Notes and expects to make the payments by end of year 2026.

The Company has recorded accrued interest of $179 thousand and $0 on the promissory notes as of September 30, 2026 and December 31, 2025, respectively.

Note 6. Capital Structure

As of September 30, 2026 and December 31, 2025, the Company was authorized to issue 785,000,000 shares, consisting of (i) 740,000,000 shares of Common Stock, and (ii) 45,000,000 shares of preferred stock, par value $0.0001 per share, of the Company ("Preferred Stock"). Holders of the Common Stock are entitled to dividends if and when declared by the Company's Board of Directors (the "Board of Directors"). The holder of each share of Common Stock is entitled to one vote. As of September 30, 2026 and December 31, 2025, no dividends were declared.

On May 22, 2026, the Board of Scilex, the Company's parent, approved a dividend (the "Semnur Dividend") consisting of shares of Common Stock payable to stockholders and certain other eligible equity holders of Scilex (the "Participating Holders"). The record date for the Semnur Dividend was June 1, 2026.

Pursuant to the Semnur Dividend, each Participating Holder became entitled to receive one (1) share of Common Stock for each share of Scilex Common Stock held as of the record date (or for each share issuable or deemed issuable upon the exercise or conversion of other eligible securities).

As of September 30, 2026, Scilex has distributed 13,971,167 shares of the Company's Common Stock to the Participating Holders.

Common Stock Reserved

As of September 30, 2026 and December 31, 2025, the Company had 37,957,122 and 67,332,122 shares of common stock reserved for future issuance, respectively, on an as-converted basis.

As of September 30, 2026, the shares reserved for future issuance consisted of 7,432,122 shares issuable upon the exercise of outstanding warrants, 28,125,000 shares issuable upon the exercise of outstanding stock options (see Note 7), and 2,400,000 shares reserved under the 2025 Inducement Plan.

As of December 31, 2025, the shares reserved for future issuance consisted of 7,432,122 shares issuable upon the exercise of outstanding warrants, 50,000,000 shares issuable upon the exercise of outstanding stock options, 1,250,000 shares issuable pursuant to the PIPE SPA, 6,250,000 shares issuable pursuant to the Semnur/Biconomy SPA, dated as of September 23, 2025, by and between the Company and Biconomy Pte.Ltd, and 2,400,000 shares reserved under the 2025 Inducement Plan.

Preferred Stock

As of September 30, 2026 and December 31, 2025, the Company had 5,423,606 shares of Series A Preferred Stock

("Series A Preferred Stock") issued and outstanding. The holders of Series A Preferred Stock have various rights and preferences as follows:

Rank

The Series A Preferred Stock shall rank (i) senior to all Common Stock, and to all other classes or series of capital stock of Semnur, except for any such other class or series, the terms of which expressly provide that it ranks on parity with the Series A Preferred Stock as to dividend rights and rights on liquidation, dissolution or winding-up of Semnur ("Junior Securities"); and (ii) on parity with each class or series of capital stock of Semnur, created specifically ranking by its terms on parity with the Series A Preferred Stock as to dividend rights and rights on liquidation, dissolution or winding-up of Semnur ("Parity Security").

Dividend Rights

Holders of Series A Preferred Stock shall not be entitled to dividends unless Semnur pays dividends to holders of Common Stock and shall be entitled to receive, when, as and if declared by the Board of Directors, such dividends (whether in cash or other property) as are paid to holders of Common Stock to the same extent as if such holders of Series A Preferred Stock had been deemed to convert their shares of Series A Preferred Stock into Common Stock and had held such shares of Common Stock on the record date for such dividends and distributions. Such payments will be made concurrently with the dividend or distribution to the holders of the Common Stock.

Liquidation Preference

In the event of a change of control, liquidation, dissolution or winding-up of Semnur, whether voluntary or involuntary, before any payment or distribution of Semnur's property or assets (whether capital or surplus) shall be made to or set apart for the holders of Junior Securities, the holders of Series A Preferred Stock shall be entitled to receive an amount per share of Series A Preferred Stock equal to the greater of (i) the sum of $10.00 (which amount shall be appropriately adjusted in the event of any stock split, stock combination or other similar recapitalization of the Series A Preferred Stock) and all accrued and unpaid dividends and (ii) the amount such share of Series A Preferred Stock would be entitled to receive pursuant to the change of control, liquidation, dissolution or winding-up of Semnur assuming that such share had been converted into shares of Common Stock in a Deemed Conversion (as defined below). If, in the event of a change of control, liquidation, dissolution or winding-up of Semnur, Semnur's assets, or proceeds thereof, are insufficient to pay in full the aggregate amount of liquidation preference payable in respect of all outstanding shares of Series A Preferred Stock, such assets or the proceeds thereof will be distributed ratably in proportion to the respective amounts of the liquidation preference if paid in full.

Conversion and Redemption Rights

The shares of Series A Preferred Stock are not convertible into Common Stock or any other securities of Semnur and are not redeemable by Semnur; provided, however, a number of the rights, preferences and privileges of the Series A Preferred Stock set forth in the certificate of designations (the "Certificate of Designations") will be determined based on an as-converted-to-Common Stock basis or otherwise assume that the shares of Series A Preferred Stock are converted into shares of Common Stock. Accordingly, the number of shares of Common Stock that each share of Series A Preferred Stock is deemed to be (or otherwise being treated as) converted into for the purpose of effecting the various rights, preferences and privileges of the Series A Preferred Stock set forth in the Certificate of Designations (a "Deemed Conversion"), whether in connection with a change of control or otherwise, shall be equal to the result obtained by dividing (i) stated value by (ii) $10.00 (subject to anti-dilution adjustments).

Voting and Other Preferred Rights

Except as otherwise required by law or as set forth in the Certificate of Designations, the holders of shares of Series A Preferred Stock are entitled to vote, together with the holders of shares of Common Stock and not separately as a class, on all matters upon which holders of shares of Common Stock have the right to vote. The holders of shares of Series A Preferred Stock are entitled to one vote for each share of Common Stock that such share of Series A Preferred Stock would otherwise be convertible into pursuant to a Deemed Conversion on the record date for the determination of the stockholders entitled to vote.

As long as any shares of Series A Preferred Stock are outstanding, Semnur shall not, without the affirmative vote of the holders of at least a majority of the outstanding shares of Series A Preferred Stock (a) change the Series A Preferred Stock (whether by merger, conversion, consolidation, reclassification or otherwise) into cash, securities or other property except in accordance with the terms of the Certificate of Designations; (b) create, authorize or issue any Parity Security or other equity security the terms of which provide that it ranks senior to the Series A Preferred Stock

with respect to dividend rights or rights upon liquidation, dissolution or winding-up of Semnur, or increase the authorized amount of any such other class or series; or (c) amend its certificate of incorporation or the Certificate of Designations in any manner that adversely affects the holders of Series A Preferred Stock.

Treasury Stock

During the three and nine months ended September 30, 2026, 12,500,000 shares of Common Stock that had previously been issued to a law firm as retainer shares were returned to the Company. None of the shares had been utilized to satisfy outstanding legal fees as of the date of return. The returned shares were accounted for as treasury stock and are presented as a deduction from stockholders' equity as of September 30, 2026.

Consulting Agreements with Stock Remuneration

Consulting Services Agreement with 450W42ND MIMA, LLC

On August 25, 2024, Legacy Semnur entered into a consulting services agreement with 450W42ND MIMA, LLC, which agreed to perform certain consulting and advisory services related to Legacy Semnur's business, financing, and mergers and acquisitions opportunities for a period of 12 months from the date of the agreement, in exchange for Common Stock.

On July 22, 2025, Legacy Semnur entered into an amendment to the foregoing consulting services agreement, pursuant to which Legacy Semnur instead agreed to issue 3,200,000 shares of Legacy Semnur common stock, subject to the satisfaction of the terms and conditions contained in the consulting services agreement, as amended.

In September 2025, the consulting agreement with 450W42ND MIMA, LLC was terminated and no shares are required to be issued.

Consulting Services Agreement with Wise Orient Investments Limited

On August 26, 2024, Legacy Semnur entered into a consulting services agreement with Wise Orient Investments Limited ("Wise Orient"), which agreed to perform certain consulting and advisory services related to Legacy Semnur's business, financing, and mergers and acquisitions opportunities for a period of 12 months from the date of the agreement, in exchange for Common Stock.

On July 22, 2025, Legacy Semnur entered into an amendment to the foregoing consulting services agreement, pursuant to which Legacy Semnur agreed to instead issue 3,200,000 shares of Legacy Semnur common stock, subject to the satisfaction of the terms and conditions contained in the consulting services agreement, as amended.

Upon Closing, 4,000,000 shares (i.e., the then-existing 3,200,000 shares of Legacy Semnur common stock multiplied by the Exchange Ratio) of Common Stock were issued to Wise Orient and the associated expense was recognized as general and administrative expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

Consulting Services Agreement with JW Investment Management Company Limited

On June 12, 2025, Legacy Semnur entered into an advisory services agreement with JW Investment Management Company Limited ("JW"), pursuant to which JW agreed to perform certain consulting and advisory services related to Legacy Semnur's business, financing, and mergers and acquisitions opportunities for a period of 12 months from the date of the agreement.

In exchange for the services provided and subject to the terms and conditions contained in the consulting services agreement, Legacy Semnur agreed to issue JW 10,000,000 shares of Common Stock following the consummation of the Business Combination, as well as a cash financing service fee of 7% of the received investment funds should JW successfully facilitate the signing of a PIPE contract on the Company's behalf.

On July 22, 2025, Legacy Semnur entered into an amendment to the foregoing consulting services agreement, pursuant to which Legacy Semnur agreed to amend the share compensation and instead issue to JW 8,000,000 shares of Legacy Semnur common stock, subject to the satisfaction of the terms and conditions contained in the consulting services agreement, as amended.

Upon Closing, 10,000,000 shares (i.e., the then-existing 8,000,000 shares of Legacy Semnur common stock multiplied by the Exchange Ratio) of Common Stock were issued to JW and the associated expense was recognized as general and administrative expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

In April 2026, the Company terminated the PIPE transaction. Accordingly, as of September 30, 2026, no obligation existed with respect to the 7% cash financing service fee.

Retainer Shares

On July 22, 2025, Legacy Semnur entered into a stock issuance agreement with the law firm named therein pursuant to which the law firm was issued 10,000,000 shares of Legacy Semnur common stock as a retainer for legal services and payment for prior services. Upon Closing, the shares were exchanged for 12,500,000 shares (i.e., the then-existing 10,000,000 shares of Legacy Semnur common stock multiplied by the Exchange Ratio) of Common Stock.

All such shares were held by the law firm as collateral for current and future outstanding legal fees due from the Company. At the option of the law firm, the retainer shares could be sold and the net proceeds applied against the outstanding legal fees. The retainer shares not applied against the outstanding legal fees due would be returned to the Company. During the three months ended September 30, 2026, all 12,500,000 retainer shares were returned to the Company, and none of the shares had been utilized to satisfy outstanding legal fees as of the date of return.The returned shares were reacquired for no consideration and are held as treasury stock, recorded at a cost of $0.

Scilex Stockholder Agreement

Concurrently with the execution of the Merger Agreement, the Company entered into a Stockholder Agreement with Scilex (the “Scilex Stockholder Agreement”). Pursuant to the Scilex Stockholder Agreement, from and after the effective time of the Business Combination, and for so long as Scilex beneficially owns any preferred stock, among other things, (i) Scilex shall have the right, but not the obligation, to designate each director to be nominated, elected or appointed to the Board of Directors (each, a “Stockholder Designee” and collectively, the “Stockholder Designees”), regardless of (i) whether such Stockholder Designee is to be elected to the Board of Directors at a meeting of stockholders called for the purpose of electing directors (or by consent in lieu of meeting) or appointed by the Board of Directors in order to fill any vacancy created by the departure of any director or increase in the authorized number of members of the Board of Directors, or (ii) the size of the Board of Directors, and the Company will be required to take all actions reasonably necessary, and not otherwise prohibited by applicable law, to cause each Stockholder Designee to be so nominated, elected or appointed to the Board of Directors as more fully described in the Scilex Stockholder Agreement. Scilex shall also have the right to designate a replacement director for any Stockholder Designee that has been removed from the Board of Directors and the right to appoint a representative of Scilex to attend all meetings of the committees of the Board of Directors. The Scilex Stockholder Agreement also provides that the Company will be prohibited from taking certain actions without the consent of Scilex. Such actions include, among other things, amendments to the Certificate of Designations, increases or decreases in the size of the Board of Directors, the incurrence of certain amounts of indebtedness and the payment of dividends on common stock. In addition, the Scilex Stockholder Agreement provides that the Company will be prohibited from taking certain actions without the consent of Oramed (but only until the date on which all payments under the Scilex-Oramed Note and all other obligations under the Scilex-Oramed Note have been paid in full in cash). The actions that require Oramed’s consent include, among other things, (i) amending certain agreements, including the Scilex Stockholder Agreement, the Merger Agreement, the Company’s certificate of incorporation or bylaws, the 2024 Plan (as defined in Note 7), the Stockholder Support Agreement and the Debt Exchange Agreement (as defined in Note 8), in each case that adversely affect the rights of capital stock held by Scilex in the Company; (ii) approval of the issuance of capital stock of the Company that would result in Scilex holding less than 55% of the outstanding shares or voting power in the Company; (iii) forming any subsidiary that is not wholly owned and controlled by the Company; (iv) permitting any option grants to Scilex Insiders (as defined therein) pursuant to the 2024 Plan prior to the execution of the Merger Agreement to be exercisable; and (v) permitting certain compensation payments to Scilex Insiders (as defined therein).

Note 7. Stock-Based Compensation

Prior to the Business Combination, the Company did not have any employees who were directly employed by the Company nor did it have its own stock-based compensation plans other than the Semnur Pharmaceuticals, Inc. 2024 Stock Option Plan (the "2024 Plan") as described below. However, certain shared employees of Scilex support the Company and also participate in Scilex’s stock-based compensation plans that provide for the granting of stock options, non-qualified stock options (“NSOs”), stock appreciation rights, restricted stock, restricted stock units, and other awards. Such shared employees’ time and efforts are partially spent on activities attributable to the Company and partially spent on activities attributable to Scilex; Scilex did not have any employees whose activities are solely dedicated or solely attributable to the Company during the three and nine months ended September 30, 2026 and 2025. For the three and nine months ended September 30, 2026 and 2025, total stock-based compensation recognized

consists of an allocation of shared employees' stock-based compensation expense based on the same allocation methodology used for salaries and benefits, as well as expense related to grants made to Wise Orient and JW (see Note 6 "*Capital Structure — Consulting Agreements with Stock Remuneration*").

Scilex calculates the fair value of stock options granted to employees and nonemployees and rights granted under the employee stock purchase plan ("ESPP") using the Black-Scholes option pricing method. The Black-Scholes option pricing method requires the use of subjective assumptions.

Total stock-based compensation expense recorded in the condensed consolidated statements of operations was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 144	$ 29	$ 290	$ 136
General and administrative	711	140,163	3,344	140,267
Total stock-based compensation expense	$ 855	$ 140,192	$ 3,634	$ 140,403

As of September 30, 2026, there was approximately $1.3 million of total unrecognized stock-based compensation expense, which is expected to be recognized over an estimated weighted-average vesting term of 0.7 years. This amount is subject to change based on the actual amount of time certain Scilex employees will spend providing services attributable to the Company.

2024 Plan

On August 30, 2024, the Board of Directors adopted the 2024 Plan, under which 40,000,000 shares of Legacy Semnur common stock were reserved for future issuance. On the same day, NSOs to purchase an aggregate of 40,000,000 shares of the Legacy Semnur common stock were granted to members of the Company's executive team and certain Scilex employees who provide services to Semnur. The NSOs granted have an exercise price of $1.58 per share, a term of 10 years (unless earlier terminated in accordance with the terms of the option agreement) and vest 1/48th on a monthly basis over a period of four years from the vesting commencement date as set forth in the applicable option agreement (subject to the holder's continuous service with the Company). Upon closing, the NSOs were exchanged for 50,000,000 NSOs (i.e., the then-existing NSOs multiplied by the Exchange Ratio) in Common Stock and the exercise price was adjusted to $1.26 per share (i.e., the then-existing exercise price divided by the Exchange ratio).

The NSOs are not exercisable until all payments and all obligations under the Scilex-Oramed Note have been paid in full. These NSOs are not considered to be granted under accounting rules as repayment of the Scilex-Oramed Note has not occurred. As such, once the NSOs are considered granted, the total amount of stock-based compensation expense attributable to these NSOs would be determined based on their accounting grant-date fair value and to be recognized, on a tranche-by-tranche basis, over forty-eight equal monthly tranches. No expense was recorded in connection with the NSOs granted under the 2024 Plan as of September 30, 2026, as the vesting is contingent upon the repayment of the Scilex-Oramed Note.

During the three and nine months ended September 30, 2026, 21,875,000 options to purchase Common Stock were forfeited to the Company. Options outstanding as of September 30, 2026 were 28,125,000.

As of September 30, 2026, the 28,125,000 NSOs have an intrinsic value of $0 and a remaining contractual term of 7.9 years. As of September 30, 2026, no shares remained available for issuance under the 2024 Plan.

2025 Plan

On November 17, 2025, the Board of Directors adopted the 2025 Equity Incentive Plan (the "2025 Plan"), the 2025 Employee Stock Purchase Plan (the "2025 ESPP") and the 2025 Inducement Plan (the "2025 Inducement Plan"). The 2025 Plan and the 2025 ESPP are subject to stockholder approval and are not effective until such approval. The 2025 Inducement Plan does not require stockholder approval and is therefore effective upon adoption by the Board of Directors.

The 2025 Plan provides for the grant of equity-based awards, including incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, performance awards, and other equity-based awards. The 2025 Plan initially reserves 45,948,195 shares of Common Stock for issuance. The share reserve is subject to an annual automatic increase beginning January 1, 2027 through January 1, 2036, equal to the

lesser of (i) 5% of the outstanding Common Stock as of the preceding December 31, (ii) 22,974,097 shares, or (iii) such lesser number as determined by the Board of Directors. The maximum number of shares issuable pursuant to incentive stock options under the 2025 Plan is 137,844,585 shares. Upon effectiveness of the 2025 Plan, no further grants will be made under the 2024 Plan; however, shares subject to awards granted under the 2024 Plan will continue to be governed by the 2024 Plan.

The 2025 ESPP permits eligible employees to purchase shares of Common Stock through payroll deductions at a purchase price generally equal to 85% of the fair market value of Common Stock on the applicable offering or purchase date, as specified in the plan. The 2025 ESPP initially reserves 2,297,409 shares of Common Stock for issuance, subject to an annual automatic increase beginning January 1, 2027 through January 1, 2036 equal to the lesser of (i) 1% of outstanding Common Stock as of the preceding December 31, (ii) 2,871,761 shares, or (iii) such lesser number as determined by the Board of Directors.

The 2025 Inducement Plan provides equity awards to newly hired employees as a material inducement to employment. The 2025 Inducement Plan provides for the grant of nonstatutory stock options, restricted stock awards, restricted stock units, and other equity-based awards. A total of 2,400,000 shares of Common Stock is reserved for issuance under the 2025 Inducement Plan. Awards under the 2025 Inducement Plan are approved by the Compensation Committee of the Board of Directors or a majority of the Company's independent directors and do not require stockholder approval.

Note 8. Related Parties

Transactions entered into between the Company and Scilex are considered related party transactions. These transactions have been reflected as related party loans, a long-term liability, on the condensed consolidated balance sheets. These amounts do not carry any interest.

The total loans received from Scilex and repaid to Scilex were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Loans from Scilex Holding Company — stock-based compensation	$ 855	$ 192	$ 3,634	$ 403
Loans from Scilex Holding Company — expenses paid by Scilex Holding Company on behalf of the Company	2,237	7,383	8,474	9,911
Loans from Scilex Holding Company — Funds received from Scilex as an agent	19,748	—	19,748	—
Loans repaid to Scilex Holding Company — Payment made on behalf of Scilex	(19,748)	—	(19,748)	—
Total loans from/(repaid to) Scilex Holding Company	$ 3,092	$ 7,575	$ 12,108	$ 10,314

Debt Exchange Agreement

On August 30, 2024, the Company and Scilex entered into the Contribution and Satisfaction of Indebtedness Agreement (the "Debt Exchange Agreement") with respect to certain amounts owed to Scilex by the Company, including accrued and unpaid interest thereon, if any, which amount may be updated pursuant to the terms thereof, for certain loans and other amounts provided by Scilex to the Company prior to the closing of the Business Combination (the "Outstanding Indebtedness").

At Closing, the Outstanding Indebtedness between the Company and Scilex totaling $54.2 million was converted into 5,423,606 shares of Series A Preferred Stock and 542,361 shares of Common Stock. The Outstanding Indebtedness is considered to be extinguished in its entirety and shall be of no further force or effect and shall be deemed paid and satisfied in full and irrevocably and automatically discharged, terminated and released.

Transition Services Agreement

On September 22, 2025, in connection with the Closing, the Company entered into the Transition Services Agreement (the "Transition Services Agreement") with Scilex, pursuant to which the Company can utilize certain employees and

other service providers of Scilex to operate the business, including with respect to the following business functions: finance, human resources, information systems, legal and administrative, R&D support and commercialization support. Transition services provided by Scilex will be on a cost plus 10% basis, provided that the service fees will not exceed $2.0 million per annum until all payments under the Scilex-Oramed Note have been paid in full in cash, and the Company will reimburse Scilex for its out of pocket fees, costs or expenses. During the transition period, the Company plans to engage and increase full time employees to support research and development, general administrative, manufacturing, regulatory and commercial functions as the Company enters the final stage of development and pre-launch commercialization planning. The term of the Transition Services Agreement is three years following the execution of such agreement, which the Company believes is sufficient time to develop commercial infrastructure and other business functions.

As of September 30, 2026 and December 31, 2025, the Company had $0.70 million and $0.37 million, respectively, of service fees accrued under the Transition Services Agreement which is included in related party loans on the condensed consolidated balance sheets.

Note 9. Net Loss Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net loss	$ (3,633)	$ (152,594)	$ (12,556)	$ (154,258)
Denominator:				
Weighted average shares of common stock outstanding, basic and diluted	224,230,881	201,686,617	228,194,489	200,568,383
Net loss per share, basic and diluted	$ (0.02)	$ (0.76)	$ (0.06)	$ (0.77)

Basic net loss per share was the same as diluted net loss per share for all periods as the inclusion of potentially dilutive securities would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations were as follows:

	Nine Months Ended September 30,	
	2026	2025
Shares subject to outstanding common stock warrants	7,432,122	8,760,000
Shares subject to outstanding common stock options	28,125,000	50,000,000
Retainer shares	-	12,500,000
Total	35,557,122	71,260,000

Note 10. Subsequent events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date through the date the condensed consolidated financial statements were issued and determined that there were no subsequent events requiring recognition or disclosure in the condensed consolidated financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report on Form 10-Q, including those set forth in the sections of this Quarterly Report on Form 10-Q titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." As a result of these risks, you should not place undue reliance on these forward-looking statements. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

Overview

We are a late-stage clinical biopharmaceutical company focused on developing and commercializing innovative non-opioid pain management products for the treatment of acute and chronic pain. We believe that our innovative non-opioid product portfolio has the potential to provide effective pain management therapies that can have a transformative impact on patients' lives. We target indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with acute and chronic pain and are dedicated to advancing and improving patient outcomes. Our lead product candidate, SP-102, if approved, has the potential to become the first U.S. Food and Drug Administration (the "FDA") approved non-opioid novel injectable corticosteroid gel formulation for patients with moderate to severe lumbosacral radicular pain ("LRP") (also known as sciatica), containing no preservatives, surfactants, solvents, or particulates and is expected to be available in a pre-filled syringe formulation following approval by the FDA.

Our guiding principle has always been and remains a patient-first approach, which drives our mission to meet the increasing global demand for more effective and safer non-opioid pain management solutions. Through rigorous research and development, we believe we are on the cusp of establishing Semnur as the preeminent name in commercial non-opioid pain management, specifically targeting the unmet needs in both acute and chronic pain sectors with our innovative and leading therapies. We believe that we have made substantial progress in demonstrating the rapid onset and enhanced tolerability of our product candidate.

We are developing SP-102 to be an injectable viscous gel formulation of a widely used corticosteroid designed to address the serious risks posed by off-label epidural injections, which are administered over 12 million times annually in the United States. SP-102 has been granted fast track designation by the FDA and, if approved, could become the only FDA-approved epidural injection for the treatment of sciatica. Although such designation has been granted, it may not lead to a faster development or regulatory review process and such designation does not increase the likelihood that SP-102 will receive marketing approval.

Legacy Semnur was founded in 2013 and we have invested substantial efforts and financial resources in building our intellectual property portfolio and infrastructure. We have conducted phospholipidosis and toxicology studies, including a Phase 1 pharmacokinetic bridging study, Phase 2 repeat dose study, a pivotal Phase 3 study and the second Phase 3 study initiated in September 2025. We expect to continue to make investments in research and development, clinical trials and regulatory affairs to develop our product candidate, SP-102.

We have completed a pivotal Phase 3 study with final results received in March 2022, which results reflected achievement of primary and secondary endpoints, with SP-102 treatment decreasing pain intensity for over a month in sciatica patients and resulting in statistically significant and clinically meaningful improvement in the disability index score while maintaining tolerability comparable to placebo. The Phase 3 study results were published in PAIN® Journal in June 2024, which is the leading journal devoted to pain medicine and research. This Phase 3 study represents a potential significant improvement in treatment of adult patients with sciatica, who struggle with the clinical consequences of no currently FDA approved therapies being available, suboptimal formulations of corticosteroids used off-label and/or excess pain and disability. We initiated a second Phase 3 study in September 2025.

We are focused on identifying treatment options for pain management with established mechanisms that have deficiencies in safety, efficacy or patient experience. We believe this approach allows us to potentially leverage the regulatory approval pathway available under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (the

"FDCA") for our product candidate.

We have incurred significant net losses to date. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of our current or future product candidates. As of September 30, 2026, we had cash and cash equivalents of $54.0 thousand and accumulated deficit of $288.4 million. During the nine months ended September 30, 2026, we had operating losses of $12.4 million and negative cash flows from operations of $7.0 million. These losses have resulted primarily from costs incurred in connection with research and development activities, certain allocated general and administrative costs associated with our operations and certain costs associated with the Business Combination. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. Further, the Company's condensed consolidated financial statements are dependent on assumptions and allocations from the Scilex Holding Company ("Scilex") financial statements that management deems were reasonable and appropriate under the circumstances. Nevertheless, the Company's condensed consolidated financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented and may not reflect the results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas, including information technology and infrastructure. The Company also may have incurred additional costs associated with being a standalone, publicly listed company that were not included in the expense allocations and, therefore, would result in additional costs that are not reflected in its historical results of operations, financial position and cash flows.

Business Combination

References to "Legacy Semnur" refer to the private Delaware corporation that is now our wholly owned subsidiary and named Semnur, Inc. (formerly known as "Semnur Pharmaceuticals, Inc."). Unless otherwise noted or the context requires otherwise, references to "Common Stock" refer to our common stock, par value $0.0001 per share.

On September 22, 2025 (the "Closing"), we consummated a business combination pursuant to an agreement and plan of merger, dated as of August 30, 2024 (the "Initial Merger Agreement," as amended by Amendment No. 1 to Agreement and Plan of Merger, dated April 16, 2025, "Amendment No. 1 to the Initial Merger Agreement" and Amendment No. 2 to Agreement and Plan of Merger, dated July 22, 2025, "Amendment No. 2 to the Initial Merger Agreement" and collectively, the "Merger Agreement"), by and among Denali Capital Acquisition Corp. ("Denali"), Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali ("Merger Sub"), and Legacy Semnur. Pursuant to the terms of the Merger Agreement, the business combination (herein referred to as the "Business Combination") between Denali and Legacy Semnur was effected through the merger of Merger Sub with and into Legacy Semnur with Legacy Semnur surviving as Denali's wholly owned subsidiary. In connection with the Business Combination, Denali changed its name from Denali Capital Acquisition Corp. to Semnur Pharmaceuticals, Inc.

Material Agreements

Securities Purchase Agreement (the "PIPE SPA")

On August 20, 2025, we and Legacy Semnur entered into the PIPE SPA with the investor named therein, pursuant to which the investor agreed to purchase 1,250,000 shares of Common Stock at a price of $16.00 per share, for an aggregate purchase price of $20.0 million following the consummation of the Business Combination. On September 22, 2025, the PIPE SPA was amended to provide that unless such agreement was terminated pursuant to its terms (or otherwise by mutual agreement of the parties thereto), the closing of the transactions contemplated thereby would occur not later than the 14th business day following the closing of the Business Combination, subject to the satisfaction or waiver of the closing conditions set forth therein. In the event the transaction did not close on or before December 31, 2025, the nonbreaching party had an option to terminate the PIPE SPA without liability. As of September 30, 2026, the transaction had not closed and accordingly, shares have not been issued and funds have not been received.

Additionally, in connection with the PIPE SPA, we would have been obligated to pay a cash financing service fee of 7% of the received investment funds.

On April 20, 2026, the Company and Semnur, Inc. delivered written notice to the investor under the PIPE SPA terminating such agreement pursuant to Section 8 thereof. As a result of such termination, the PIPE SPA is no longer in effect and the transactions contemplated thereby will not be consummated.

Bitcoin Securities Purchase Agreement (the "Semnur/Biconomy SPA")

On September 23, 2025, we entered into the Semnur/Biconomy SPA with Biconomy Pte.Ltd ("Biconomy"). Pursuant to the Semnur/Biconomy SPA, we agreed to issue and sell, and Biconomy agreed to purchase, 6,250,000 shares of Common Stock, at a purchase price of $16.00 per share, for an aggregate purchase price of $100.0 million, payable in Bitcoin blockchain ("Bitcoin"), with such amount of Bitcoin equal to the quotient of (A) the buyer's aggregate purchase price divided by (B) the spot exchange rate for Bitcoin as published by Coinbase.com at 8:00 p.m. (New York City time) on the trading day immediately prior to the closing date of the purchase. In the event the transaction did not close on or before December 31, 2025, the nonbreaching party had an option to terminate the Semnur/Biconomy SPA without liability. As of September 30, 2026, the transaction had not closed and accordingly, shares have not been issued and funds have not been received.

On April 20, 2026, the Company delivered written notice to Biconomy terminating the Semnur/Biconomy SPA pursuant to Section 8 thereof. Accordingly, the Semnur/Biconomy SPA was terminated effective April 20, 2026, and the transactions contemplated thereby will not be consummated.

Promissory Notes

As of September 30, 2026 and December 31, 2025, we have promissory notes totaling $2.3 million and $3.5 million, respectively, all of which are due in less than a year.

Notwithstanding the payment schedules in the promissory notes, the balance due on any notes (less any payments previously made to the holder thereunder) shall be accelerated and become immediately due and payable in the event we receive gross proceeds from any equity or debt financing (including any private placement offering or registered offering), in an amount equal to or greater than the then-outstanding principal of such note plus any accrued but unpaid interest due thereon.

In addition, in the case of an event of default, the promissory notes shall bear interest at a rate of 10% per annum until such event of default is cured. The promissory notes shall become immediately due and payable (in accordance with the terms thereof), upon our failure to make payments thereunder when due (subject to a 14-day cure period) or certain other actions related to voluntary or involuntary bankruptcy proceedings (as more fully described therein).

Lifecore Master Services Agreement

On January 27, 2017, we entered into a Master Services Agreement (as amended, the "Lifecore Master Services Agreement"), with Lifecore Biomedical, LLC ("Lifecore"). Pursuant to the Lifecore Master Services Agreement, Lifecore is responsible for clinical trial material manufacturing and development services for SP-102 as set forth in each separate statement of work. For the purposes of Lifecore's development and clinical trial material manufacturing obligations, we granted Lifecore a nonexclusive, worldwide and royalty-free license under our owned or controlled intellectual property rights necessary to manufacture SP-102, without additional right, title or interest in our intellectual property. The Lifecore Master Services Agreement expires on December 31, 2028, unless terminated earlier in accordance with the terms of such agreement, or unless renewed further by the parties.

During the three and nine months ended September 30, 2026, we incurred expenses of $0.07 million and $0.15 million, respectively, related to the Lifecore Master Services Agreement.

Legacy Semnur Merger Agreement

On March 18, 2019, Legacy Semnur was acquired by Scilex pursuant to an Agreement and Plan of Merger with Semnur (as amended, the "Legacy Semnur Merger Agreement"), Sigma Merger Sub, Inc., a wholly owned subsidiary of Scilex ("Sigma Merger Sub"), Fortis Advisors LLC, solely as representative of the holders of Legacy Semnur's equity, and for limited purposes, Sorrento Therapeutics, Inc. Pursuant to the Legacy Semnur Merger Agreement, Sigma Merger Sub merged with and into Legacy Semnur, and Legacy Semnur survived as Scilex's wholly owned subsidiary.

Pursuant to the Legacy Semnur Merger Agreement, and upon the terms and subject to the conditions contained therein, Scilex agreed to pay the former holders of Legacy Semnur's capital stock up to $280.0 million in aggregate contingent cash consideration based on the achievement of certain milestones (which amount is expected to be charged back to us through an intercompany arrangement), comprised of a $40.0 million payment that will be due upon obtaining the first approval of a new drug application of our product by the FDA and additional payments that will be due upon the achievement of certain amounts of net sales of our products, as follows: (i) a $20.0 million payment upon the achievement of $100.0 million in cumulative net sales of our product, (ii) a $20.0 million payment upon the

achievement of $250.0 million in cumulative net sales of our product, (iii) a $50.0 million payment upon the achievement of $500.0 million in cumulative net sales of our product, and (iv) a $150.0 million payment upon the achievement of $750.0 million in cumulative net sales of our product. To date, none of the foregoing payments have been triggered.

Shah Assignment Agreement

On August 6, 2013, Legacy Semnur entered into an Assignment Agreement (the "Shah Assignment Agreement") with Shah Investor LP ("Shah Investor"). Pursuant to the Shah Assignment Agreement, Shah Investor assigned to Legacy Semnur the patents, know-how and other intellectual property related to pharmaceutical compositions of corticosteroids.

In consideration of the license and rights granted by Shah Investor, Legacy Semnur agreed to pay royalties (i) at the rate of 1.5% of the Net Sales for Annual Net Sales (each as defined therein) up to $250.0 million and (ii) at the rate of 2.5% of the Net Sales for Annual Net Sales of $250.0 million and above, subject to certain adjustments as set out in the Shah Assignment Agreement. Such royalty payment for a given calendar quarter shall be due and payable on the date the royalty report for such quarter is due under the Shah Assignment Agreement. To date, none of the foregoing payments have been triggered.

The Shah Assignment Agreement continues in full force and effect on a country-by-country and product-by-product basis until royalties are no longer due on such product under the agreement.

Comparability of Our Results and Our Relationship with Scilex

Legacy Semnur was wholly owned by Scilex during the Business Combination and remained controlled by Scilex thereafter. As a result, our historical financial statements may not be reflective of what our results of operations would have been had we been a standalone public company and no longer a majority owned subsidiary of Scilex. In particular, certain clinical trial management, regulatory, information technology, legal, accounting and finance, facilities and other corporate and infrastructural functions have historically been provided to us by Scilex. We expect that Scilex will continue to provide us with some of the services related to these functions on a transitional basis in exchange for agreed-upon fees pursuant to the Transition Services Agreement (the "TSA") with Scilex. The costs associated with these services and support were allocated to our operating expenses based on the estimated percentage of time certain Scilex employees spent supporting the SP-102 program, and we expect to incur other costs to replace the services and resources that will not be provided by Scilex. We will also incur additional costs as a standalone public company. As a standalone public company, our total costs related to certain support functions may differ from the costs that were historically allocated to us from Scilex. In addition, in the future, we expect to incur internal costs to implement certain new systems, including infrastructure and an enterprise resource planning system, while our systems are currently being fully supported by Scilex.

Components of Our Results of Operations

Operating Expenses

Research and Development

Research and development expenses are expensed when incurred and consist primarily of direct and allocated costs incurred for our research activities, including the development of our product candidate, and include:

- direct costs related to clinical trials, including contract manufacturing and supply;
- allocated portion of salaries, benefits and other related costs, including stock-based compensation expense for Scilex personnel engaged in research and development functions related to the SP-102 program;
- allocated costs of facilities and support services incurred by Scilex used in drug development related to the SP-102 program; and
- direct and allocated costs related to outside consultants engaged in research and development functions related to the SP-102 program.

We expect our research and development expenses to increase, as we will incur incremental expenses associated with our lead product candidate, SP-102, currently under development and in clinical trials. Product candidates in later stages of clinical development generally have higher development costs, primarily due to the increased size and duration of later-stage clinical trials. Accordingly, we expect to incur significant research and development expenses in connection with our clinical trials for SP-102.

General and Administrative

General and administrative expenses consist primarily of allocated costs related to salaries and other related costs, including stock-based compensation, for personnel in Scilex's executive, marketing, finance, corporate and business development and administrative functions. General and administrative expenses also include allocated professional fees for legal, patent, accounting, auditing, tax and consulting services and expenses related to the Business Combination.

We expect that our general and administrative expenses will vary year over year in the future as we adapt our strategies to changes in the business environment. We also expect to incur increased expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission ("SEC"), listing standards applicable to companies listed on a national securities exchange, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to allocate additional expenses relating to administrative, finance, legal, and other corporate functions to adapt to the changes above and the anticipated growth of our business.

Results of Operations

Comparison of the three and nine months ended September 30, 2026 and 2025

The following tables summarize our results of operations for the periods presented (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Operating expenses:						
Research and development	$ 1,443	$ 1,143	$ 300	$ 3,958	$ 1,832	$ 2,126
General and administrative	2,134	151,451	(149,317)	8,419	152,426	(144,007)
Total operating expenses	**3,577**	**152,594**	**(149,017)**	**12,377**	**154,258**	**(141,881)**
Loss from operations	**(3,577)**	**(152,594)**	**149,017**	**(12,377)**	**(154,258)**	**141,881**
Other expense:						
Interest expense	(56)	-	(56)	(179)	-	(179)
Total other expense	**(56)**	**-**	**(56)**	**(179)**	**-**	**(179)**
Net loss	**$ (3,633)**	**$ (152,594)**	**$ 148,961**	**$ (12,556)**	**$ (154,258)**	**$ 141,702**

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
SP-102:						
Contracted R&D	$ 708	$ 949	$ (241)	$ 1,981	$ 1,126	$ 855
Personnel	592	159	433	1,553	629	924
Other	143	35	108	424	77	347
Total research and development expenses	$ 1,443	$ 1,143	$ 300	$ 3,958	$ 1,832	$ 2,126

Total research and development expenses for the three months ended September 30, 2026 and 2025 were $1.4 million and $1.1 million, respectively. The increase of $0.3 million was primarily driven by higher personnel-related costs of approximately $0.4 million, including salaries, stock-based compensation and employee-related expenses, and increased consulting and contracted service costs of approximately $0.4 million related to the SP-102 study. Clinical development costs also increased by approximately $0.1 million due to activities associated with the SP-102 study. These increases were partially offset by a decrease in CMC development costs of approximately $0.2 million.

Total research and development expenses for the nine months ended September 30, 2026 and 2025 were $4.0 million and $1.8 million, respectively. The increase of $2.1 million was primarily driven by higher consulting and contracted

service costs of approximately $1.6 million related to the SP-102 study and higher personnel-related costs of approximately $0.9 million, including salaries, stock-based compensation and employee-related expenses. Clinical development costs also increased by approximately $0.5 million due to activities associated with the SP-102 study. These increases were partially offset by a decrease in CMC development costs of approximately $0.7 million.

General and Administrative Expenses

Total general and administrative expenses for the three months ended September 30, 2026 and 2025 were $2.1 million and $151.5 million, respectively. The decrease of $149.3 million was primarily attributable to the recognition of approximately $140.0 million of issuance costs associated with the Business Combination in September 2025 and higher consulting costs of approximately $10.0 million incurred in the prior-year period in connection with the Business Combination.

Total general and administrative expenses for the nine months ended September 30, 2026 and 2025 were $8.4 million and $152.4 million, respectively. The decrease of $144.0 million was primarily attributable to the recognition of approximately $140.0 million of issuance costs associated with the Business Combination in September 2025 and higher consulting costs of approximately $10.0 million incurred in the prior-year period in connection with the Business Combination. These decreases were partially offset by an increase in personnel-related costs of approximately $4.4 million, including salaries, stock-based compensation and employee-related expenses.

Other Expense

Other expense for the three months ended September 30, 2026 was $0.1 million, compared to nil for the three months ended September 30, 2025. The expense during the 2026 period consisted primarily of interest expense of approximately $0.1 million related to outstanding promissory notes.

Other expense for the nine months ended September 30, 2026 was $0.2 million, compared to nil for the nine months ended September 30, 2025. The expense during the 2026 period consisted primarily of interest expense of approximately $0.2 million related to outstanding promissory notes.

Liquidity and Capital Resources

As of September 30, 2026, we had cash and cash equivalents of $54.0 thousand and accumulated deficit of $288.4 million. During the nine months ended September 30, 2026, we had operating losses of $12.4 million and negative cash flows from operations of $7.0 million. We are dependent upon Scilex and its affiliates to provide services and funding to support our operations until, at least, such time as external financing is obtained. We expect to incur significant expenses and operating losses for the foreseeable future as we continue our efforts to develop and seek regulatory approval for SP-102.

Future Liquidity Needs

We estimate that our planned operating expenses will be approximately $21.0 million during the next twelve months, which includes the cost of clinical work of approximately $10.0 million. We do not anticipate significant increases in our costs of clinical work during this period.

Over the next twelve months, we expect our primary sources of liquidity to include existing cash on hand and available financing sources. We are evaluating various alternatives to support our liquidity needs and fund our operations, including debt financings, equity financings, strategic collaborations, licensing arrangements and other potential capital-raising transactions. The timing and availability of additional financing, if required, will depend on a variety of factors, including market conditions and our operating performance. There can be no assurance that additional financing will be available on acceptable terms, or at all.

In connection with the TSA that we entered into with Scilex, we expect to receive approximately $2.0 million of continued support from Scilex, inclusive of fees, in the twelve months following the Business Combination. The continued support from Scilex is expected to consist of (a) clinical support to run the planned Phase 3 trial for approximately $0.8 million, (b) CMC manufacturing support for approximately $0.7 million, (c) general and administrative support, such as human resources, legal and accounting, for approximately $0.4 million and (d) IT support for approximately $0.1 million. Semnur and Scilex continue to review and discuss additional support that may be provided under the TSA based on Semnur’s ongoing operational needs. Accordingly, the scope and value of services provided under the TSA may exceed the currently estimated $2.0 million.

We have based our anticipated operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources sooner than we expect. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the scope, progress, results and costs of conducting studies and clinical trials for our product candidate, SP-102;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidate;
- the continuity of contract manufacturing of active pharmaceutical ingredients, raw materials, packaging components, process equipment, and drug products;
- the costs of manufacturing and process validation of our clinical and commercial product candidate;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the extent to which our product candidate, if approved for commercialization, is adopted by the physician community;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- the effect of competing products and product candidates and other market developments;
- the number and types of future products or product candidates we develop and commercialize;
- any product liability or other lawsuits related to our current or future product candidates;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Should the clinical programs of our product candidate not materialize at the anticipated rate contemplated in our business plan, we will need to raise additional capital in order to continue to fund our research and development, including our plans for clinical and preclinical trials and new product development and manufacturing, as well as to fund operations generally. We will seek to raise additional funds through various potential sources, such as equity offerings, debt financings, collaborations, government contracts or other capital sources, including potential collaborations with other companies or other strategic transactions.

We cannot be certain that we will be able to secure additional sources of funds to support our operations on acceptable terms, or at all, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. These conditions, among others, raise substantial doubt about our ability to continue as a going concern. If we raise additional funds by issuing equity or convertible debt securities, it could result in dilution to our existing stockholders or increased fixed payment obligations. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term, but we may have to relinquish valuable rights to our product candidate or grant licenses on terms that are not favorable to us. Any of the foregoing could significantly harm our business, financial condition and results of operations. If we are unable to raise

additional capital in sufficient amounts or on terms acceptable to us, we may be required to delay, scale back or discontinue the development of our product candidate.

We are dependent upon Scilex and its affiliates to provide services and funding to support our operations until, at least, such time as external financing is obtained. We may also need to take certain other actions to allow us to maintain our projected cash and projected financial position including but not limited to, additional reductions in general and administrative costs, suspension or winding down of clinical development programs and other discretionary costs. Although we believe such plans, if executed and coupled with the above described sources of liquidity, should provide us with financing to meet our needs, successful completion of such plans is dependent on factors outside of our control.

We anticipate that we will continue to incur net losses into the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidate, and expand our corporate infrastructure. As a result, we have concluded that there is substantial doubt about our ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued. See Note 1 section titled "*Liquidity and Going Concern*" of the notes to our interim consolidated financial statements included elsewhere in the Form 10-Q for additional information. Our existing cash and cash equivalents may be insufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to raise additional funds through equity offerings, debt financings, collaborations, government contracts or other strategic transactions.

Material Cash Requirements

As of September 30, 2026, we have promissory notes totaling $2.3 million, all of which are due in less than a year.

As of September 30, 2026, we have a long-term related party loan totaling $24.1 million due to Scilex.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules, other than as discussed below.

Subsidiary Guarantee to Scilex-Oramed Note

On September 21, 2023, Scilex entered into, and consummated the transactions contemplated by, a Securities Purchase Agreement (the "Scilex-Oramed SPA") with Oramed Pharmaceuticals Inc. ("Oramed") and the Agent (as defined below), pursuant to which, among other things, Scilex issued to Oramed the Scilex-Oramed Note. In connection with the Scilex-Oramed SPA, Scilex and each of its subsidiaries, including us (collectively, the "Guarantors"), entered into a subsidiary guarantee (as amended, the "Subsidiary Guarantee") with Oramed and Acquiom Agency Services LLC, as the collateral agent for the holders of the Scilex-Oramed Note (the "Agent"), pursuant to which, the Guarantors have agreed to guarantee and act as surety for payment of the Scilex-Oramed Note and any additional notes issued by Scilex in full or partial substitution of the Scilex-Oramed Note. As of the consummation of the Business Combination, we are no longer a Guarantor under the Subsidiary Guarantee.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Nine Months Ended September 30,		
	2026	2025	Change
Net cash used in operating activities	$ (7,030)	$ (2,262)	$ (4,768)
Net cash from financing activities	7,064	2,335	4,729
Net change in cash and cash equivalents	$ 34	$ 73	$ (39)

Cash Flows from Operating Activities

Net cash used in operating activities increased by $4.8 million during the nine months ended September 30, 2026, compared to the corresponding period in 2025. The increase was primarily attributable to changes in working capital accounts, including a $10.5 million unfavorable year-over-year change in prepaid expenses and other current assets, partially offset by favorable changes in operating liabilities, including increases in accounts payable and accrued expenses. The increase in cash used in operating activities was also partially offset by lower non-cash stock-based compensation expense, which decreased to $3.6 million in 2026 from $140.4 million in 2025.

Cash Flows from Financing Activities

Net cash provided by financing activities increased by $4.7 million for the nine months ended September 30, 2026, compared to the corresponding period in 2025. Financing activities during the nine months ended September 30, 2026 primarily reflected proceeds from related-party loans of $28.2 million (including funds received from Scilex as an agent), partially offset by repayments of related-party loans of $19.7 million (payments made on behalf of Scilex) and repayments of promissory notes of $1.4 million. In comparison, financing activities during the nine months ended September 30, 2025 primarily reflected proceeds from related-party loans of $9.9 million, partially offset by payments of deferred offering costs of $7.6 million.

Critical Accounting Estimates

Our accounting policies are more fully described in Note 2 of the condensed consolidated financial statements to this Quarterly Report. As disclosed in Note 2, the preparation of condensed consolidated financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions about future events that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following discussion addresses our most critical accounting estimates, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

Stock-Based Compensation

We account for stock-based compensation in accordance with ASC Topic 718, *Compensation – Stock Compensation* which establishes accounting for equity instruments exchanged for employee and consulting services.

Stock-based compensation cost is measured at the grant date, based on the fair value of the award determined using the Black-Scholes option pricing model, and is recognized as an expense, under the straight-line method, over the employee's requisite service period (generally the vesting period of the equity grant) or non-employee's vesting period. We account for forfeitures as incurred.

For purposes of determining the inputs used in the calculation of stock-based compensation, we determine the expected life assumption for options issued using the simplified method, which is an average of the contractual term of the option and its ordinary vesting period since we do not have historic exercise behavior. We determine an estimate of option volatility based on an assessment of historical volatilities of comparable companies whose share prices are publicly available. We use these estimates, in conjunction with the fair value of Scilex Common Stock, risk-free interest rate, and the expected dividend yield as inputs in the Black-Scholes option pricing model. Depending upon the number of stock options granted, any fluctuations in these calculations could have a material effect on the results presented in our statement of operations.

Emerging Growth Company

An "emerging growth company" as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), is eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in GAAP or their interpretation, the adoption of new guidance or the application of existing guidance to changes in Semnur's business could significantly affect our business, financial condition and results of operations.

In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we may take advantage of certain exemptions from various reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include, but are not limited to:

- an exemption from compliance with the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act");

- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements.

Semnur qualifies and will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of the initial public offering, (b) in which Semnur has a total annual gross revenue of at least $1.235 billion, or (c) in which Semnur is deemed to be a large accelerated filer, which means the market value of the common equity of Semnur that is held by non-affiliates equals or exceeds $700 million as of the last business day of its most recently completed second fiscal quarter; and (ii) the date on which Semnur has issued more than $1.00 billion in non-convertible debt securities during the prior three-year period. References herein to "emerging growth company" have the meaning associated with it in the JOBS Act.

Smaller Reporting Company

Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. Semnur qualifies and will remain a smaller reporting company until the last day of the fiscal year in which (i) Semnur has annual revenue of at least $100 million and a public float that equals or exceeds $700 million as of the last business day of its most recently completed second fiscal quarter or (ii) Semnur has a public float that equals or exceeds $250 million as of the last business day of its most recently completed second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

Our cash and cash equivalents as of September 30, 2026 consisted of $54.0 thousand in bank deposits and money market funds. We invest primarily in high-quality money market funds, which we believe are subject to limited credit risk. Due to the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As of September 30, 2026, as required by Rules 13a-15 and 15d-15 under the Exchange Act, our principal executive officer and principal financial officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon their evaluation, and as a result of the material weaknesses described below, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were not effective at the reasonable assurance level as of such date. Notwithstanding the identified material weaknesses, management has concluded that the condensed consolidated financial statements included in this Form 10-Q present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods disclosed in accordance with U.S. GAAP.

Remediation Efforts to Address the Previously Disclosed Material Weaknesses

In connection with the audit of Legacy Semnur's financial statements for the years ended December 31, 2023 and 2022, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

For the years ended December 31, 2023 and 2022, the material weaknesses identified in our internal control over financial reporting related to ineffective control activities in the areas of preparation of the carve-out financial statements and stock-based compensation expense. As a result of the material weaknesses, we are implementing remediation measures including, but not limited to, performing a comprehensive assessment of the control environment in order to design and implement additional preventive and/or detective review controls as well as hiring additional personnel with sufficient accounting expertise to improve the operating effectiveness of our review controls and monitoring activities, and utilizing external accounting experts as appropriate. Any potential material misstatements were identified and corrected as audit adjustments in the applicable periods and are properly reflected in our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

In the future, in order to properly manage our internal control over financial reporting, we may need to take additional measures to further augment our finance resources, and we cannot be certain that the measures we have taken, and expect to take, to improve our internal controls will be sufficient to ensure that our internal controls will remain effective and eliminate the possibility that other material weaknesses or deficiencies may develop or be identified in the future. If we experience future material weaknesses or deficiencies in internal controls and we are unable to correct them in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC, will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of the Common Stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weaknesses, our business, financial condition and results of operations could suffer.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are currently not a party to any legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, financial condition, and results of operations.

Item 1A. Risk Factors.

Investing in our securities involves a high degree of risk. Before making an investment decision, you should consider carefully the following risk factors, as well as the other information set forth in this Quarterly Report on Form 10-Q, including matters addressed in the section of this Quarterly Report on Form 10-Q titled "Cautionary Note Regarding Forward-Looking Statements". If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described in this Quarterly Report on Form 10-Q are not the only risks and uncertainties that we face. We may face additional risks and uncertainties that are not presently known to us, or that we currently deem immaterial. The following discussions should be read in conjunction with our condensed consolidated financial statements and the notes to the condensed consolidated financial statements included therein.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties:

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

- We are a late-stage clinical biopharmaceutical company and have incurred significant losses since our inception. We anticipate that we will incur continued losses for the foreseeable future.
- We have only one product candidate, SP-102, no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.
- We currently have no sales and marketing organization and if we do not establish satisfactory sales and marketing capabilities or secure a third-party sales and marketing relationship, we may not successfully commercialize SP-102 or any future product candidates.
- Our recurring losses from operations, negative cash flows and substantial cumulative net losses raise substantial doubt about our ability to continue as a going concern.

Risks Related to Our Product Development

- We have historically obtained our clinical supply of our only product candidate, SP-102, and certain of the raw materials and packaging components used in SP-102, from a sole or single source supplier and manufacturer, and we may not be able to find an alternative source on commercially reasonable terms, or at all. In addition, if any such analytical testing laboratory, supplier or manufacturer fails to comply with FDA regulations, we may be subject to sanctions or delays caused by FDA-issued voluntary action indicated or official action indicated status.
- We rely on third parties to conduct clinical trials and intend to rely on third parties to conduct all future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approvals.
- Delays in clinical trials could result in increased costs to us and delay our ability to obtain commercial approval and generate revenue.

- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for our product candidates and the approval may be for a more narrow indication than we seek.

Risks Related to Our Business and Operations

- If we are unable to retain our key executives, it may delay our development efforts and harm our business, financial condition and results of operations.
- We may need to increase the size of our company and may not effectively manage our growth.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.
- Any disruption in our research and development facilities could adversely affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

- If we are unable to maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- If our intellectual property rights are invalidated or circumvented, our business will be adversely affected.
- Confidentiality agreements with employees may not prevent disclosure of our trade secrets and proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

Risks Related to Government Regulations

- The regulatory approval processes of the FDA and comparable non-U.S. regulatory authorities are time-consuming and unpredictable, and if we are unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. Moreover, gaining approval for a product candidate in one jurisdiction does not ensure approval in other jurisdictions, which could limit our total market.
- If the FDA does not conclude that our product candidate satisfies the requirements for the Section 505(b)(2) regulatory approval pathway, pre-approval manufacturing inspection or if the requirements for our product candidate under Section 505(b)(2) are not as we expect, the approval pathway for our product candidate could take significantly longer, cost significantly more and entail greater risks than anticipated, and in either case may not be successful.
- Any approved product candidate will be subject to ongoing and continued regulatory requirements, which may result in significant expense and limit our ability to commercialize such products.

Risks Related to Our Relationship with Scilex

- Certain of our directors and officers may have conflicts of interest because of their positions with Scilex.
- Scilex currently performs or supports many of our important corporate functions. Our financial statements may not necessarily be indicative of the conditions that would have existed or our results of operations if we had been operated as an unaffiliated company of Scilex, and we incurred significant charges in connection with the Business Combination and will incur incremental costs as a stand-alone public company.
- Our Executive Chairman and Chief Financial Officer each holds an executive officer position at Scilex and devotes time to both companies, which could cause a diversion of their time and attention from our business.
- We are controlled by Scilex, whose interests may differ from those of our public shareholders.

Risks Related to Ownership of Our Common Stock

- If our operations and performance do not meet the expectations of investors or securities analysts, the market price of our securities may decline.
- We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of Common Stock.

Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements

We are a late-stage clinical biopharmaceutical company and have incurred significant losses since our inception.

We anticipate that we will incur continued losses for the foreseeable future.

We are a late-stage clinical biopharmaceutical company focused on developing and commercializing innovative non-opioid pain management products for the treatment of acute and chronic pain, and we have a limited operating history. We have not commenced revenue-producing operations and to date, we have focused on organizing and staffing our company, business planning, raising capital, identifying potential non-opioid pain therapy candidates, undertaking preclinical studies and clinical trials of our product candidate and establishing research and development collaborations. Our relatively short operating history as a company makes any assessment of our future success and viability subject to significant uncertainty.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We will encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. Our ability to execute on our business model and generate revenues depends on a number of factors including our ability to:

- successfully complete ongoing pre-clinical studies and clinical trials and obtain regulatory approvals for our current and future product candidates;
- identify new acquisition or in-licensing opportunities;
- successfully identify new product candidates and advance those product candidates into pre-clinical studies and clinical trials;
- raise additional funds when needed and on terms acceptable to us;
- attract and retain experienced management and advisory teams;
- add operational, financial and management information systems and personnel, including personnel to support clinical, pre-clinical manufacturing and planned future commercialization efforts and operations;
- launch commercial sales of our current and future product candidates, whether alone or in collaboration with others;
- initiate and continue relationships with third-party suppliers and manufacturers;
- set acceptable prices for current and future product candidates and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of current and future product candidates in the medical community and with third-party payors and consumers; and
- maintain, expand and protect our intellectual property portfolio.

If we cannot successfully execute any one of the foregoing, our business may not succeed or become profitable. Since our inception, we have incurred significant net losses. For the nine months ended September 30, 2026 and 2025, we had net losses of $12.6 million and $154.3 million, respectively. As of September 30, 2026, we had an accumulated deficit of $288.4 million. For the foreseeable future, we expect to continue to incur significant expenses related to the research and development of our product candidate, SP-102. We expect to incur substantial losses for the foreseeable future and may never become profitable.

We are subject to risks incidental to the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

We have only one product candidate, SP-102, no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.

We currently only have one product candidate, SP-102. Our ability to generate revenue from product sales and achieve profitability will depend on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, SP-102 and any future product candidates, if any. As a result, we intend to devote a substantial portion of our research and development resources and business efforts to the

development of SP-102. We do not anticipate generating revenues from product sales for the next several years, if ever. Our ability to generate future revenue from product sales depends heavily on our, or our future collaborators', ability to successfully:

- identify additional product candidates and complete research, preclinical and clinical development and commercial manufacturing of SP-102 and any other product candidates we may identify;
- seek and obtain regulatory and marketing approvals for any product candidates for which we complete clinical trials;
- launch and commercialize any product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for coverage and adequate reimbursement by government and third-party payors for any product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of any product candidates as viable treatment options;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter, and perform our obligations in such arrangements;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property rights, including patents, trade secrets and know-how, in the United States and internationally;
- avoid and defend against third-party interference, infringement and other intellectual property claims in the United States and internationally; and
- attract, hire and retain qualified personnel.

Even if one or more of the product candidates we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency (the "EMA") or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from completing the development of our current and future product candidates, obtaining regulatory approvals or commercializing our product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. A failure to become or remain profitable could result in a decline in the value of our company and could also cause you to lose all or part of your investment.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities or secure a third-party sales and marketing relationship, we may not be able to successfully commercialize SP-102 or any future product candidates, if any.

At present, we have no sales or marketing personnel. We intend to leverage the sales force and marketing capacities of our parent company, Scilex, to commercialize our current product candidate, SP-102, if approved. As we further grow after the launch of SP-102, if approved, we will establish our sales, marketing or product distribution strategy for our product candidates. We may use strategic partners, distributors, a contract sales force or establish our own commercial sales force. If we are not successful in recruiting sales and marketing personnel and building a sales and marketing infrastructure or entering into appropriate collaboration arrangements with third parties, we will have difficulty successfully commercializing our product candidate, if approved, which would adversely affect our business, operating results and financial condition.

Even if we enter into third-party marketing and distribution arrangements, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. In terms of establishing a sales and marketing infrastructure, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to build an internal sales organization or enter into collaboration arrangements with third parties include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any of our product candidates, if approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an internal sales and marketing organization.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance development of our current product candidate and launch and commercialize any product candidate for which we receive regulatory approval. Furthermore, we expect to incur additional costs associated with operating as a public company. We will also require additional capital to fund our other operating expenses and capital expenditures.

As of September 30, 2026, our cash and cash equivalents were $54.0 thousand and we had an accumulated deficit of $288.4 million. The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the scope, progress, results and costs of conducting studies and clinical trials for our product candidate, SP-102;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidate;
- the costs of manufacturing our product candidate;
- the timing and amount of any milestone, royalty or other payments we are required to make pursuant to any current or future collaboration or license agreements;
- the potential requirement to reimburse Scilex for up to an aggregate of $280.0 million in respect of milestone payments under the Legacy Semnur Merger Agreement through an intercompany arrangement between Scilex and Semnur;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the extent to which our product candidate, if approved for commercialization, is adopted by the physician community;
- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, product candidates and technologies;
- the effect of competing products and product candidates and other market developments;
- the number and types of future products or product candidates we develop and commercialize;
- any product liability or other lawsuits related to our current or future product candidates;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;

- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the extent and scope of our general and administrative expenses.

Until we are able to generate revenue, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, government contracts or other strategic transactions. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we raise additional funds through collaborations or strategic alliances with third parties, we may have to relinquish valuable rights to our current or future product candidates, future revenue streams, research programs or technologies, or grant licenses on terms that may not be favorable to us. If we are unsuccessful in our efforts to raise additional financing on acceptable terms, we may be required to significantly reduce or cease our operations.

We may not be able to generate sufficient cash to service our indebtedness and other liquidity needs.

Our ability to make payments on and to refinance our indebtedness and to fund our other obligations, planned capital expenditures and other strategic investments will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, legislative, regulatory and other factors that are beyond our control. We may not generate sufficient cash flow from operations, and we cannot assure you that future borrowings will be available to us in an amount sufficient to enable us to pay our indebtedness or to fund our other liquidity needs.

If we do not generate cash flow from operations sufficient to pay our debt service or other obligations, we may have to undertake alternative financing plans, such as refinancing or restructuring our debt, selling assets, reducing or delaying capital investments or seeking to raise additional capital. Our ability to refinance our debt and fund other obligations will depend on the condition of the capital markets and our financial condition at that time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. See the section titled "*Liquidity and Going Concern*" under Note 1 of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, for a discussion regarding our ability to continue as a going concern.

Our recurring losses from operations, negative cash flows and substantial cumulative net losses raise substantial doubt about our ability to continue as a going concern.

In the section titled "*Liquidity and Going Concern*" under Note 1 of our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we disclose that there is substantial doubt about our ability to continue as a going concern. In addition, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2025, which stated that substantial doubt existed about our ability to continue as a going concern. We have negative working capital and have incurred significant operating losses and negative cash flows from operations and expect to continue incurring losses for the foreseeable future. Further, we had an accumulated deficit of $288.4 million and $275.8 million as of September 30, 2026 and December 31, 2025, respectively. These conditions raise substantial doubt about our ability to continue as a going concern. Our condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Our ability to become a profitable operating company is dependent upon our ability to generate revenue and obtain financing adequate to fulfill our development and commercialization activities, and achieving a level of revenue adequate to support our cost structure. We have plans to obtain additional resources to fund our currently planned operations and expenditures through additional debt and equity financing. If we are unable to obtain sufficient funding, our financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. Our future financial statements may disclose substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We have identified material weaknesses in our internal control over financial reporting. Any material weakness may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our

financial statements.

In connection with the audit of our financial statements for the years ended December 31, 2023 and 2022, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

For the years ended December 31, 2023 and 2022, the material weaknesses identified in our internal control over financial reporting related to ineffective control activities in the areas of preparation of the carve-out financial statements and stock-based compensation expense. As a result of the material weaknesses, we are implementing remediation measures including, but not limited to, performing a comprehensive assessment of the control environment in order to design and implement additional preventive and/or detective review controls as well as hiring additional personnel with sufficient accounting expertise to improve the operating effectiveness of our review controls and monitoring activities, and utilizing external accounting experts as appropriate. Any potential material misstatements were identified and corrected as audit adjustments in the applicable periods and are properly reflected in our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

In the future, in order to properly manage our internal control over financial reporting, we may need to take additional measures to further augment our finance resources, and we cannot be certain that the measures we have taken, and expect to take, to improve our internal controls will be sufficient to ensure that our internal controls will remain effective and eliminate the possibility that other material weaknesses or deficiencies may develop or be identified in the future. If we experience future material weaknesses or deficiencies in internal controls and we are unable to correct them in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC, will be adversely affected. Any such failure could negatively affect the market price and trading liquidity of the Common Stock, lead to delisting, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and generally materially and adversely impact our business and financial condition.

If we identify future material weaknesses in our internal controls over financial reporting or fail to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our business, financial condition and results of operations could suffer.

Risks Related to Our Product Development

We are substantially dependent on the success of our only product candidate, SP-102. If we are unable to complete development of, obtain approval for and commercialize SP-102 in a timely manner or at all, our business will be harmed.

Our future success is dependent on our ability to timely advance and complete clinical trials, obtain marketing approval for and successfully commercialize our product candidate, SP-102. We are not permitted to market or promote SP-102 or any other future product candidate before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of SP-102 and any future product candidates, if any, will depend on several factors, including the following:

- the acceptance of individual institutional review boards ("IRBs") and scientific review committees at each clinical trial site as to the adequacy of the preclinical data package to support clinical development of SP-102 and their overall general agreement with the use of SP-102 in the intended patient population in the intended manner;
- the initiation and successful patient enrollment and completion of additional clinical trials of SP-102 on a timely basis;
- the frequency and severity of adverse events ("AEs") in the clinical trials;
- maintaining and establishing relationships with contract research organizations ("CROs") and clinical sites for the clinical development of SP-102 both in the United States and internationally;

- successful completion of toxicology studies, biodistribution studies and minimally efficacious dose studies in animals, where applicable;
- successful completion of clinical trials, under the FDA's current Good Clinical Practices ("GCP") and the FDA's current Good Laboratory Practices ("GLPs");
- effective investigational new drug applications or Clinical Trial Authorizations that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party suppliers and manufacturers for clinical development of SP-102;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of SP-102, if it is approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;
- our ability to obtain coverage and adequate reimbursement from third-party payors for our product candidates, if approved, and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement; and
- our ability to compete with other treatments.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize SP-102, which would materially harm our business. If we do not receive marketing approvals for SP-102, we may not be able to continue our operations.

We have historically obtained our clinical supply of our only product candidate, SP-102, and certain of the raw materials and packaging components used in SP-102, from a sole or single source supplier and manufacturer, and we may not be able to find an alternative source on commercially reasonable terms, or at all. In addition, if any such supplier or manufacturer fails to comply with FDA regulations, we may be subject to sanctions or delays caused by FDA-issued voluntary action indicated or official action indicated status.

Historically, we have purchased our clinical and commercial supply requirements for sodium hyaluronate (NaHa), one of the excipients for SP-102, solely from Sanofi (f/k/a Genzyme Corporation) pursuant to a supply agreement, which terminated as of May 31, 2024. We anticipate finding a different manufacturer of NaHa to continue our clinical manufacturing, and upon FDA approval, commercial manufacturing of SP-102. There is also no guarantee that we will be able to commence a commercial launch of SP-102, as any such launch would be subject to regulatory approval, which we may not receive.

Under our Master Services Agreement, dated January 27, 2017 (as amended, the "Lifecore Master Services Agreement"), with Lifecore Biomedical, LLC ("Lifecore"), we depend on Lifecore to manufacture clinical supplies of SP-102. Lifecore has the right to terminate the Lifecore Master Services Agreement under certain circumstances, including, but not limited to: (1) if we are in material breach of the agreement and fail to cure such breach within 30 days of written notice; (2) if we (a) become insolvent, (b) cease to function as a going concern, (c) become convicted of or plead guilty to a charge of violating any law relating to either party's business, or (d) engage in any act which materially impairs goodwill associated with SP-102 or materially impairs the terminating party's trademark or trade

name; (3) if we fail to pay past due invoices upon 30 days' written notice, or (4) if we reject or fail to respond to a major change proposed by Lifecore that does not change our written and approved acceptance criteria in our product specifications. In the event that Lifecore decides to terminate the Lifecore Master Services Agreement, finding an alternative manufacturer on commercially reasonable terms, or at all, may be difficult. The Lifecore Master Services Agreement expires on December 31, 2028, unless terminated earlier in accordance with the terms of such agreement, or unless renewed further by the parties.

Additionally, the manufacturing facilities used by our third-party suppliers and manufacturers must continue to comply with FDA regulations and are subject to periodic announced or unannounced inspections. We have limited control over the ability of our third-party suppliers and manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our third-party suppliers and manufacturers fail to comply with FDA regulations, the FDA may not authorize the manufacture of our product candidate at these facilities, and we may be unable to find alternative manufacturing facilities in a timely manner or at all. The failure by such third parties to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, import detention, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of our product, operating restrictions and criminal prosecutions.

In addition, our product candidate may compete with other product candidates and products for access to manufacturing facilities and other supplies. There are a limited number of manufacturers that operate under current Good Manufacturing Practices ("cGMP") regulations and that might be capable of manufacturing for us. Also, prior to the approval of our product candidate, we would need to identify a contract manufacturer that could produce our products at a commercial scale and that could successfully complete FDA pre-approval inspection and inspections by other health authorities. Agreements with such manufacturers or suppliers may not be available to us at the time we would need to have that capability and capacity.

If our clinical supply of our product candidate and certain of the raw materials used in our product candidate are disrupted or delayed, there can be no assurance that alternative sources can serve as adequate replacements or that supplies will be available on terms that are favorable to us, if at all. Any disruption in supply could affect the development of SP-102.

We rely on third parties to conduct our clinical trials and intend to rely on third parties to conduct all of our future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our current and future product candidates.

We currently do not have the ability to independently conduct any clinical trials. The FDA and regulatory authorities in other jurisdictions require us to comply with regulations and standards, commonly referred to as GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP-compliant clinical trials of our current and future product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GCP-compliant clinical trials play a significant role in the conduct of these studies and trials and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount and timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GCP-compliant clinical trials, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. For any violations of laws and regulations in the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement actions that may include civil penalties up to and including criminal prosecution.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. We face the risk of potential unauthorized disclosure or infringement, misappropriation or other violation of our intellectual property by CROs, which may reduce our trade secret and intellectual property protection and allow our potential competitors to access and exploit our proprietary technology.

Further, any of these third parties may terminate their engagements with us or be unable to fulfill their contractual

obligations. If the third parties conducting our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GCP, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval or successful commercialization in a timely fashion, or at all, for the applicable product candidate. Our financial results and the commercial prospects for our current and future product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

We may in the future enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues.

We may in the future enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances to develop proposed products and to pursue new markets.

Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all, and may not realize the anticipated benefits of any such transactions or arrangements.

Additionally, with respect to current and future collaborations, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' products or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

Delays in clinical trials could result in increased costs to us and delay our ability to obtain commercial approval and generate revenue.

Before obtaining marketing approval for the sale of any of our current or future product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates for their intended indications. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in obtaining regulatory authorizations to commence a clinical trial or reaching a consensus with regulatory authorities on trial design;
- delays in identifying prospective clinical investigators or clinical trial sites that have necessary qualifications, interest and capacity to perform a requested protocol;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at the investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;

- changes to the clinical trial protocol;
- delays in recruiting suitable subjects to participate in our clinical trials;
- failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with GCP;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- delays in subjects completing participation in a trial or returning for post-treatment follow-up;
- clinical trial sites or subjects dropping out of a trial;
- key investigators departing their clinical sites;
- lack of adequate funding to continue the trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- subjects experiencing severe or unexpected drug-related adverse effects;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, after an inspection of our clinical trial operations, trial sites or manufacturing facilities, or for other reasons;
- occurrence of serious adverse events ("SAEs") in our trials or in trials of the same class of agents conducted by other sponsors;
- changes in regulatory requirements or guidance that require amending or submitting new clinical protocols;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials and/or not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by subcontractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, participants being exposed to unacceptable health risks, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Our product development costs will increase if we experience delays in testing or marketing approvals. The FDA and other regulatory agencies may impose new or refined testing expectations based on experience and increased knowledge over time. In addition, if we make manufacturing or other changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. We do not know whether

any of our clinical trials, including our planned clinical trial of SP-102, will begin or continue as planned, will need to be restructured or will be completed on schedule, or at all. We may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any clinical trials we initiate in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval for our product candidates and the approval may be for a more narrow indication than we seek.

We cannot commercialize our current and future product candidates, if any, until the appropriate regulatory authorities have reviewed and approved the product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals. Even if a product candidate meets the safety and efficacy endpoints in clinical trials, the data may not be considered sufficient by regulatory authorities, those regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA advisory committee is convened, including if such advisory committee recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in regulatory authority policy or data requirements during the period of product development, clinical trials and the regulatory review process.

Even if we receive regulatory approval, the FDA may approve a product candidate for more limited indications than requested or it may impose significant limitations in the form of narrow indications, black box warnings or a Risk Evaluation and Mitigation Strategy ("REMS"). The FDA may require labeling that includes warnings and precautions or contra-indications with respect to conditions of use, or may grant approval subject to the performance of costly post-marketing clinical trials. In addition, the FDA may not approve the labeling claims that are considered necessary or desirable for the successful commercialization of a product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for a product candidate.

Additionally, if the results of any clinical trials are inconclusive or if there are safety concerns or SAEs associated with a product candidate, we may:

- be delayed or fail in obtaining marketing approval for a product candidate;
- obtain approval for indications or patient populations that are not as broad as we intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way the product candidate is administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified REMS;
- be sued and held liable for harm caused to patients; or
- experience damage to our reputation.

We may find it difficult to enroll or maintain patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates.

Identifying and qualifying patients to participate in any clinical trials of our current and future product candidates is critical to our success. The timing of any clinical trials depends on our ability to recruit patients and to complete required follow-up periods. If patients are unwilling to participate in our clinical trials due to negative publicity from adverse events, competitive clinical trials for similar patient populations, or for other reasons, the timeline for recruiting patients, conducting trials and potentially obtaining regulatory approval may be delayed.

We may also experience delays if patients withdraw from a clinical trial or do not complete the required monitoring period. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our product candidates or termination of clinical trials altogether.

Patient enrollment is affected by many factors, including:

- the size and nature of the patient population;
- the proximity of patients to clinical sites;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- competing clinical trials;
- the risk that enrolled patients will not complete a clinical trial;
- ability to monitor patients adequately during and after treatment;
- potential disruptions caused by the COVID-19 pandemic (or other similar disruptions), including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented and other factors;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience; and
- clinicians' and patients' perceptions as to the potential advantages of the product candidate in relation to other available products.

The conditions for which we currently plan to evaluate our product candidates are common, but the eligibility criteria of our clinical trials limit the pool of available trial participants. For example, we experienced a delay in the enrollment of our now completed SP-102 Phase 3 clinical trial in sciatica due to the selective eligibility criteria in place to reduce the placebo effect and the impacts of COVID-19, and may experience similar issues with enrollment of our other planned clinical trials.

Under the federal Food and Drug Omnibus Reform Act (the "FDORA"), sponsors are required to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug product. These plans are meant to encourage enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for diversity action plans. Unlike most guidance documents issued by the FDA, the diversity action plan guidance, when finalized, will have the force of law. In January 2025, in response to an executive order issued by President Trump on diversity, equity and inclusion programs, the FDA removed this draft guidance from its website. The implications of this action are not yet known. If we are not able to adhere to any new or future requirements, our ability to conduct clinical trials may be delayed or halted.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a competitor. We may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

The incidence and prevalence of target patient populations of our product candidates are based on estimates and third-party sources. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations of our product candidates based on various third-party sources and internally generated analyses and use such estimates in making decisions regarding our product development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in preclinical studies or clinical trials.

These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunities will depend on, among other things, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

We face significant competition and our competitors may discover, develop or commercialize products faster or

more successfully than us.

The biotechnology and pharmaceutical industries are characterized by intense competition and rapid technological advances. In addition, the competition in the pain management market, and other relevant markets, is intense.

SP-102, if approved, has the potential to become the first FDA-approved epidural steroid product for the treatment of sciatica. While there are currently no FDA approved epidural steroid injections indicated for the treatment of sciatica, we are aware of certain non-steroid product candidates in development. SP-102, if approved, also will compete with various opioid pain medications, Nonsteroidal Anti-Inflammatory Drugs ("NSAIDs"), muscle relaxants, antidepressants, anticonvulsants and surgical procedures. Procedures may include nerve blocks and transcutaneous electrical nerve stimulations. We may also face indirect competition from the off-label and unapproved use of branded and generic injectable steroids.

We expect that the market will become increasingly competitive in the future. Many of our competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in: developing product candidates and technologies, undertaking preclinical studies and clinical trials, obtaining FDA and other regulatory approvals of product candidates, formulating and manufacturing product candidates, and launching, marketing and selling product candidates.

Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products as well. Smaller or early-stage companies or generic or biosimilar pharmaceutical manufacturers may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our commercial opportunity could be reduced or eliminated if our competitors succeed in developing, acquiring or licensing on an exclusive basis, products that are more effective or less costly than any product candidate that we are currently developing or that we may develop. If approved, our product candidates will face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors and later enter the market.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do, which would have a material adverse impact on our business, financial condition and results of operations.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payers and operators of major clinics, and we may not be successful in attaining such market acceptance.

Even with the requisite approvals from the FDA in the U.S., the EMA in the EU and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including our management's time and financial resources, and may not be successful. Even if any product candidate we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any product candidate we develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidate as demonstrated in clinical trials;
- the efficacy and safety of other products that are used in combination or in sequence with our product candidates;
- the potential and perceived advantages of our product candidates compared to alternative treatments;

- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA or other regulatory agencies;
- the willingness of the target patient population to try novel biologics and of physicians to prescribe these treatments, as well as their willingness to accept an intervention that involves the alteration of the patient's gene;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- availability of third-party coverage and sufficiency of reimbursement; and
- the prevalence and severity of any side effects.

Even if a product candidate is approved, such product may not achieve an adequate level of acceptance, we may not generate significant product revenues, and we may not become profitable.

The third-party payor coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for our current or future product candidates, if approved, could decrease our ability to generate product revenue.

There is significant uncertainty related to the third-party coverage and reimbursement of existing and newly approved products. Market acceptance and sales of our current and future product candidates, if approved, in domestic markets will depend significantly on the availability of coverage and adequacy of reimbursement from third-party payors, including government programs (such as Medicare and Medicaid) and private payor healthcare and insurance programs. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Coverage and reimbursement for a product candidate, if approved, may differ significantly from payor to payor, and we may not be able to obtain adequate coverage and reimbursement in the future.

Further, obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of such product candidate, if approved, to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Additionally, coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Assuming that coverage is obtained for a given product, the resulting reimbursement rates might not be adequate or may require co-payments or co-insurance that patients find unacceptably high. Patients, physicians, and other healthcare providers may be less likely to prescribe, dispense or use, as applicable, any approved product unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost.

The market for our current and future product candidates, if approved, will depend significantly on access to third-party payors' drug formularies for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded product in their formularies or otherwise restrict patient access to a branded product when a less costly generic equivalent or other alternative is available.

In addition, even if we obtain adequate levels of reimbursement, third-party payors carefully review and increasingly question the coverage of, and challenge the prices charged for, products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices for products. We cannot be sure that coverage and reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, what the level of reimbursement will be. If coverage and reimbursement of our

product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Furthermore, the requirements governing medical product pricing vary widely from country to country. In some foreign countries, the proposed pricing for a prescription device must be approved before it may be lawfully marketed. Historically, products launched in the European Union ("EU") do not follow price structures of the United States and generally prices tend to be significantly lower.

Our product candidate SP-102 is expected to be a physician-administered injectable viscous gel and as such, separate reimbursement for the product itself may not be available. Instead, if SP-102 receives regulatory approval, the administering physician may be reimbursed only for providing the treatment or procedure in which SP-102 is used. To the extent separate coverage and reimbursement should become available for SP-102, we anticipate that it will be sold to physicians on a "buy and bill" basis. Buy and bill products must be purchased by healthcare providers before they can be administered to patients. Healthcare providers subsequently must seek reimbursement for the product from the applicable third-party payor, such as Medicare or a health insurance company. Healthcare providers may be reluctant to administer our product candidates, if approved, because they would have to fund the purchase of the product and then seek reimbursement, which may be lower than their purchase price, or because they do not want the additional administrative burden required to obtain reimbursement for the product.

Further, the codes used by providers to bill for SP-102, if approved, could also affect reimbursement. J-Codes are codes maintained by the Centers for Medicare and Medicaid Services ("CMS"), which are a component of the Healthcare Common Procedure Coding System and are typically used to report injectable drugs that ordinarily cannot be self-administered. We do not have a specific J-Code for SP-102. If our product candidate is approved, we may apply for one but cannot guarantee that a J-Code will be granted. To the extent separate coverage or reimbursement is available for any product candidate, if approved, and a specific J-Code is not available, physicians would need to use a non-specific miscellaneous J-Code to bill third-party payors for these physician- administered drugs. Because miscellaneous J-Codes may be used for a wide variety of products, health plans may have more difficulties determining the actual product used and billed for the patient. These claims must often be submitted with additional information and manually processed, which can create delays in claims processing times as well as increasing the likelihood for claim denials and claim errors.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and such results do not guarantee approval of a product candidate by regulatory authorities. In addition, our clinical trials to date have been limited in scope, and results received to date may not be replicated in expanded or additional future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials do not necessarily predict success in the results of completed clinical trials. There can be no assurance that any of our current or future preclinical and clinical trials will ultimately be successful or support further preclinical or clinical development of our current and future product candidates, if any. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for their product candidates. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development. Any such adverse events may cause us to delay, limit or terminate planned clinical trials, any of which would have a material adverse effect on our business, financial condition, results of operations and prospects.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. If we fail to receive positive results in clinical trials of our product candidate, the development timeline and regulatory approval and commercialization prospects for our only product candidate, and, correspondingly, our business and financial prospects would be negatively impacted. A Phase 3 trial was completed for SP-102 for the treatment of sciatica and the second Phase 3 trial was initiated in September 2025. We may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of such clinical trials in a way that leads to our obtaining marketing approval for our product candidate in a timely manner, or at all. Our clinical trials may produce negative or

inconclusive results, and, in the future, we may decide, or regulators may require us, to conduct additional clinical trials and preclinical studies in addition to those we have planned.

In March 2022, we announced final results from our Phase 3 trial for SP-102 and believed that we had sufficient data to support the safety and efficacy of SP-102, which would provide us with a pathway for a 505(b)(2) New Drug Application ("NDA") submission. In November 2023, we had a Type C meeting with the FDA to discuss the requirements for filing a 505(b)(2) NDA for SP-102. In the Type C meeting, the FDA indicated that it did not agree that the clinical data collected from the single CLEAR-1 trial was sufficient to support the safety and efficacy of SP-102, given the risks associated with interventional procedures. The FDA requested that a confirmatory trial be conducted, noting the absence of any existing FDA-approved epidural steroid product for the treatment of sciatica. The FDA provided guidance regarding expectations for this additional trial needed prior to a 505(b)(2) NDA filing, including expectations for the size of the safety database and specific safety monitoring requirements. Specifically, the FDA requested that the confirmatory CLEAR-2 trial include a larger safety database to further validate the safety and efficacy of SP-102. In February 2024, we had a Type D meeting with the FDA to preview the newly designed trial with the FDA, in order to reduce the potential need for any other additional confirmatory trials prior to a 505(b)(2) NDA filing. During the Type D meeting, the FDA provided further guidance with respect to the requirements needed to help best position us to be able to satisfy the requirements for a 505(b)(2) NDA pathway approval. Specifically, the FDA reaffirmed the need for a larger sample size and further requested confirmatory evidence of efficacy through a repeat injection.

Interim "top-line" and preliminary data 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 audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim "top-line" or preliminary data from our clinical trials, which are based on a preliminary analysis of then-available data. Preliminary or interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. In some instances, there can be significant variability in safety or efficacy results between different clinical trials or clinical trial sites for the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial procedures and the rate of dropout among clinical trial participants. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business, financial condition and results of operations.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. Data disclosures must be carefully managed to conform to limitations on preapproval promotion and laws related to clinical trial registration and posting of results. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and stockholders may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product, product candidate or our business. If the "top-line" data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition and results of operations.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of product candidates that we may identify and pursue for their intended uses, which would prevent, delay or limit the scope of regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our current and future product candidates, we must demonstrate through lengthy, complex and expensive non-clinical studies, pre-clinical studies and clinical trials that the applicable product candidate is both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can

occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We cannot be certain that our current clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations. In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable non-U.S. regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or comparable non-U.S. regulatory authorities for support of a marketing approval, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

Even if we obtain FDA approval for any of our current or future product candidates in the United States, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in the foreign countries, the standards for clinical trials and approval may be different.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be impeded.

Our business may suffer reputational harm due to failures of our product candidates.

The failure of our current or future product candidates could have a lasting negative impact on our reputation, which could, in turn, impact our ability to successfully enter into future licensing arrangements or other transactions with potential counterparties, raise future capital or attract key personnel to join us. As a result, our business and prospects would be materially harmed, and our results of operations and financial condition would likely suffer materially.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our current or future product candidates. In the clinical trials we conduct with our current or future product candidates, patients may experience changes in their health, including illnesses, injuries, discomforts or a fatal outcome. Often, it is not possible to determine whether the product candidate being studied caused or was associated with these conditions. In addition, it is possible that as we test our clinical products in larger, longer and more extensive clinical programs, or as use of these product candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier clinical trials, as well as conditions that did not occur or went undetected in previous clinical trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials.

In the event that our current or future product candidates reveal an unacceptable severity and prevalence of these or other side effects, the clinical trials could be suspended or terminated, and the FDA could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and results of operations significantly.

Our current product candidate is complex and difficult to manufacture. We could experience delays in satisfying regulatory authorities or manufacturing problems that result in delays in our development or commercialization programs, limit the supply of our current product candidate, or otherwise harm our business.

We currently depend on contract manufacturers to conduct the manufacturing and supply activities for SP-102. Manufacturing this product candidate requires facilities specifically designed for and validated for this purpose and sophisticated quality assurance and quality control procedures are necessary. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of our suppliers.

If contaminations are discovered in our supply of our current product candidate, or any future product candidates, or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We may not be successful in securing additional sources at all or on a timely basis, which could materially harm our development timelines. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

In addition, there are risks associated with large-scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition and results of operations.

Furthermore, our manufacturers may encounter problems hiring and retaining the experienced scientific, quality assurance, quality-control and manufacturing personnel needed to operate our complex manufacturing processes, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger biotechnology companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in our manufacturing process could restrict our ability to meet potential future market demand for products, which could harm our business, financial condition and results of operations.

Risks Related to Our Business and Operations

If we are unable to retain our key executives, it may delay our development efforts and harm our business, financial condition and results of operations.

Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, retain and motivate key executives to accomplish our business objectives, we may experience constraints that will significantly impede our ability to raise additional capital and our ability to implement our overall business strategy. In particular, we are highly dependent upon our executive officers, including Henry Ji, Ph.D., our Chief Executive Officer and President, and Stephen Ma, our Chief Financial Officer. The loss of services of these executive officers could delay or prevent the successful development of our product pipeline and completion of our planned clinical trials. We do not carry “key person” insurance on any of our executive officers or other employees.

Competition for key executives in the biotechnology and pharmaceuticals field is intense, due to the limited number of individuals who possess the skills and experience required by our industry. Many of the pharmaceutical companies against which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to qualified candidates than what we have to offer. 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. Further, 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. Moreover, we conduct our operations in the San Francisco Bay Area, a region that is home to many other biopharmaceutical

companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. As such, we could have difficulty attracting and retaining experienced executives and may be required to expend significant financial resources in our recruitment and retention efforts.

We may need to increase the size of our company and may not effectively manage our growth.

As of September 30, 2026, we have six full-time employees, including one employee who has an M.D. As a subsidiary of Scilex, we have been dependent upon the services provided by Scilex employees. As of September 30, 2026, Scilex has 29 full-time employees, including four employees who have M.D.s or Ph.D.s providing services to us. We will need to expand our managerial, operational, sales and marketing, finance and other resources in order to manage our operations, clinical trials, research and development activities, regulatory filings, manufacturing and supply activities, and any marketing and commercialization activities, including co-promotion activities. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and internal regulatory review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our current and future product candidates will depend, in part, on our ability to effectively manage any future growth, if any, which may cause a significant strain on our management, and our operational, financial and other resources. Our ability to manage our growth effectively will require us to implement and improve our operational, financial and management systems and to expand, train, manage and motivate our employees. These demands may require the hiring of additional management personnel and the development of additional expertise by management. Any increase in resources devoted to research and product development without a corresponding increase in our operational, financial and management systems could have a material adverse effect on our business, financial condition and results of operations.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

Although we endeavor to obtain appropriate insurance coverage for insurable risks that we identify, we do not carry insurance for all categories of risk that our business may encounter.

Insurance coverage is becoming increasingly expensive. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles and lower coverage limits. We may not be able to maintain insurance coverage at a reasonable cost, or in sufficient amounts to protect us against losses due to liability. While we maintain property, casualty and general liability coverage, we do not carry specific biological or hazardous waste insurance coverage and our insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

We do not know if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

Clinical testing of our product candidates may expose us to individual product liability claims, class action lawsuits or actions, and other individual or mass tort claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. In addition, physicians may misuse our product candidates, if approved, with their patients if they are not adequately trained, potentially leading to injury and increased risk of product liability. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of risks inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates, if approved. Even successful defense would

require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- loss of revenue from product sales;
- decreased demand for any product candidates or products that we develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- restrictions on labeling, the marketing or manufacturing of any product candidates, if approved, withdrawal of the product candidates, if approved, from the market or voluntary or mandatory product recalls;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients; and
- the inability to commercialize any of our product candidates.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of any products we develop. We currently carry product liability insurance covering use in our clinical trials in the amount of $10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage.

We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

Any disruption in our research and development facilities could adversely affect our business, financial condition and results of operations.

Our principal executive offices are in the San Francisco Bay Area, California. Our facilities may be affected by natural or man-made disasters. Earthquakes are of particular significance since our facilities are located in an earthquake-prone area. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fires, floods and similar events. If our facilities are affected by a natural or man-made disaster, we may be forced to curtail our operations and/or rely on third parties to perform some or all of our research and development activities. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In the future, we may choose to expand our operations in either our existing facilities or in new facilities. If we expand our worldwide manufacturing locations, there can be no assurance that this expansion will occur without implementation difficulties, or at all.

We may seek to grow our business through acquisitions and may fail to realize the anticipated benefits of any acquisition, and acquisitions can be costly and dilutive.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may expand our business and intellectual property portfolio through the acquisition of new businesses and technologies. We cannot assure that we will achieve anticipated benefits from any acquisition to justify the transaction.

Competition within our industry for acquisitions of businesses, technologies and assets may become intense. Even if we are able to identify an acquisition that we would like to consummate, we may not be able to complete the acquisition on commercially reasonable terms or the target may be acquired by another company. We may enter into negotiations for acquisitions that are not ultimately consummated. Those negotiations could result in diversion of management time and significant out-of-pocket costs.

The success of any acquisition depends on, among other things, our ability to combine our business with an acquired business in a manner that does not materially disrupt existing relationships and that allows us to achieve development and operational synergies. If we are unable to achieve these objectives, the anticipated benefits of an acquisition may not be realized fully, or at all, or may take longer to realize than expected. If we are obligated to make any milestone payments in connection with an acquisition or licensing agreement, such obligations could impose substantial additional costs on us and divert resources from other aspects of our business. In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant future amortization expenses. As a result, an acquisition may not be accretive to our stock value or development pipeline in the near or long term.

We expect to incur higher development and regulatory costs, and additional costs integrating the operations and personnel of any companies we acquire, which cannot be estimated accurately at this time. If the total costs of the integration of our companies and advancement of acquired product candidates and technologies exceed the anticipated benefits of the acquisition, our business, financial condition and results of operations could be adversely affected.

If we conduct business outside of the United States, the international components of our business will expose us to business, legal, regulatory, political, operational, financial and economic risks associated with conducting business outside of the United States.

We may collaborate with international manufacturing partners and expand our business internationally in the future. The purchase and shipment of components from international sources will subject us to U.S. and foreign governmental trade, import and export, and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act (the "FCPA"), as well as export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Moreover, the current Trump administration has substantially altered prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi- lateral trade agreements and treaties with foreign countries. In addition, the current Trump administration has initiated or is considering imposing tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. It remains unclear what the current Trump administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. Although the current Trump Administration has not yet implemented tariffs on pharmaceuticals, there can be no assurance that it will not implement such tariffs in the future. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our products, impact our ability to sell our products outside the United States or to sell our products outside the United States at competitive prices and/or to affect the United States or global economy or certain sectors thereof and, thus, could adversely impact our business.

Conducting business internationally involves a number of risks, including:

- multiple, sometimes conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, anti-bribery and anti-corruption laws, regulatory requirements and other governmental approvals, permits and licenses;
- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors or any of our third-party suppliers;
- failure by us or our distributors to obtain appropriate licenses or regulatory approvals for the sale or use of our product candidates, if approved, in various countries;
- difficulties in managing foreign operations;
- cost and availability of shipping and other means of product transportation;
- foreign currency exchange rate fluctuations;

- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- complexities associated with managing multiple payor-reimbursement regimes or self-pay systems;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, and similar anti-bribery and anti-corruption laws in other jurisdictions, for example by failing to maintain accurate information and control over sales or distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, negatively impact our business, financial condition and results of operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our research, product candidates, investigational medicines and the diseases our product candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of non-compliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blind clinical study or to report an alleged adverse event.

When such disclosures occur, there is a risk that we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. Furthermore, our employees, affiliates and/or business partners may use social media for their personal use, and their activities on social media or in other forums could result in adverse publicity for us. Any negative publicity as a result of social media posts, whether or not such claims are accurate, could adversely impact us. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business, financial condition and results of operations.

Our business and operations would suffer in the event of a system failure.

While we have implemented and maintain security measures, our computer systems and those of our CROs and other contractors and consultants are vulnerable to computer viruses, unauthorized access, cybersecurity attacks, and other security incidents, including as perpetrated by hackers, or as the result of natural disasters, terrorism, war, or telecommunications or electrical failures. While we have not experienced any material system failure or a security breach to date, if such an event were to occur, it could result in a material disruption of our product development programs or a loss of our trade secrets or other proprietary information. For example, the loss of clinical trial data from completed, ongoing, or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce such data. To the extent that any disruption or security breach were to result in the loss of or damage to our data or applications, or the unauthorized disclosure of confidential or proprietary information, including personal data, we could incur material legal liability or be the subject of legal claims, suffer damage to our reputation, lose or harm our intellectual property rights, and delay the continued research, development and commercial efforts of our product candidates, if approved. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of cybersecurity matters or some other matter, that claim could have a material adverse effect on our business, financial condition, and results of operations.

Further, a security incident or privacy violation that leads to the unauthorized acquisition, interruption, modification, loss, theft, corruption, interference, or other unauthorized disclosure of, or prevents access to, personal data, including patient data or other protected health information, could harm our reputation, compel us to comply with federal or state breach notification laws and foreign equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents, and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. Our ability to effectively manage and maintain our

internal business information depends significantly on our enterprise resource planning ("ERP") system and other information systems. Portions of our information technology systems may experience interruptions, delays, or cessations of service or produce errors in connection with ongoing systems implementation work. Cybersecurity attacks in particular are continually evolving and include, but are not limited to, malicious software, ransomware, attempts to gain unauthorized access to data under our custody or control, and other electronic security breaches that could lead to disruptions in systems, misappropriation of confidential or otherwise protected information, and corruption of data. If we are unable to prevent such cybersecurity attacks or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, we may suffer loss of reputation, we may be the subject of governmental investigations, legal claims, or litigation, or we may incur financial loss or other regulatory penalties, each of which may not be covered by our insurance. In addition, these breaches and other unauthorized access to our systems can be difficult to detect, and any delay in identifying any such event may lead to increased harm of the type described above.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and results of operations.

As widely reported, global credit and financial markets have experienced volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, as well as the ongoing geopolitical conflicts in Ukraine, war in Iran and other conflicts and instability in the Middle East, instability in Venezuela, tensions between not only the U.S. and China, but also between the U.S. and other countries in the international community.

The ongoing conflict between Russia and Ukraine, war in Iran and other conflicts and instability in the Middle East and instability in Venezuela are causing disruptions to global economic conditions. It is not possible to predict the broader consequences of these ongoing conflicts. It is also not possible to predict with certainty the duration of these ongoing conflicts or their additional adverse effects on existing U.S. macroeconomic conditions and financial markets, all of which could impact our business, financial condition, and results of operations, as well as our ability to raise capital. There can be no assurances that further deterioration in credit and financial markets and confidence in economic conditions will not occur. In addition, the closure of any additional national or regional commercial banks could lead to further economic instability.

Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and price of our Common Stock, and could require us to delay or abandon clinical development plans.

Our ability to effectively monitor and respond to the rapid and evolving developments and expectations relating to sustainability, including the environmental, social and governance matters, may impose unexpected costs or results in reputational or other harm that could have a material adverse effect on our business.

There is an increasing focus from certain investors, employees, regulators, listing exchanges and other stakeholders concerning corporate responsibility and sustainability matters, including with regard to environmental, social and governance ("ESG") factors. Some investors and investor groups may use these factors—either positively or negatively—to guide their investment strategies and, in some cases, investors may choose not to invest in us if they believe our policies or practices relating to corporate responsibility and sustainability do not align with their expectations. Currently, a variety of third-party providers of corporate responsibility and sustainability ratings measure the performance of companies on 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 major institutional investors have publicly emphasized the importance of ESG measures to their investment decisions. Topics taken into account in such assessments include, among others, companies' efforts and impacts on climate change, human rights, business ethics and compliance, diversity, equity and inclusion and the role of companies' boards of directors in overseeing various sustainability-related issues. In light of investors' increased focus on sustainability matters, if we are, for example, perceived as lagging in taking steps with respect to ESG initiatives, certain investors may seek to engage with us on improving our ESG disclosures or performance. They may also make voting decisions or take other actions to hold us and our Board of Directors (the "Board of Directors") accountable.

In addition, there are rapidly evolving developments and changing expectations relating to sustainability matters. As

a result, the criteria by which our corporate responsibility and sustainability practices are assessed may change, which could cause us to undertake costly initiatives or actions to satisfy new demands. If we elect not to or are unable to adequately recognize and respond to such developments and changing governmental, societal, investor and/or consumer expectations relating to sustainability matters, we may miss corporate opportunities, become subject to additional scrutiny or incur unexpected costs. We may face risk of litigation or reputational damage in the event that our sustainability policies or practices do not meet the standards set by various constituencies.

We may also face reputational damage if we are unable to achieve an acceptable sustainability rating from third- party rating services. A low 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 competitors instead. Ongoing focus on corporate responsibility and sustainability matters by investors and other stakeholders 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, financial condition or results of operations, including the sustainability of our business over time, and could cause the market value of our Common Stock to decline.

Further, our emphasis on sustainability issues may not maximize short-term financial results and may yield financial results that conflict with the market's expectations. We may in the future make business decisions consistent with our sustainability goals that we believe, based on considered analysis, will create value and improve our financial performance over the long-term. These decisions, however, may not be consistent with the short-term expectations of our stockholders and may not produce the long-term benefits that we expect, in which case our business, financial condition and results of operations could be harmed.

Risks Related to Our Intellectual Property

Potential disputes over intellectual property rights that we have licensed may prevent or impair our ability to maintain our current licensing arrangements on acceptable terms.

Licensing of intellectual property rights is of high importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the licensing agreement;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current product candidate, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors, us and our partners.

If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, our business, financial condition and results of operations may be adversely affected. We may enter into additional licenses in the future and if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

Furthermore, if our licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical or competitive to ours and we may be required to cease our development and commercialization of our current and future product candidates, if approved. Moreover, if disputes over intellectual property that we license prevent or impair our ability to maintain other licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to maintain patent protection for our product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trademarks, trade secret protection, and confidentiality agreements to protect the intellectual property related to our current and future product candidates. Our success depends in part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates. We seek to protect our proprietary position by filing and/or in-licensing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patents and patent applications that we own or in-license may fail to result in issued patents with claims that protect our product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application, or be used to invalidate a patent. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the U.S. Patent and Trademark Office (the "PTO") and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the non-compliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position;
- any successful intellectual property challenge to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any product candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses; and
- an interference proceeding can be provoked by a third party or instituted by the PTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications for any application with an effective filing date before March 16, 2013.

The patent prosecution process is also expensive and time-consuming, and we and our licensors may not be able to

file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we and our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

If the patent applications we hold or in-license with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize our product candidates. Any such outcome could have a materially adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes and brands for our development pipeline through acquisitions and in-licenses.

Our current and future product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. It may also be commercially advantageous to use trademarks held by others. We may be unable to acquire or in-license proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for our product candidates. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing and prosecution of patent and trademark applications, or to maintain the patents covering technology that we license from third parties and associated trademark registrations, or such activities, if controlled by us, may require the input of such third parties. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents, trademarks and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents and trademarks, or any patents and trademark registrations that may be issued from such applications. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, or loss of trademark rights, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents or trademarks against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. We may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the third-party may offer, on an exclusive basis, its proprietary rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights on commercially reasonable terms, our ability to commercialize our product candidates, if approved, and our business, financial condition and results of operations could suffer.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any 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. 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.

Claims that we infringe, misappropriate, or violate the intellectual property rights of third parties may give rise to costly and lengthy litigation, and we could be prevented from selling product candidates, if approved, forced to pay damages, and defend against litigation.

Third parties may assert patent or other intellectual property infringement or misappropriation claims against us or our strategic partners, licensors or licensees with respect to our product candidates. If any of our current or future product candidates, methods, processes and other technologies are alleged to infringe on or be improperly based on the proprietary rights of other parties, we could face adverse consequences.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert or are infringed by one of our current or future product candidates.

There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our product candidates or our technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our current or future product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of our valuable management and employee resources from our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;

- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing; and/or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do either. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Furthermore, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates, if approved. Further, we may incorrectly determine that our technologies or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and future approved products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts

would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. 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.

Even if we were to prevail, any litigation or administrative proceeding could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Furthermore, as a result of a patent infringement suit brought against us or our strategic partners or licensees, we or our strategic partners or licensees may be forced to stop or delay developing, manufacturing or selling technologies, product candidates or potential products that are claimed to infringe a third party's intellectual property unless that party grants us or our strategic partners' or licensees' rights to use its intellectual property. Ultimately, we may be unable to develop some of our product candidates or may have to discontinue development of a product candidate or cease some of our business operations as a result of patent infringement claims, which could severely harm our business, financial condition and results of operations.

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

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

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments.

Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. Any of the foregoing may have a material adverse effect on our business, financial condition and results of operations.

If our intellectual property rights are invalidated or circumvented, our business, financial condition and results of operations will be adversely affected.

Our long-term success depends on our ability to continually discover, develop and commercialize innovative new pharmaceutical products. Without strong intellectual property protection, we would be unable to generate the returns necessary to support the enormous investments in research and development and capital as well as other expenditures required to bring new product candidates to the market and for commercialization.

Intellectual property protection varies throughout the world and is subject to change over time. In the United States, for small molecule drug products the Hatch-Waxman Amendments provide generic companies powerful incentives to seek to invalidate our pharmaceutical patents. As a result, we expect that our U.S. patents on major pharmaceutical products will be routinely challenged, and there can be no assurance that our patents will be upheld. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a distraction to management and other employees. We face generic manufacturer challenges to our patents outside the United States as well. In addition, competitors or other third parties may claim that our activities infringe patents or other intellectual property rights held by them. If successful, such claims could result in our being unable to market a product in a particular territory or being required to pay damages for past infringement or royalties on future sales.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition and our business, financial condition and results of operations may be adversely affected.

We have registered trademarks with the PTO for the marks "SEMNUR PHARMACEUTICALS" and "SEMDEXA" in the United States. Our trademarks or trade names may be challenged, infringed, diluted, tarnished, 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. At times, competitors or other third parties 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, dilution or tarnishment 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, financial condition and results of operations 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.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology and pharmaceutical industries involve both technological and legal complexity. Therefore, obtaining and enforcing biotechnology and pharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act (the "AIA"), which was passed in September 2011, resulted in significant changes to the U.S. patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the PTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide opportunities for third parties to challenge any issued patent in the PTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in PTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a PTO proceeding sufficient for the PTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the PTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could

increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents.

We may become involved in opposition, interference, derivation, inter partes review, post-grant review, or other proceedings challenging our or our licensors' patent rights, and the outcome of any proceedings is highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our owned or in-licensed patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Additionally, 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, and there are other open questions under patent law that courts have yet to decisively address. 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 Congress, the federal courts and the PTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any waiver of our patent or other intellectual property protection by the U.S. and other foreign governments could have a material adverse effect on our competitive position, business, financial condition and results of operations. For example, recent decisions raise questions regarding the award of patent term adjustment ("PTA") for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, but the complexity and uncertainty of European patent laws have also increased in recent years. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the "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 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 will 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 any potential changes. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. For example, periodic maintenance fees on any issued patent are due to be paid to the PTO and other foreign patent agencies in several stages over the lifetime of the patent. The PTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or any of our licensors fail to maintain the patents or patent applications covering our product candidates, our competitors may be able to enter the market, which would have an adverse effect on our business, financial condition and results of operations.

Confidentiality agreements with employees may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.

To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, or prior to seeking patent protection, we rely on trade secret protection and confidentiality agreements. To this

end, we intend to require all our future employees to enter into agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements typically limit the rights of the third parties to use or disclose our confidential information. We also typically obtain agreements from these parties that provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property.

However, our future employees may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our competitive position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business, financial condition and results of operations. Enforcing a claim that a third party obtained illegally, and is using, trade secrets and/or confidential know-how is expensive, time-consuming and unpredictable, and the enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer. Moreover, our third-party licensing partners may retain rights in some of our proprietary or joint trade secrets, know-how, patented inventions or other proprietary information, including rights to sublicense and rights of publication, which may adversely impact our ability to obtain patents and protect trade secrets, know-how or other proprietary information.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

We may hire employees, consultants or advisors who are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, as well as our academic partners. Although we will try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We may also be subject to claims that patents and applications that we may file to protect inventions of our employees or consultants are rightfully owned by their former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. An inability to incorporate such technologies or features would have a material adverse effect on our business, financial condition and results of operations and may prevent us from successfully commercializing our product candidates, if approved. Moreover, any such litigation or the threat of such litigation may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, if approved. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our future employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, individuals executing agreements with us may have preexisting or competing obligations to a third party.

Our position as a relatively small company may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against infringement claims by third parties.

Litigation relating to the ownership and use of intellectual property is expensive, and our position as a relatively small company in an industry dominated by very large companies may cause us to be at a significant disadvantage in defending our intellectual property rights and in defending against claims that any of our current or future product candidates infringes or misappropriates third-party intellectual property rights. However, we may seek to use various

post-grant administrative proceedings, including procedures created under the AIA, to invalidate potentially overly-broad third-party rights. Even if we can defend our position, the cost of doing so may adversely affect our ability to grow, generate revenue or become profitable. In the course of the ongoing litigation or any future additional litigation to which we may be subject, we may not be able to protect our intellectual property at a reasonable cost, or at all. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities or otherwise affect our legal, contractual or intellectual property rights, which could have a significant adverse effect on our business, financial condition and results of operations.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including PTO administrative proceedings, such as *inter partes* reviews, post-grant reviews and reexamination proceedings before the PTO or oppositions and revocations and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our current and future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current and future product candidates may give rise to claims of infringement of the patent rights of others.

Despite safe harbor provisions for products prior to commercial launch, third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents, of which we are currently unaware, with claims to materials, formulations, methods of doing research, methods of manufacture or methods for treatment related to the use or manufacture of our current and future product candidates. Because patent applications can take many years to issue, there may be currently pending unpublished patent applications which may later result in issued patents that our current and future product candidates may infringe. In addition, third parties may obtain patents in the future and claim that the use of our technologies infringes these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our current and future product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable.

Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize one or more of our current and future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, or, in developing our current and future product candidates, limit our uses, pay royalties or redesign our infringing current and future product candidates, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our current and future product candidates, if approved. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to develop and commercialize one or more of our current and future product candidates, which could harm our business, financial condition and results of operations significantly.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our future employees, we may engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade

secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

The requirements for patentability and the patent enforcement differ in many countries. Filing, prosecuting and defending patents on all of our current and future product candidates throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement in some countries is not as strong as that in the United States. These products may compete with our current and future product candidates, if approved, in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

The ongoing conflict in Ukraine and related sanctions could significantly devalue our Ukrainian and Russian patent applications. Russian decrees may significantly limit our ability to enforce Russian patents. We cannot predict when or how this situation will change.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly in certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals and methods of treatment of the human body, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

In addition, many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. Furthermore, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents and limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition and results of operations.

If we do not obtain patent term extension and data exclusivity for any of our product candidates we are developing or may develop, our business may be materially harmed.

Depending upon the timing, duration and conditions of any FDA marketing approval of our current and future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended; the extension cannot extend the total patent term beyond 14 years from approval; and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain a patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened, and our competitors may obtain approval to market competing products sooner.

As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our competitive position, business, financial condition, results of operations, and prospects could be materially harmed.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Scilex relies in part on confidentiality agreements with its employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and inventions agreements with employees, consultants and advisors, to protect its trade secrets and other proprietary information. We plan to rely on the same arrangement. In addition to contractual measures, we will try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of 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. For example, in 2010, the FDA, as part of its Transparency Initiative, recommended steps that the FDA could take to increase transparency, including with respect to making additional information publicly available on a routine basis, which may include information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Competitors and other third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to help manufacture and supply SP-102, and we expect to collaborate with third parties on the continuing development of future product candidates, we must, at times, share trade secrets with them. We also expect to conduct research and development programs that may require us to share trade secrets under the terms of our partnerships or agreements with CROs, research institutions and/or investigators. We seek to protect our proprietary technology in part by entering into agreements containing confidentiality and use restrictions and obligations, including, material transfer agreements, consulting agreements, confidentiality agreements or other similar agreements with our advisors, contractors, service providers and consultants prior to disclosing proprietary

information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business, financial condition and results of operations.

In addition, these agreements typically restrict the ability of our advisors, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, financial condition and results of operations.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- We or our licensors or strategic partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- We or our licensors or strategic partners might not have been the first to file patent applications covering certain of our inventions;
- Others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- Our pending patent applications may not lead to issued patents;
- Issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- Our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- We may not develop additional proprietary technologies that are patentable; and
- The patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, financial condition and results of operations.

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex

legal and factual questions, and has been and will continue to be the subject of litigation and new legislation. Publications in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our own patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result of these and other factors, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. If these changes were to occur, they could have a material adverse effect on our ability to generate revenue. For example, recent decisions raise questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will or will not be viewed in the future and whether patent expiration dates may be impacted. Similarly, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, a new unitary patent system took effect on June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the 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 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 will 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 any potential changes.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the PTO or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of defending our patents or enforcing our proprietary rights in post-issuance administrative proceedings and litigation can be substantial and the outcome can be uncertain. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and potentially licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Generally, patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, patent term can be adjusted and increased to recapture a portion of delay incurred by the PTO in examining the patent application. The scope of patent protection may also be limited. Without patent protection for our current or future product candidates, we may be open to competition from generic versions of such products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Risks Related to Government Regulations

The regulatory approval processes of the FDA and comparable non-U.S. regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business, financial condition and results of operations will be substantially harmed. Moreover, gaining approval for a product candidate in one country or jurisdiction does not guarantee that we will be able to obtain approval for or commercialize it in any other jurisdiction, which would limit our ability to realize our full market potential.

The time required to obtain marketing approval from the FDA or comparable non-U.S. regulatory authorities for a product candidate is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities, and its outcome is inherently uncertain. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For example, following our March 2022 announcement of the final results from our Phase 3 trial for SP-102, we believed that we had sufficient data to support the safety and efficacy of SP-102, which would provide us with a pathway for a 505(b)(2) NDA submission. In November 2023, we had a Type C meeting with the FDA to discuss the requirements for filing a 505(b)(2) NDA for SP-102. In the Type C meeting, the FDA indicated that it did not agree that the clinical data collected from the single CLEAR-1 trial was sufficient to support the safety and efficacy of SP-102, given the risks associated with interventional procedures. The FDA requested that a confirmatory trial be conducted, noting the absence of any existing FDA-approved epidural steroid product for the treatment of sciatica. The FDA provided guidance regarding expectations for this additional trial needed prior to a 505(b)(2) NDA filing, including expectations for the size of the safety database and specific safety monitoring requirements. Specifically, the FDA requested that the confirmatory CLEAR-2 trial include a larger safety database to further validate the safety and efficacy of SP-102. In February 2024, we had a Type D meeting with the FDA to preview the newly designed trial with the FDA, in order to reduce the potential need for any other additional confirmatory trials prior to a 505(b)(2) NDA filing. During the Type D meeting, the FDA provided further guidance with respect to the requirements needed to help best position us to be able to satisfy the requirements for a 505(b)(2) pathway approval. Specifically, the FDA reaffirmed the need for a larger sample size and further requested confirmatory evidence of efficacy through a repeat injection. Our future success depends on our ability to develop, receive regulatory approval for, and introduce new products or product enhancements that will be accepted by the market in a timely manner.

The FDA or comparable non-U.S. regulatory authorities can delay, limit or deny approval of any product candidate for many reasons, including:

- it may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to such authorities' satisfaction that a product candidate is safe and effective for its proposed indication;
- negative or ambiguous results from our clinical trials may not meet the level of statistical significance required for approval by the FDA;
- it may disagree with our interpretation of data from preclinical studies or clinical trials;
- it may not agree that the data collected from clinical trials of our product candidate are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- it may disagree regarding the formulation, labeling and/or the specifications of our product candidate;
- such authorities may decline to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable non-U.S. regulatory authority may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidate, which would significantly harm our business, financial condition and results of operations. In addition, regulatory authorities may approve our product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for our product candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidate.

We have limited experience submitting applications for marketing authorization to the FDA, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if our clinical trials are successful. With the change in

presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the current Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Furthermore, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo, which overturned the long-standing Chevron doctrine that required courts to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes, could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. The Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rule-making process, any of which could adversely impact our business and operations.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Moreover, in order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval of a product candidate by the FDA does not ensure approval by regulatory authorities in any other country or jurisdiction outside the United States. In addition, the clinical trials conducted in one country, and the data generated therefrom, may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. If we do not receive regulatory approvals for our product candidate, our business, financial condition and results of operations will be substantially harmed.

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

For our product candidate SP-102, we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Hatch-Waxman Amendments added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2) allows an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidate by potentially decreasing the amount of data that we would need to generate in order to obtain FDA approval. If the FDA does not agree that the Section 505(b)(2) regulatory pathway is acceptable as we anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval.

Even if the FDA accepts our plan to pursue the Section 505(b)(2) regulatory pathway, we cannot assure that our product candidate will receive the requisite approvals for commercialization. In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent and market exclusivity rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation against us and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. Further, a manufacturer of an approved product may file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products.

The FDA imposes strict requirements on such petitions in part to dissuade companies from improperly using these petitions to delay approval of competing drug products. Nonetheless, if successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Any approved product candidate will be subject to ongoing and continued regulatory requirements, which may

result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the manufacturing, testing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events and, among other things, any failure of a distributed product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed.

Other requirements include submissions of safety and other post-marketing information and reports, registration and listing, product tracking and tracing, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval. The future discovery of previously unknown problems with a product, including adverse events of unanticipated type, severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- investigation or additional study obligations;
- communications to prescribers or patients about specific information or issues;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our product candidate and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. We may not be able to regain compliance, or we may only be able to regain compliance after a lengthy delay, significant expense, lost revenues and damage to our reputation.

The FDA's and other regulatory authorities' policies may change, and additional laws or government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidate. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our ability to generate revenue and achieve or sustain profitability. Changes in law or government regulations may also alter the competitive landscape, potentially to our disadvantage.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. administration may impact our business and industry. Namely, recent U.S. administrations have taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions, including the Executive Orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business, financial condition and results of operations may be negatively affected.

In addition, three decisions from the U.S. Supreme Court in June and July 2024 may lead to an increase in litigation against regulatory agencies that could create uncertainty and thus negatively impact our business. The first decision overturned established precedent that required courts to defer to regulatory agencies' interpretations of ambiguous statutory language. The second decision overturned a regulatory agency's ability to impose civil penalties in administrative proceedings. The third decision extended the statute of limitations within which entities may challenge agency actions. These cases may result in increased litigation by industry against regulatory agencies and impact how

such agencies choose to pursue enforcement and compliance actions. However, the specific, lasting effects of these decisions, which may vary within different judicial districts and circuits, are unknown. We also cannot predict the extent to which FDA and other agency regulations, policies, and decisions may become subject to increasing legal challenges, delays and changes.

A fast track product designation or other designation to facilitate product candidate development may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that SP-102 will receive marketing approval.

A product sponsor may apply for fast track designation from the FDA if a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition. The FDA has broad discretion whether or not to grant this designation.

We have received fast track designation for SP-102 for the treatment of sciatica. Even though SP-102 has received fast track designation, we may not experience a faster process, review or approval compared to conventional FDA procedures. A fast track designation does not expedite clinical trials, or mean that regulatory requirements are less stringent or provide assurance of ultimate marketing approval by the FDA. Instead, fast track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review of individual sections of an NDA submitted to the FDA as they become finalized. The FDA may rescind the fast track designation if it believes that the designation is no longer supported by data from our clinical development program. The FDA may also withdraw any fast track designation at any time.

Changes in funding for the FDA could hinder its ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business, financial condition and results of operations.

The ability of the FDA to review and approve new products and conduct other regulatory activities can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, 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 government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other regulatory authorities may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business, financial condition and results of operations. For example, over the last several years, including for 43 days beginning on October 1, 2025, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA temporarily postponed routine surveillance inspections of manufacturing facilities in 2020. Additionally, the current administration announced plans to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. For example, on October 10, 2025, the U.S. government implemented substantial layoffs and workforce reductions in connection with the federal government shutdown, which resulted in the suspension or delay of various government-funded programs. If a prolonged government shutdown occurs, if funding for the FDA or other federal agencies (including their workforce) is reduced or if future global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business, financial condition and results of operations.

A sustained government shutdown could adversely affect our business, financial condition and results of operations.

Government funding of the SEC and other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. If a prolonged government shutdown or significant reduction in force of federal employees occurs, including those working for the SEC, it could significantly impact the ability of the SEC to timely review and process our regulatory filings, which could have a material adverse effect on our business. Further, a sustained government shutdown, or future government shutdowns, and cost-cutting efforts could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions and civil or criminal penalties, private litigation or adverse publicity and could negatively affect our

operating results and business.

We and our collaborators are subject to federal, state and foreign data protection laws and regulations. In the United States, such laws may include, but are not limited to, U.S. state personal data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act (the "FTC Act"), each of which govern the collection, use, disclosure and protection of health-related and other personal information.

Although we are not subject to U.S. federal Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA"), as we are neither a Covered Entity nor Business Associate (as such terms are defined in HIPAA), we may have access to very sensitive data regarding patients who participate in, or whose tissue samples or other biospecimens are used in, our clinical trials. The maintenance of this data imposes upon us administrative and financial burdens and litigation risks. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data that are subject to HIPAA and other privacy, data security and consumer protection laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a Covered Entity in a manner that is not authorized by HIPAA, and we may be subject to other civil and/or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. Our ability to use or disclose information may be limited by the scope of an authorization signed by clinical trial subjects or the terms of the contract that we enter into with providers or other data sources.

Furthermore, U.S. state laws and regulations relating to data privacy and security and consumer protection are constantly evolving. For example, the California Consumer Privacy Act (as amended by the California Privacy Rights Act, the "CCPA") created new individual privacy rights for California residents, including the right to opt out of certain disclosures of their data, the right to limit the use and disclosure of sensitive personal information (including health information). The CCPA places increased privacy and security obligations on entities handling certain personal data of California residents or households, limits data use and mandates audit requirements for higher risk data. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, as currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and PHI. The CCPA is enforced by the California Privacy Protection Agency, a data protection authority, which has the power to issue substantive regulations resulting in increased privacy and information security enforcement. Several other states have implemented similar consumer privacy laws that took effect in the past year or will take effect in the near future and states have implemented or are considering laws that specifically focus on the processing of personal data related to individuals' health, including California's Confidentiality of Medical Information Act and Washington's My Health My Data Act. In addition, all 50 U.S. states and territories and international jurisdictions have varying breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential data experienced by us or our service providers. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. The state privacy laws vary from each other in many ways, which may complicate compliance efforts. The effects on our business of the state privacy laws and general consumer protection authorities are potentially significant, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to so comply. Privacy laws and regulations are constantly evolving and there are a number of legislative proposals at both the state and federal levels that could impose new obligations or limitations in areas affecting our business.

The FTC has stated that failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice), may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. Additionally, the FTC's Health Breach Notification Rule, which the FTC has clarified applies to health apps and other similar technologies, includes breach notification requirements that add complexity to compliance obligations. Further, the SEC implemented rules around incident reporting, requiring cybersecurity incidents to be reported 4 business days after determining that an incident is material.

The U.S. Department of Justice issued a final rule entitled, "Access to U.S. Sensitive Personal Data and

Government-Related Data by Countries of Concern or Covered Persons," codified at 28 CFR part 202 (the "Bulk Transfer Rule"). The Bulk Transfer Rule prohibits and restricts bulk transfers of sensitive personal data (including genetic and health data) to countries of concern, such as China, Russia, and Iran to prevent access by foreign adversaries. It restricts our ability to engage in certain cross-border transactions involving genomic or biological samples and related data, which may increase compliance costs, lead to increased regulatory scrutiny or liability, and may require additional contractual negotiations, which may adversely impact our business, financial condition and results of operations.

International data protection laws, including the EU's and UK's General Data Protection Regulation ("GDPR"), may also apply to health-related and other personal information obtained outside of the United States. The GDPR imposes several data protection requirements in the EU, as well as fines for violations that can reach up to the greater of €20 million or 4% of annual global revenue. The regulation imposes numerous requirements for the collection, use, storage and disclosure of personal information, including more stringent requirements relating to consent and the information that must be shared with data subjects about how their personal information is used, the obligation to notify regulators and affected individuals of personal data breaches, extensive new internal privacy governance obligations and obligations to honor expanded rights of individuals in relation to their personal information, including the right to access, correct and delete their data. Such requirements may be subject to change in the near future as the European Commission announced proposed amendments to the GDPR in November 2025. In addition, on June 19, 2025, the UK's Data (Use and Access) Act 2025, or the DUAA, was granted Royal Assent, implementing various measures concerning data usage in the UK and reforming data protection laws. The provisions within the DUAA will come into force through 2026, and it remains too soon to tell how the DUAA will be implemented and what impact it will have on our international activities. Further, other EU and member state laws and regulations may impose further obligations or restrictions on processing health information in the EEA, such as the European Health Data Space Regulation.

Certain jurisdictions, including the EEA, have enacted laws and regulations governing cross-border personal information transfer and providing for data localization in certain cases. For example, absent appropriate safeguards or other circumstances, the GDPR and laws in Switzerland and the UK generally restrict the transfer of personal information to countries outside the EEA, Switzerland and the UK, such as the United States. Such safeguards include the use of standard contractual clauses approved by the European Commission and the UK and Swiss Data Protection Authorities as well as the EU-U.S. Data Privacy Framework. If we are unable to implement a valid solution to transfer personal data from the EEA to the United States or other countries that have not been deemed to provide an essentially equivalent level of data protection, we may face increased exposure to regulatory action, substantial fines, or injunction orders to stop processing personal data from EEA, Swiss, or UK residents. Any inability to import personal data to the United States may also restrict our clinical trials activities in the EU; limit our ability to collaborate with contract research organizations as well as other service providers, contractors and other companies subject to EU data privacy and security laws; and require us to increase our data processing capabilities in the EU and the UK at a significant expense. Additionally, other countries outside of the EU have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business. The types of challenges we face in the EEA, Switzerland, and the UK will likely also arise in other jurisdictions that adopt laws similar to the GDPR or regulatory frameworks of equivalent complexity.

Compliance with international data protection laws and regulations could require us to take on more onerous obligations in our contracts, increase our compliance costs, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. We cannot guarantee that we are or will be in compliance with all applicable international regulations as they are enforced now or as they evolve. Claims that we have violated individual privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend against and could result in adverse publicity that could harm our business, financial condition, and results of operations.

Our business involves the use of hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our current or future product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts,

research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could have a material adverse effect on our business, financial condition and results of operations.

We are exposed to the risk of fraud, illegal activity or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by employees could include intentional, reckless and/or negligent conduct that fails to comply with the laws and regulations of the FDA, EU Member States, EMA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, comply with laws and regulations, including, but not limited to the FCPA and internal policies restricting payments to government agencies and representatives, 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 commission or contracting, customer incentive programs and other business arrangements. Misconduct by employees, independent contractors, consultants, commercial partners and vendors could also 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 misconduct by our employees, independent contractors, consultants, commercial partners and vendors, 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, FDA debarment, exclusion from government-funded healthcare programs 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 significant impact on our business, financial condition and results of operations, including the imposition of significant fines or other sanctions and serious harm to our reputation.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, transparency and disclosure, or sunshine, laws, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future arrangements with healthcare professionals, clinical sites and clinical investigators, consultants, customers, patient organizations and third-party payors may subject us to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with clinical study investigators and research subjects, as well as our current and future sales, marketing, patient assistance or advocacy and education programs. In addition, we may be subject to physician payment transparency laws and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the furnishing, recommending, or arranging for an item or service for which payment may be made under a federal healthcare program, such as the Medicare and

Medicaid programs — a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or special intent to violate the statute in order to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price ("AMP"), and improper promotion of off-label uses (i.e., uses not expressly approved by the FDA in a drug's label);
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals and, beginning in 2022, certain other healthcare professionals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; federal government price reporting laws, which require drug manufacturers to calculate and report complex pricing metrics to government agencies, including CMS and the Department of Veterans Affairs (the "VA"), referred to as Government Program Statutory Price Reporting, where such reported prices are used in the calculation of reimbursement and/or discounts on marketed products paid by government healthcare programs. Participation in these programs and compliance with the applicable requirements may result in potentially significant discounts on products subject to reimbursement under federal healthcare programs and increased infrastructure costs, and may potentially limit a drug manufacturer's ability to offer certain marketplace discounts. Additionally, if it is determined by the government, which could include a government agency such as CMS, Health Resources and Services Administration, the VA, or by the Office of Inspector General or Department of Justice, that the Statutory Price Reporting was incorrect, causing the government to essentially pay more than they should through the reimbursement and/or discount, the manufacturer may be subject to significant False Claims Act investigations, civil monetary penalties and/or additional fines;
- the Prescription Drug Marketing Act, which restricts the manner in which manufacturers may disseminate complimentary drug samples to healthcare practitioners, requires physical and accounting controls, and establishes penalties for improper sample distribution; and
- state law equivalents of each of the above federal laws, such as licensing, anti-kickback, false claims, consumer protection and unfair competition laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing information and marketing expenditures, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, our current and future research and development of our product candidates outside the United States, and any future sales of our product or product candidates once commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business practices and arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to, without limitation, civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition and results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business, financial condition and results of operations.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our current or future product candidates, if approved, or if we are found to have improperly engaged in pre-approval promotion prior to the approval of such product candidates, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies 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 or such other regulatory agencies as reflected in the product's approved labeling. Physicians may use our product candidates if they receive marketing approval, for their patients in a manner that is inconsistent with the approved labels, if the physicians believe in their professional medical judgment they could be used in such manner. However, if we are found to have promoted any of our future products for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA, Department of Justice or other regulatory authorities could also request that we enter into a consent decree, a corporate integrity agreement or corporate mentorship, 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.

Healthcare reform measures could hinder or prevent our product candidate's commercial success.

There have been, and we expect there will continue to be, a number of legislative and regulatory changes to health care systems in the United States and abroad that could impact our ability to sell our products profitably. The United States government and other governments have shown significant interest in pursuing healthcare reform. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. Healthcare reform measures like the ACA may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

Since its enactment, there have been ongoing efforts to modify the ACA and its implementing regulations. For example, tax legislation enacted at the end of 2017 included provisions that, effective January 1, 2019, eliminated the tax penalty for individuals who do not maintain sufficient health insurance coverage, or the so-called "individual mandate." It is unclear how healthcare reform measures enacted by Congress or implemented by the current Trump administration or efforts, if any, to modify the ACA or its implementing regulations, or portions thereof, will impact our business. Litigation and legislation over the ACA and other healthcare reform measures are likely to continue, with unpredictable and uncertain results. Further, additional legislative changes to and regulatory changes under or related to the ACA remain possible.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted.

In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of, on average, 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through May 31, 2022, due to the COVID-19 pandemic. The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. While any proposed measures may require authorization through additional legislation to become effective, Congress and recent presidential administrations have each indicated an intent to seek new legislative and/or administrative measures to control drug costs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal health care programs and commercial payers will pay for healthcare products and services, which could result in reduced demand for our product candidate, if approved, or additional pricing pressures.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition and results of operations. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices. These or other reforms could reduce the ultimate demand for our product candidate, if approved, or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, we may lose any regulatory approvals that may have been obtained and we may not achieve or sustain profitability.

We will need to obtain prior FDA authorization for any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business, financial condition and results of operations.

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

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, financial condition and results of operations.

Our operations are subject to certain anti-corruption laws, including the FCPA, and other anti-corruption laws that apply in countries where we conduct business, including performing clinical trials. The FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to foreign government officials or other persons to obtain or retain business or gain some other business advantage. We, our commercial partners and our affiliates operate in a number of jurisdictions that pose a risk of potential FCPA violations and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA 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.

There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA or other legal requirements, such as trade control laws. Any investigation of potential violations of the FCPA, other anti-corruption laws or trade control laws by U.S., EU or other authorities could have an adverse impact on our reputation, our business, financial condition and results of operations. Furthermore, should we be found not to be in compliance with the FCPA, other anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, financial condition and results of operations.

We may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We expect to conduct clinical trials internationally in the future. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Risks Related to Our Relationship with Scilex

Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with Scilex.

Dr. Ji, Dr. Chun, Mr. Followwill and Dr. Wu serve on our Board of Directors. Dr. Ji is also one of our executive officers and continues to serve as a member of the board of directors of Scilex and as Scilex's Chairperson, Chief Executive Officer and President. Mr. Ma, our Chief Financial Officer and Chief Operating Officer, continues to serve as Chief Financial Officer, Senior Vice President, Secretary and director of Scilex.

Service as an overlapping director or officer of Scilex and us could create, or appear to create, conflicts of interest with respect to matters involving or affecting more than one of the companies to which such directors or officers owe fiduciary duties. For example, these matters could relate to potential acquisitions of businesses or products, the development and ownership of technologies and product candidates, the sale of products, markets and other matters in which our best interest and the best interests of our stockholders may conflict with the best interests of Scilex and its stockholders. In particular, it is possible that we may be precluded from participating in certain business opportunities that we might otherwise have participated in as those opportunities may be presented to Scilex because such directors may deem such opportunities to have a greater benefit to Scilex than to us.

In addition, such directors and officers may own shares of common stock, par value $0.0001 per share ("Scilex Common Stock") of Scilex, options to purchase shares of Scilex Common Stock or other Scilex equity awards. These individuals' holdings of Scilex Common Stock, options to purchase shares of Scilex Common Stock or other equity awards of Scilex may be significant for some of these persons compared to these persons' total assets. Their position at Scilex and the ownership of any Scilex equity or equity awards create, or may create, the appearance of conflicts of

interest when these directors and officers are faced with decisions that could have different implications for Scilex than the decisions have for us. For example, potential conflicts of interest could arise in connection with the resolution of any dispute that may arise between Scilex and us regarding the terms of the agreements governing the transition services and the relationship thereafter between the companies. Potential conflicts of interest may also arise if we enter into commercial arrangements with Scilex in the future. As a result of these actual or apparent conflicts, we may be precluded from pursuing certain growth initiatives.

Any potential conflict that qualifies as a "related party transaction" (as defined in Item 404 of Regulation S-K under the Securities Act) is subject to review by our audit committee (the "Audit Committee") in accordance with our related person transaction policy. There can be no assurance that the terms of any such transactions will be as favorable to us or our stockholders as would be the case where there are no overlapping officers or directors.

Scilex currently performs or supports many of our important corporate functions. Our consolidated financial statements may not necessarily be indicative of the conditions that would have existed or our results of operations if we had been operated as an unaffiliated company of Scilex, and we incurred significant charges in connection with the Business Combination and will incur incremental costs as a stand-alone public company.

We will need to replicate or replace certain functions, systems and infrastructure provided by Scilex to which we no longer have the same access after the Business Combination. We may also need to make investments or hire additional employees to operate without the same access to Scilex's existing operational and administrative infrastructure. These initiatives may be costly to implement. Due to the scope and complexity of the underlying projects relative to these efforts, the amount of total costs could be materially higher than our estimate, and the timing of the incurrence of these costs is subject to change.

Scilex currently performs or supports many important corporate functions for our company. Our financial statements as of and for the periods ended September 30, 2026 and December 31, 2025 reflect charges for these services on an allocation basis. As a result, our financial statements may not be reflective of conditions that would have existed or what our results of operations would have been had we been a stand-alone public company and no longer a majority owned subsidiary of Scilex. In connection with the closing of the Business Combination, we entered into the Transition Services Agreement with Scilex, pursuant to which we will be able to utilize certain employees and other service providers of Scilex (including Scilex's sales force) to operate our business, including with respect to the following business functions: finance, human resources, information systems, legal and administrative, R&D support and commercialization support. The services under the Transition Services Agreement will be provided for a period of three years on a cost plus 10% basis, provided that the service fees will not exceed $2.0 million per annum until all payments under the Scilex-Oramed Note have been paid in full in cash, and we will reimburse Scilex for its out-of-pocket fees, costs or expenses. We expect to incur other costs to replace the services and resources that will not be provided by Scilex. We will also incur additional costs as a stand-alone public company. As a stand-alone public company, our total costs related to certain support functions may differ from the costs that were historically allocated to us from Scilex. In addition, in the future, we expect to incur internal costs to implement certain new systems, including infrastructure and an ERP system, while our systems are currently being fully supported by Scilex.

While we believe that the term of the Transition Services Agreement is sufficient time for us to develop our commercial infrastructure and other business functions, we may not be able to replace these services or enter into appropriate third-party agreements on terms and conditions, including cost, comparable to those that we will receive from Scilex under the Transition Services Agreement. Additionally, after the Transition Services Agreement terminates, we may be unable to sustain the services at the same levels or obtain the same benefits as when we were receiving such services and benefits from Scilex. When we begin to operate these functions separately from Scilex, if we do not have our own adequate systems and business functions in place, or are unable to obtain them from other providers, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline. In addition, we have historically received informal support from Scilex, which may not be addressed in the Transition Services Agreement.

Our Executive Chairman and Chief Financial Officer each holds an executive officer position at Scilex and devotes time to both companies, which could cause a diversion of their time and attention from our business and operations, and as a result could have a material adverse effect on our business and operations.

Dr. Ji serves as our Executive Chairman and also serves as the Chairman of the board of directors of Scilex and its Chief Executive Officer and President. Mr. Ma, our Chief Financial Officer and Chief Operating Officer, also serves as the Chief Financial Officer of Scilex. The amount of time that each of Dr. Ji and Mr. Ma devotes to us varies day-to-day and week-to-week depending on the then current needs and demands of each company's business, transactions

each company may be evaluating, and other corporate matters. Such diversion of management attention could have a material adverse effect on our business and operations.

We are controlled by Scilex, whose interests may differ from those of our public shareholders.

As of September 30, 2026, Scilex (together with certain of its subsidiaries) controls approximately 78.9% of the voting power of our company (excluding voting power represented by the Series A Preferred Stock held by Scilex), which means that, based on its percentage voting power controlled, Scilex will control the vote of all matters submitted to a vote of our stockholders. This control will enable Scilex to control the election of the members of our Board of Directors and all other corporate decisions. In particular, for so long as Scilex continues to own a majority of our Common Stock, Scilex will be able to cause or prevent a change of control of our company or a change in the composition of our Board of Directors and could preclude any unsolicited acquisition of us.

Pursuant to the Amended and Restated Registration Rights Agreement by and among us and certain stockholders, dated September 22, 2025 (the "Registration Rights Agreement"), and the Restated Certificate of Incorporation of Semnur Pharmaceuticals, Inc., filed with the Secretary of State of the State of Delaware on September 22, 2025 (the "Charter"), Scilex has certain rights, and the ability to take certain actions, that are not otherwise available to all our stockholders. For example, the Registration Rights Agreement provides Scilex the right, subject to certain conditions, to demand that we file a registration statement or request that their shares of Common Stock be covered by a registration statement that we are otherwise filing. In addition, until such time as Scilex first ceases to own greater than 50% of the outstanding voting power of our Common Stock, the Charter effectively provides Scilex with the ability to fill vacancies on our Board of Directors, remove directors (with or without cause), call a special meeting of our stockholders, amend the Charter (subject to approval of our Board of Directors) and amend the Bylaws of Semnur Pharmaceuticals, Inc., effective as of September 22, 2025 (the "Bylaws"). The directors so elected have the authority, subject to the terms of our indebtedness and applicable rules and regulations, to issue additional stock, implement stock repurchase programs, declare dividends and make other decisions.

Even when Scilex ceases to control a majority of our total voting power, for so long as Scilex continues to own a significant percentage of our Common Stock and for so long as Scilex together with its affiliates, subsidiaries, successors and assigns (other than Semnur and its subsidiaries) (the "Scilex Group") owns any shares of our Series A Preferred Stock, Scilex will still be able to significantly influence the composition of our Board of Directors and the approval of actions requiring stockholder approval. Accordingly, for such period of time, Scilex will have significant influence with respect to our management, business plans and policies. Because of the significant ownership position held by Scilex, our classified board structure and the rights granted to Scilex under the Stockholder Agreement with Scilex (the "Scilex Stockholder Agreement"), new investors may not be able to effect a change in our business or management. The concentration of ownership and availability of the foregoing rights could deprive our stockholders of an opportunity to receive a premium for their shares of Common Stock as part of a sale of our company and ultimately might affect the market price of our Common Stock. See the risk factor below titled "*Scilex, as the holder of Series A Preferred Stock, has rights, preferences and privileges that are not held by, and are preferential to, the rights of holders of our Common Stock.*"

Furthermore, the interests of Scilex may not be aligned with those of other stockholders and this could lead to actions that may not be in the best interests of our other stockholders. For example, Scilex may have different tax positions or strategic plans for Semnur, which could influence its decisions regarding whether and when we should dispose of assets or incur new or refinance existing indebtedness.

Additionally, Scilex's significant ownership of us may discourage someone from making a significant equity investment in us, or could discourage transactions involving a change in control.

In addition, Scilex and its affiliates engage in a broad spectrum of activities, including investments in our industry generally. In the ordinary course of their business activities, Scilex and its affiliates may engage in activities where their interests conflict with our interests or those of other stockholders, such as investing in or advising businesses that directly or indirectly compete with certain portions of our business or those businesses that are suppliers or customers of ours. The Charter will provide that, to the fullest extent permitted by law, none of Scilex and its affiliates and any person or entity who, while a stockholder, director, officer or agent of us or any of our affiliates, is a director, officer, principal, partner, member, manager, employee, agent and/or other representative of Scilex and its affiliates (each an "Identified Person") will have any duty to refrain from (i) engaging in a corporate opportunity in the same or similar business activities or lines of business in which we or our affiliates are engaged or that are deemed to be competing with us or any of our affiliates or (ii) otherwise investing in or providing services to any person that competes with us or our affiliates engaging, directly or indirectly, in the same or similar business activities or lines of business in which

we operate. In addition, to the fullest extent permitted by law, no Identified Person will have any obligation to offer us or our subsidiaries or affiliates the right to participate in any corporate opportunity in the same or similar business activities or lines of business in which we or our affiliates are engaged or that are deemed to be competing with us or any of our affiliates. This means that Scilex may pursue acquisition opportunities that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us. In addition, Scilex may have an interest in pursuing acquisitions, divestitures and other transactions that, in its judgment, could enhance its investment, even though such transactions might involve risks to our stockholders or may not prove beneficial.

Scilex, as the holder of Series A Preferred Stock, has rights, preferences and privileges that are not held by, and are preferential to, the rights of holders of our Common Stock.

The Series A Preferred Stock was issued only to Scilex and is not convertible into shares of Common Stock. However, the holders of Series A Preferred Stock have rights, preferences and privileges that are senior, or in addition, to the rights, preferences and privileges of the holders of Common Stock, including the right to receive, in the event of a change of control, liquidation dissolution or winding up of Semnur, a preference amount out of the assets available for distribution to stockholders before any distribution can be made to holders of Common Stock. The preference amount is $10.00 per share (subject to adjustment as set forth in the certificate of designations ("Certificate of Designations")). If our Board of Directors declares or pays a dividend on the Common Stock, the holders of the Series A Preferred Stock will participate, on a deemed as-converted-to-common stock basis, in such dividend with the holders of Common Stock.

The holders of Series A Preferred Stock have certain voting rights over our corporate actions (including, among others, any change to the shares of Series A Preferred Stock into cash or other property, the issuance of equity securities that rank on a parity with or senior to the Series A Preferred Stock with respect to dividend rights) or rights upon liquidation, dissolution or winding-up of our company and the amendment of the Charter in a manner that adversely affects the holders of shares of Series A Preferred Stock.

Pursuant to the terms of the Scilex Stockholder Agreement (and subject to certain rights of Oramed), from and after the effective time of the Business Combination, and for so long as the Scilex Group beneficially owns any shares of Series A Preferred Stock, among other things, (i) Scilex shall have the right, but not the obligation, to designate each director to be nominated, elected or appointed to our Board of Directors (each, a "Stockholder Designee" and collectively, the "Stockholder Designees"), regardless of (a) whether such Stockholder Designee is to be elected to our Board of Directors at a meeting of stockholders called for the purpose of electing directors (or by consent in lieu of meeting) or appointed by our Board of Directors in order to fill any vacancy created by the departure of any director or increase in the authorized number of members of our Board of Directors, or (b) the size of our Board of Directors and (ii) we are required to take all actions reasonably necessary, and not otherwise prohibited by applicable law, to cause each Stockholder Designee to be so nominated, elected or appointed to our Board of Directors as more fully described in the Scilex Stockholder Agreement. Scilex shall also have the right to designate a replacement director for any Stockholder Designee that has been removed from our Board of Directors and the right to appoint a representative of Scilex to attend all meetings of the committees of our Board of Directors. Notwithstanding the foregoing, the parties have agreed to ensure that our Board of Directors complies with all applicable requirements of the stock exchange, including independence requirements.

The Scilex Stockholder Agreement also provides that we are prohibited from taking certain actions without the consent of Scilex. Such actions include, among other things, amendments to the Certificate of Designations, increases or decreases in the size of our Board of Directors, the incurrence of certain amounts of indebtedness and the payment of dividends on Common Stock.

Risks Related to Ownership of Our Common Stock

If our operations and performance do not meet the expectations of investors or securities analysts, the market price of our securities may decline.

Any of the factors listed below could have a negative impact on your investment in our securities, and our securities may trade at prices significantly below the price you paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline.

Factors affecting the trading price of our securities may include:

- our ability to commercialize our product candidate, if approved;
- the status and cost of our marketing commitments for our product candidate;

- announcements regarding results of any clinical trials relating to our product candidate;
- unanticipated serious safety concerns related to the use of our product candidate;
- adverse regulatory decisions;
- changes in laws or regulations applicable to our product candidate, including but not limited to clinical trial requirements for approvals;
- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidate, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or stockholder litigation;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- our dependence on third parties;
- announcements of the introduction of new products by our competitors;
- market conditions and trends in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- future issuances of common stock or other securities;
- the recruitment or departure of key personnel;
- failure to meet or exceed any financial guidance or expectations regarding product development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- our failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- fluctuation of the market values of any of our potential strategic investments;
- issuances of debt or equity securities;
- compliance with our contractual obligations;
- sales of Common Stock by us or our stockholders in the future;
- trading volume of Common Stock;
- ineffectiveness of our internal controls;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- our relationship with Scilex;
- general political and economic conditions, including the wars in Ukraine and the Middle East region, and regime change in Venezuela;
- effects of natural or man-made catastrophic events;
- effects of public health crises, pandemics and epidemics; and
- other events or factors, many of which are beyond our control, such as the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions.

Further, the global equity markets in general have recently experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, economic uncertainty and increased interest rates, inflation, the government closure of Silicon Valley Bank and Signature Bank, and liquidity concerns at other financial institutions that may be unrelated to our operating performance. Continued market fluctuations could result in extreme volatility in the price of our Common Stock, which could cause a decline in the value of our Common Stock. Price volatility of the Common Stock might worsen if the trading volume of the Common Stock is low. In the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. The realization of any of the above risks or any of a broad range of other risks, including those described in these "Risk Factors," could have a dramatic and material adverse impact on the market price of our Common Stock.

We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future. Any return on investment may be limited to the capital appreciation, if any, of Common Stock.

We have not paid cash dividends on our Common Stock and do not anticipate paying cash dividends on our Common Stock in the foreseeable future. The payment of dividends on our capital stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. In addition, our ability to pay dividends may be limited by covenants in future outstanding indebtedness that we or our subsidiaries may incur. Since we do not intend to pay dividends, a stockholder's ability to receive a return on such stockholder's investment will depend on any future appreciation in the market value of our Common Stock. There is no guarantee that our Common Stock will appreciate or even maintain the price at which our stockholders have purchased it.

Our operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly, and possibly annual, fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our development programs;
- the addition or termination of clinical trials;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidate, regulatory approvals of our product candidate, and the level of underlying demand for such product candidate and purchasing patterns;
- our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- the effect on pharmaceutical purchases and prices of the timing during which patients who purchase our product satisfy their deductibles under the reimbursement requirements of their health providers' plans.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our Common Stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our Common Stock to fluctuate substantially.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

On March 10, 2023, the Federal Deposit Insurance Corporation (the "FDIC") announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation and on March 12, 2023, Signature Bank was closed by the New York State Department of Financial Services and the FDIC was named receiver. Although we do not maintain any bank accounts with Silicon Valley Bank or Signature Bank, we regularly maintain cash balances at third-party financial institutions in excess of the FDIC insurance limit. Any failure of a depository institution to return any of our deposits, or any other adverse conditions in the financial or credit markets affecting depository institutions, could impact access to our invested cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse opinion regarding our stock, our stock price and trading volume could decline.

The trading market for Common Stock will be influenced by the research and reports that industry or securities

analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issues an adverse opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations 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, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

We may issue additional equity securities to fund future expansion and pursuant to equity incentive or employee benefit plans. We may also issue additional equity for other purposes. These securities may have the same rights as Common Stock or, alternatively, may have dividend, liquidation or other preferences to our Common Stock. The issuance of additional equity securities will dilute the holdings of existing stockholders and may reduce the share price of our Common Stock.

Pursuant to the Registration Rights Agreement entered into in connection with the Business Combination, certain stockholders can each demand that we register their registrable securities under certain circumstances and will each also have piggyback registration rights for these securities. In addition, we are required to file and maintain an effective registration statement under the Securities Act covering such securities and certain of its other securities. The registration of these securities will permit the public sale of such securities, subject to certain contractual restrictions imposed by the Registration Rights Agreement and the Merger Agreement. The presence of these additional shares of common stock trading in the public market may have an adverse effect on the market price of our securities.

If we raise additional funds through collaboration, licensing or other similar arrangements, we may have to relinquish valuable rights to our product candidate, or grant licenses on terms unfavorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product candidate.

Our principal stockholders, directors and executive officers will own a significant percentage of our capital stock, and have significant influence over our management.

As of September 30, 2026, our directors, executive officers, holders of 5% or more of our capital stock and their respective affiliates beneficially own, in the aggregate, approximately 94.6% of our outstanding voting stock (excluding voting power represented by the Series A Preferred Stock held by Scilex). This concentration of voting power may make it less likely that any other holder of Common Stock will be able to affect the way we are managed and could delay or prevent an acquisition of our company on terms that other stockholders may desire. This could prevent transactions in which stockholders might otherwise recover a premium for their shares over current market prices. See "*Risk Factors — We are controlled by Scilex, whose interests may differ from those of our public shareholders*" above for additional information regarding Scilex's influence and control over us.

Our ability to use our net operating loss and tax credit carryforwards may be subject to limitation.

Generally, a change of more than 50% in the ownership of a company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carryforwards attributable to the period prior to the change. We have experienced a corporate reorganization in the past and may experience ownership changes in the future as a result of the Business Combination and/or subsequent changes in our stock ownership (some of which shifts are outside our control). As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability for us.

The Tax Cuts and JOBS Act of 2017 (the "TCJA"), as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing net operating loss ("NOL") carryforwards. The TCJA, as modified by the CARES Act, limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income (as calculated before taking the NOLs, and certain other tax attributes, into account) for taxable years beginning after December 31, 2020. In addition, NOLs arising in tax years ending after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. NOLs arising in tax years beginning after December 31, 2017 can be

carried forward indefinitely. NOLs generated in tax years beginning before January 1, 2021 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and 20-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods, as well as the new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Common Stock.

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of Common Stock.

Anti-takeover provisions in the Charter and the Bylaws and under Delaware law could make an acquisition of our company, which may be beneficial to its stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

The Charter and the Bylaws, each of which became effective upon completion of the Business Combination, and the General Corporation Law of the State of Delaware ("DGCL") contain provisions that could make it more difficult for a third party to acquire our company, even if doing so might be beneficial to our stockholders. Among other things, these provisions include:

- allow our Board of Directors to authorize the issuance of undesignated preferred stock, the terms of which may be established and the shares of which may be issued without stockholder approval, and which may include supermajority voting, special approval, dividend, or other rights or preferences superior to the rights of other stockholders;
- provide for a classified board of directors with staggered three-year terms;
- provide that, at any time after the time that the Scilex Group first ceases to beneficially own more than 50% of voting power of the then-outstanding shares of Common Stock entitled to vote generally in the election of directors (the "Scilex Trigger Event"), directors may only be removed for cause, and only by the affirmative vote of holders of at least 66 2/3% in voting power of all the then-outstanding shares of Common Stock entitled to vote thereon, voting together as a single class;
- prohibit stockholder action by written consent from and after the Scilex Trigger Event;
- provide that, at any time after the Scilex Trigger Event, special meetings may only be called by or at the direction of the Chairman of our Board of Directors, our Board of Directors or the Chief Executive Officer;
- provide that, at any time after the Scilex Trigger Event, any alteration, amendment or repeal, in whole or in part, of any provision of the Bylaws by stockholders will require the affirmative vote of the holders of at least 66 2/3% in voting power of all the then-outstanding shares of the Common Stock entitled to vote thereon, voting together as a single class; and
- establish advance notice requirements for nominations for elections to our Board of Directors and for proposing matters that can be acted upon by stockholders at stockholder meetings.

Section 203 of the DGCL generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. We have expressly elected not to be governed by Section 203 of the DGCL until the occurrence of a Scilex Trigger Event. At that time, such election shall be automatically withdrawn and we will thereafter be governed by Section 203 of the DGCL, except that the restrictions on business combinations of Section 203 of the DGCL will not apply to Scilex or its current or future Affiliates (as defined in the Charter)

regardless of its percentage ownership of Common Stock. These provisions could discourage, delay or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for our stockholders to elect directors of their choosing and cause us to take other corporate actions they desire, including actions that our stockholders may deem advantageous. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

These anti-takeover provisions and other provisions in the Charter, the Bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our Board of Directors or initiate actions that are opposed by our then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving us. The existence of these provisions could negatively affect the price of Common Stock and limit opportunities for a stockholder to realize value in a corporate transaction. In addition, if prospective takeovers are not consummated for any reason, we may experience negative reactions from the financial markets, including negative impacts on the price of our Common Stock.

The Charter designates the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation that may be initiated by our stockholders and the federal district courts of the United States as the exclusive forum for litigation arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to the Charter, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom, will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, employees or stockholders to us or our stockholders; (iii) any action asserting a claim against us or any of our current or former directors, officers, employees or stockholders arising pursuant to any provision of the DGCL, the Charter or the Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the Charter or the Bylaws; (v) any action or proceeding asserting a claim against us or any of our current or former directors, officers, employees or stockholders as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware and (vi) any action asserting an "internal corporate claim," as that term is defined in Section 115 of the DGCL; *provided that*, for the avoidance of doubt, the foregoing forum selection provision will not apply to claims arising under the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

The Charter also provides that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The Charter further provides that any person or entity purchasing or otherwise acquiring any interest in shares of our Common Stock is deemed to have notice of and consented to the provisions of the Charter described above.

The forum selection provisions in the Charter may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings and there is uncertainty as to whether a court would enforce such provisions. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. If the enforceability of our forum selection provisions were to be challenged, it may incur additional costs associated with resolving such challenge. While we currently have no basis to expect any such challenge would be successful, if a court were to find our forum selection provisions to be inapplicable or unenforceable with respect to one or more of these specified types of actions or proceedings, we may incur additional costs associated with having to litigate in other jurisdictions, which could result in a diversion of the time and resources of our employees, management and Board of Directors, and could have an adverse effect on our business, financial condition and results of operations.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our Common Stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding

executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our Common Stock less attractive because we may rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of the IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our Common Stock that is held by non-affiliates to equal or exceed $700 million as of the last business day of the second fiscal quarter of such year, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our business, financial condition and results of operations.

As of the date of this Quarterly Report on Form 10-Q, we are a controlled company within the meaning of the Nasdaq Listing Rules and, as a result, if our Nasdaq listing application is approved, will qualify for, and may rely on, exemptions from certain corporate governance requirements. Stockholders may not have the same protection afforded to stockholders of companies that are subject to such governance requirements.

As of the date of this Quarterly Report on Form 10-Q, Scilex controls a majority of the voting power of the outstanding shares of Common Stock. As a result, if our Nasdaq listing application is approved, we will be a "controlled company" within the meaning of the corporate governance standards of Nasdaq. Under these corporate governance standards, a company of which more than 50% of the voting power for the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements. For example, controlled companies, within one year of the date of the listing of their common stock:

- are not required to have a board of directors that is composed of a majority of "independent directors" as defined under the Nasdaq Listing Rules;
- are not required to have a compensation committee that is composed entirely of independent directors or have a written charter addressing the committee's purpose and responsibilities; and
- are not required to have director nominations be made, or recommended to the full board of directors, by their independent directors or by a nominating and corporate governance committee that is composed entirely of independent directors, and to adopt a written charter or a board resolution addressing the nominations process.

While we do not presently intend to rely on these exemptions, we may opt to utilize these exemptions in the future as long as we remain a controlled company. Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq.

If we cease to be a "controlled company" in the future and we are then listed on Nasdaq, we will be required to comply with the Nasdaq listing standards, which may require replacing a number of directors and will require development of certain other governance-related policies and practices. These and any other actions necessary to achieve compliance with such rules may increase our legal and administrative costs, will make some activities more difficult, time-consuming and costly and may also place additional strain on our personnel, systems and resources.

We will incur increased costs as a result of operating as a public company, and our management will devote substantial time to related compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), as well as rules and regulations adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel will need to devote a substantial amount

of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain directors' and officers' liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our board committees or as executive officers. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

In addition, we expect that we will need to implement an ERP system. An ERP system is intended to combine and streamline the management of our financial, accounting, human resources, sales and marketing and other functions, enabling us to manage operations and track performance more effectively. However, an ERP system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, financial condition and results of operations, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

As a public company, we will be required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. See "*Risk Factors — We have identified material weaknesses in our internal control over financial reporting. Any material weakness may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our financial statements.*" above for additional information regarding previously identified material weaknesses. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of our management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and there could be a material adverse effect on our business, financial condition and results of operations.

If we cannot satisfy the initial listing requirements and other rules of Nasdaq, our securities may not be listed on Nasdaq, which could negatively impact the price of our securities and your ability to sell them.

We intend to seek a listing of our securities on Nasdaq. We cannot assure you that we will be able to meet those initial listing requirements at that time. Our securities are currently quoted on the OTC Markets.

Even if our securities are listed on Nasdaq, we cannot assure you that our securities will continue to be listed on Nasdaq. If we fail to satisfy Nasdaq's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our Common Stock. Such a delisting would likely have a negative effect on the price of Common Stock and would impair a stockholder's ability to sell or purchase Common Stock when a stockholder wishes to do so.

If Nasdaq does not list our securities, or subsequently delists our securities from trading, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our Common Stock is a "penny stock," which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our Common Stock;
- limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Even if Nasdaq approves our listing application, in the event of a subsequent delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Common Stock to become listed again, stabilize the market price or improve the liquidity of our Common Stock, prevent our Common Stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq Listing Rules.

Comprehensive U.S. federal income tax reform could adversely affect us.

Changes to tax laws, which changes may have retroactive application, could adversely affect us or holders of our Common Stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

The TCJA, which was enacted in 2017, included changes to U.S. federal tax rates, imposed significant additional limitations on the deductibility of interest, allowed for the expensing of capital expenditures, and put into effect the migration from a "worldwide" system of taxation to a modified territorial system.

On March 27, 2020, President Trump signed into law the CARES Act, which included certain changes in tax law (including to the TCJA) intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. On August 16, 2022, former President Biden signed the IRA into law, which contained certain tax measures, including a corporate alternative minimum tax of 15% on some large corporations, an excise tax of 1% on certain corporate stock buy-backs, and an excise tax with respect to certain drug sales for failing to offer a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation.

On July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act (the "OBBBA") was signed into law. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the TCJA, allowing for accelerated tax deductions for qualified property and research expenditures, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in calendar year 2025 and others implemented through calendar year 2027. The aggregate impact of the OBBBA remains uncertain. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. The impact of these tax reforms on holders of our Common Stock is uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our Common Stock.

The Warrants are exercisable for Common Stock, which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

Outstanding public and private placement warrants ("Public Warrants" and "Private Warrants," respectively, and together, the "Warrants") to purchase an aggregate of 8,760,000 shares of Common Stock became exercisable in accordance with the terms of the warrant agreement, dated April 6, 2022, by and between VStock Transfer, LLC ("VStock"), as warrant agent, and Denali (the "Warrant Agreement"), governing those securities, upon completion of

the Business Combination. The exercise price of these Warrants is $11.50 per share. To the extent such Warrants are exercised, additional shares of Common Stock will be issued, which will result in dilution to the holders of Common Stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market, or the fact that such Warrants may be exercised, could adversely affect the prevailing market prices of Common Stock. However, there is no guarantee that the Warrants will ever be in the money prior to their expiration, and as such, the Warrants may expire worthless. See below risk factor, "*The Warrants may never be in the money, they may expire worthless and the terms of the Warrants may be amended in a manner adverse to a holder if holders of a majority of the then-outstanding Warrants approve of such amendment*."

The Warrants may never be in the money, they may expire worthless and the terms of the Warrants may be amended in a manner adverse to a holder if holders of a majority of the then-outstanding Warrants approve of such amendment.

The Warrants were issued in registered form under the Warrant Agreement between VStock, as warrant agent, and Denali. The Warrant Agreement provides that the terms of the Warrants may be amended without the consent of any holder to cure any ambiguity or correct any defective provision or correct any mistake, but requires the approval by the holders of a majority of the then-outstanding Warrants to make any change that adversely affects the interests of the registered holders of Warrants. Accordingly, we may amend the terms of the Warrants in a manner adverse to a holder if holders of a majority of the then-outstanding Warrants approve of such amendment. Although our ability to amend the terms of the Warrants with the consent of majority of the then-outstanding Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the Warrants, convert the Warrants into cash, shorten the exercise period, or decrease the number of shares of Common Stock purchasable upon exercise of a Warrant.

We may redeem any unexpired Warrants prior to their exercise at a time that is disadvantageous to you, thereby making the Warrants worthless.

We have the ability to redeem outstanding Warrants at any time after they become exercisable and prior to their expiration, at a price of $0.01 per Warrant, provided that the closing price of Common Stock equals or exceeds $16.50 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on each of 20 trading days within any 30-trading-day period commencing after the Warrants became exercisable and ending on the third trading day prior to the date on which notice of redemption is given. If and when the Warrants become redeemable, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Warrants could force the holders thereof to: (i) exercise such Warrants and pay the exercise price therefor at a time when it may be disadvantageous for a holder to do so; (ii) sell such Warrants at the then-current market price when a holder might otherwise wish to hold such Warrants; or (iii) accept the nominal redemption price that, at the time the outstanding Warrants are called for redemption, is likely to be substantially less than the market value of such Warrants.

In addition, we may redeem the Warrants at any time after they become exercisable and prior to their expiration for a number of shares of Common Stock determined based on the fair market value of Common Stock. The value received upon exercise of the Warrants (1) may be less than the value the holders would have received if they had exercised their Warrants at a later time where the underlying share price is higher and (2) may not compensate the holders for the value of the Warrants.

Risks Related to Artificial Intelligence

The development, adoption, and use of artificial intelligence ("AI") technologies are rapidly transforming the life sciences industry, enabling faster data analysis, personalized medicine, and advancements in genomic services and sample management through machine learning and predictive modeling. However, the use of AI technologies by us or our vendors presents risks and challenges that could adversely impact our business. For example, disruption or failure in AI functionality could adversely affect our business, cause delays or inaccuracies in our offerings, or harm our reputation. Additionally, AI algorithms may be flawed and datasets in AI training, development and/or operations may be insufficient, of poor quality, or embed unwanted forms of bias. Outputs of AI systems may include hallucinations, bias or other forms of discrimination. Inappropriate or controversial data practices by, or practices reflecting inherent biases of, data scientists, engineers, and end-users of our systems could impair the acceptance of AI enhanced solutions. If the recommendations, forecasts, or analyses that AI-powered applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability, and brand or reputational harm. The use of agentic AI models could take unanticipated actions, generate unauthorized code paths

or initiate transactions that breach client policies, regulatory requirements or our internal controls, or produce outputs or take action that is incorrect, that reflects biases included in the training data that results in infringements on property rights of others or that is otherwise harmful. The autonomous nature of AI presents unique challenges, particularly regarding third-party systems which may operate in ways that are difficult to monitor. There is a risk that these autonomous systems could bypass internal system security, lack adequate third-party governance, or result in unauthorized access to data, including research and development data, data leakage, and non-compliance with applicable data privacy laws. These systems may also produce inaccurate outputs, leading to unintended operational decisions or outcomes. Further, if we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed.

If we are unable to adopt and deploy AI effectively as quickly as our competitors, it may cause us to be relatively less productive or innovative, adversely impacting our competitiveness and requiring additional investments that increase our costs. Laws and regulations regarding AI technologies are rapidly evolving as well, including in the areas of intellectual property, cybersecurity, privacy, and data protection. Some AI scenarios may also present ethical issues, for example, due to unintentional biases that may stem from the predictive nature of AI algorithms and we may enable or offer solutions that draw controversy due to their perceived and actual impact on society. We could suffer reputational or competitive damage in addition to regulatory scrutiny. Compliance with new or changing laws, regulations, or industry standards relating to AI may impose significant operational and financial burdens and may limit our ability to develop, deploy, or use AI technologies in our business.

Risks Related to Cryptocurrency

Our cryptocurrency treasury strategy has not been implemented or tested.

Our cryptocurrency acquisition and treasury strategy has not been tested. Although we believe cryptocurrency has the potential to serve as a hedge against inflation in the long term, the short-term price of cryptocurrency as an asset class declined in recent periods during which the inflation rate increased. Some investors and other market participants may disagree with our cryptocurrency acquisition strategy or actions we undertake to implement it. If cryptocurrency prices were to decrease or our cryptocurrency acquisition strategy otherwise proves unsuccessful, our financial condition, results of operations, and the market price of our Common Stock would be materially adversely impacted.

Bitcoin and other digital assets are novel assets, and are subject to significant legal, commercial, regulatory and technical uncertainty, which could materially adversely affect the Company's financial position, operations and prospects.

Bitcoin and other digital assets are relatively novel and are subject to significant uncertainty, which could adversely impact their price. The application of state and federal securities laws and other laws and regulations to digital assets is unclear in certain respects, and it is possible that regulators in the United States or foreign countries may interpret or apply existing laws and regulations in a manner that adversely affects the price of Bitcoin or other digital assets.

The U.S. federal government, states, regulatory agencies, and foreign countries may also enact new laws and regulations, or pursue regulatory, legislative, enforcement or judicial actions, that could materially impact the price of Bitcoin or the ability of individuals or institutions such as us to own or transfer Bitcoin. For example, the U.S. executive branch, SEC, the European Union's Markets in Crypto Assets Regulation, among others, have been active in recent years, and in the U.K., the Financial Services and Markets Act 2023, or FSMA 2023 became law. It is not possible to predict whether, or when, any of these developments will lead to Congress granting additional authorities to the SEC, Commodity Futures Trading Commission ("CFTC"), or other regulators, or whether, or when, any other federal, state or foreign legislative bodies will take any similar actions. It is also not possible to predict the nature of any such additional authorities, how additional legislation or regulatory oversight might impact the ability of digital asset markets to function or the willingness of financial and other institutions to continue to provide services to the digital assets industry, nor how any new regulations or changes to existing regulations might impact the value of digital assets generally and Bitcoin specifically. The consequences of increased regulation of digital assets and digital asset activities could adversely affect the market price of Bitcoin and in turn adversely affect the market price of our Common Stock.

Moreover, the risks of engaging in a digital asset treasury strategy are relatively novel and have created, and could continue to create, complications due to the lack of experience that third parties have with companies engaging in such a strategy, such as increased costs of director and officer liability insurance or the potential inability to obtain such coverage on acceptable terms in the future.

The growth of the digital assets industry in general, and the use and acceptance of Bitcoin in particular, may also impact the price of Bitcoin and is subject to a high degree of uncertainty. The pace of worldwide growth in the adoption and use of Bitcoin may depend, for instance, on public familiarity with digital assets, ease of buying, accessing or gaining exposure to Bitcoin, institutional demand for Bitcoin as an investment asset, the participation of traditional financial institutions in the digital assets industry, consumer demand for Bitcoin as a means of payment, and the availability and popularity of alternatives to Bitcoin. Even if growth in Bitcoin adoption occurs in the near or medium-term, there is no assurance that Bitcoin usage will continue to grow over the long-term.

Because Bitcoin has no physical existence beyond the record of transactions on the Bitcoin blockchain, a variety of technical factors related to the Bitcoin blockchain could also impact the price of Bitcoin. For example, malicious attacks by miners, inadequate mining fees to incentivize validating of Bitcoin transactions, hard "forks" of the Bitcoin blockchain into multiple blockchains, and advances in digital computing, algebraic geometry, and quantum computing could undercut the integrity of the Bitcoin blockchain and negatively affect the price of Bitcoin. The liquidity of Bitcoin may also be reduced and damage to the public perception of Bitcoin may occur, if financial institutions were to deny or limit banking services to businesses that hold Bitcoin, provide Bitcoin-related services or accept Bitcoin as payment, which could also decrease the price of Bitcoin. Similarly, the open-source nature of the Bitcoin blockchain means the contributors and developers of the Bitcoin blockchain are generally not directly compensated for their contributions in maintaining and developing the blockchain, and any failure to properly monitor and upgrade the Bitcoin blockchain could adversely affect the Bitcoin blockchain and negatively affect the price of Bitcoin.

The liquidity of Bitcoin may also be impacted to the extent that changes in applicable laws and regulatory requirements negatively impact the ability of exchanges and trading venues to provide services for Bitcoin and other digital assets.

If any of the digital assets that we hold are classified as a security, we may be subject to extensive regulation, which could result in significant costs or force us to cease operations.

Regulatory changes or interpretations that classify digital assets that we hold as a security under the Securities Act of 1933, as amended, or Investment Company Act of 1940, as amended (the "Investment Company Act"), could require us to register and comply with additional regulations. Compliance with these requirements could impose extraordinary, non-recurring expenses on our business. If the costs and regulatory burdens become too great, we may be forced to modify or cease certain operations, which could be detrimental to our investors.

The SEC has previously indicated that certain digital assets may be considered securities depending on their structure and use. Future developments could change the legal status of digital assets that we may hold, requiring us to comply with securities laws. If we fail to do so, we may be forced to discontinue some or all of our business activities, negatively impacting investments in our securities.

If the SEC or other regulators determine that digital assets that we may hold qualify as securities, we may be required to register as an investment company under the Investment Company Act. This classification would subject us to additional periodic reporting, disclosure requirements, and regulatory compliance obligations, significantly increasing our operational costs. In addition, if Bitcoin or another digital asset we hold were determined to constitute a security for purposes of the federal securities laws, we would likely take steps to reduce the percentage of Bitcoin or such other digital assets that constitute investment assets under the Investment Company Act. These steps may include, among others, selling Bitcoin that we might otherwise hold for the long term and deploying our cash in non-investment assets, and we may be forced to sell our Bitcoin or other digital assets at unattractive prices.

Although we do not currently engage in investing, reinvesting, or trading securities, and we do not hold ourselves out as an investment company, we could inadvertently be deemed one under the Investment Company Act. If we are unable to rely on an exclusion, we would be required to register with the SEC, which could impose additional financial and regulatory burdens.

Further, state regulators may conclude that the digital assets we hold are securities under state laws, requiring us to comply with state-specific securities regulations. States like California have stricter definitions of "investment contracts" than the SEC, increasing the risk of additional regulatory scrutiny.

The emergence or growth of other digital assets, including those with significant private or public sector backing, could have a negative impact on the price of cryptocurrencies we hold and adversely affect our business.

The emergence or growth of digital assets other than cryptocurrencies we may hold could have a material adverse effect on our financial condition. There are numerous alternative digital assets and many entities, including consortia and financial institutions, are researching and investing resources into private or permissioned blockchain platforms or digital assets. For example, some cryptocurrency networks utilize proof-of-work mining. Others use a

"proof-of-stake" mechanism for validating transactions that requires significantly less computing power than proof-of-work mining. If the mechanisms for validating transactions in alternative digital assets are perceived as superior to the mechanisms used by the digital assets in which we invest, those digital assets could gain market share.

Other alternative digital assets could include "stablecoins," which are designed to maintain a constant price because of, for instance, their issuers' promise to hold high-quality liquid assets (such as U.S. dollar deposits and short-term U.S. treasury securities) equal to the total value of stablecoins in circulation. Stablecoins have grown rapidly as an alternative to other digital assets as a medium of exchange and store of value, particularly on digital asset trading platforms.

Additionally, central banks in some countries have started to introduce digital forms of legal tender. For example, China's Central Bank Digital Currency ("CBDC") project was made available to consumers in January 2022, and governments including the United States, the United Kingdom, the European Union, and Israel have discussed the potential creation of new CBDCs. Whether or not they incorporate blockchain or similar technology, CBDCs, as legal tender in the issuing jurisdiction, could also compete with, or replace, other digital assets as a medium of exchange or store of value. As a result, the emergence or growth of these or other digital assets could cause the market price of cryptocurrencies we hold to decrease, which could have a material adverse effect on our business, financial condition and results of operations.

The lack of legal recourse and insurance for digital assets increases the risk of total loss in the event of theft or destruction.

Digital assets that we acquire will not be insured against theft, loss or destruction. If an event occurs where we lose our digital assets, whether due to cyberattacks, fraud or other malicious activities, we may not have any viable legal recourse or ability to recover the lost assets. Unlike funds held in insured banking institutions, our digital assets are not protected by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. If our digital assets are lost under circumstances that render another party liable, there is no guarantee that the responsible party will have the financial resources to compensate us. As a result, we and our stockholders could face significant financial losses.

The irreversibility of digital asset transactions exposes us to risks of theft, loss and human error, which could negatively impact our business.

Digital asset transactions are not, from an administrative perspective, reversible without the consent and active participation of the recipient of the transaction or, in theory, control or consent of a majority of the processing power on that digital asset network. Once a transaction has been verified and recorded in a block that is added to the blockchain, an incorrect transfer of digital assets or a theft of digital assets generally will not be reversible, and we may not be capable of seeking compensation for any such transfer or theft.

Although we plan to regularly transfer digital assets to or from vendors, consultants and services providers, it is possible that, through computer or human error, or through theft or criminal action, such assets could be transferred in incorrect amounts or to unauthorized third parties.

To the extent we are unable to seek a corrective transaction to identify the third party which has received our digital assets through error or theft, we will be unable to revert or otherwise recover the impacted digital assets, and any such loss could adversely affect our business, results of operations and financial condition.

Changes in the accounting treatment of cryptocurrency holdings could have significant accounting impacts, including increasing the volatility of our results.

In December 2023, the FASB issued ASU 2023-08, which upon our adoption will require us to measure in-scope cryptocurrency assets at fair value in our statement of financial position, and to recognize gains and losses from changes in the fair value of our cryptocurrency in net income each reporting period. ASU 2023-08 will also require us to provide certain interim and annual disclosures with respect to our cryptocurrency holdings. The standard is effective for our interim and annual periods beginning January 1, 2025, with a cumulative-effect adjustment to the opening balance of retained earnings as of the beginning of the annual reporting period in which we adopt the guidance. We adopted ASU 2023-08 for the fiscal year beginning January 1, 2025 and the adoption did not have any impact to our consolidated financial statements as we did not have any cryptocurrency holdings at adoption. Due in particular to the volatility in the price of cryptocurrencies, we expect the adoption of ASU 2023-08 to have a material impact on our financial results in future periods, increase the volatility of our financial results, and affect the carrying value of our cryptocurrency on our balance sheet, and it could also have adverse tax consequences, which in turn could have a material adverse effect on our financial results and the market price of our Common Stock. Additionally, as a result

of ASU 2023-08 requiring a cumulative-effect adjustment to our opening balance of retained earnings as of the beginning of the annual period in which we adopt the guidance and not permitting retrospective restatement of our historical financial statements, our future results will not be comparable to results from periods prior to our adoption of the guidance.

The broader digital assets industry, including the technology associated with digital assets, the rate of adoption and development of, and use cases for, digital assets, market perception of digital assets, and the legal, regulatory, and accounting treatment of digital assets are constantly developing and changing, and there may be additional risks in the future that are not possible to predict.

Changes in our ownership of cryptocurrency could have accounting, regulatory and other impacts, as well. While we currently intend to primarily own cryptocurrency directly, we may investigate other potential approaches to owning cryptocurrencies, including indirect ownership (for example, through ownership interests in a fund that owns cryptocurrencies and deemed ownership via ownership of cryptocurrency derivative assets). If we were to own all or a portion of our cryptocurrencies in a different manner, the accounting treatment for our cryptocurrencies, our ability to use our cryptocurrencies as collateral for additional borrowings, and the regulatory requirements to which we are subject, may correspondingly change. For example, the volatile nature of cryptocurrencies may force us to liquidate our holdings to use it as collateral, which could be negatively impacted by any disruptions in the cryptocurrency market, and if liquidated, the value of the collateral would not reflect potential gains in market value of our cryptocurrency.

Cryptocurrency holdings are less liquid than our existing cash and cash equivalents and may not be able to serve as a source of liquidity for us to the same extent as cash and cash equivalents.

Historically, the crypto markets have been characterized by significant volatility in price; limited liquidity and trading volumes compared to sovereign currencies markets; relative anonymity; a developing regulatory landscape; potential susceptibility to market abuse and manipulation; compliance and internal control failures at exchanges; and various other risks inherent in its entirely electronic, virtual form and decentralized network. During times of market instability, we may not be able to sell our cryptocurrency at favorable prices or at all. Further, cryptocurrency which we hold with our custodians does not enjoy the same protections as are available to cash or securities deposited with or transacted by institutions subject to regulation by the Federal Deposit Insurance Corporation or the Securities Investor Protection Corporation. If we are unable to sell our cryptocurrency, enter into additional capital raising transactions using cryptocurrency as collateral, or otherwise generate funds using our cryptocurrency holdings, or if we are forced to sell our cryptocurrency at a significant loss, in order to meet our working capital requirements, our business and financial condition could be negatively impacted.

Cryptocurrencies do not pay interest or dividends.

Cryptocurrencies do not pay interest or other returns and we will only generate cash from our cryptocurrency holdings if we sell our cryptocurrency or implement strategies to create income streams or otherwise generate cash by using our cryptocurrency holdings. Even if we pursue any such strategies, we may be unable to create income streams or otherwise generate cash from our cryptocurrency holdings, and any such strategies may subject us to additional risks.

We are not subject to legal and regulatory obligations that apply to investment companies such as mutual funds and exchange-traded funds, or to obligations applicable to investment advisers.

Mutual funds, exchange-traded funds and their directors and management are subject to extensive regulation as “investment companies” and “investment advisers” under U.S. federal and state law; this regulation is intended for the benefit and protection of investors. We are not subject to, and do not otherwise voluntarily comply with, these laws and regulations. This means, among other things, that the execution of or changes to our cryptocurrency treasury strategy, our use of leverage, the manner in which our cryptocurrency is intended to be custodied, our ability to engage in transactions with affiliated parties and our operating and investment activities generally are not subject to the extensive legal and regulatory requirements and prohibitions that apply to investment companies and investment advisers. Consequently, our Board of Directors has broad discretion over the investment, leverage and cash management policies it authorizes, whether in respect of our cryptocurrency holdings or other activities we may pursue, and has the power to change our current policies, including our strategy of acquiring and holding cryptocurrency.

If we or our third-party service providers experience a security breach or cyberattack and unauthorized parties obtain access to our cryptocurrency, or if our private keys are lost or destroyed, or other similar circumstances or events occur, we may lose some or all of our cryptocurrency and our financial condition and results of operations

could be materially adversely affected.

Security breaches and cyberattacks are of particular concern with respect to cryptocurrency. Blockchain-based cryptocurrencies and the entities that provide services to participants in the cryptocurrency ecosystem have been, and may in the future be, subject to security breaches, cyberattacks, or other malicious activities. For example, in October 2021, it was reported that hackers exploited a flaw in the account recovery process and stole from the accounts of at least 6,000 customers of the Coinbase exchange, although the flaw was subsequently fixed and Coinbase reimbursed affected customers. Similarly, in November 2022, hackers exploited weaknesses in the security architecture of the FTX Trading digital asset exchange and reportedly stole over $400 million in digital assets from customers. In October 2026, Binance issued a public announcement that approximately $6.3 billion in funds had been stolen from digital asset wallets held at Binance, and Binance temporarily suspended withdrawals in connection with this incident. A successful security breach or cyberattack could result in:

- a partial or total loss of our cryptocurrency in a manner that may not be covered by insurance or the liability provisions of the custody agreements with the custodians who hold our cryptocurrency;
- harm to our reputation and brand;
- improper disclosure of data and violations of applicable data privacy and other laws; or
- significant regulatory scrutiny, investigations, fines, penalties, and other legal, regulatory, contractual and financial exposure.

Further, any actual or perceived data security breach or cybersecurity attack directed at other companies with digital assets or companies that operate digital asset networks, regardless of whether we are directly impacted, could lead to a general loss of confidence in the broader cryptocurrency ecosystem or in the use of the cryptocurrency network to conduct financial transactions, which could negatively impact us.

Attacks upon systems across a variety of industries, including industries related to cryptocurrency, are increasing in frequency, persistence, and sophistication, and, in many cases, are being conducted by sophisticated, well-funded and organized groups and individuals, including state actors. The techniques used to obtain unauthorized, improper or illegal access to systems and information (including personal data and digital assets), disable or degrade services, or sabotage systems are constantly evolving, may be difficult to detect quickly, and often are not recognized or detected until after they have been launched against a target. These attacks may occur on our systems or those of our third-party service providers or partners. We may experience breaches of our security measures due to human error, malfeasance, insider threats, system errors or vulnerabilities or other irregularities. In particular, we expect that unauthorized parties will attempt to gain access to our systems and facilities, as well as those of our partners and third-party service providers, through various means, such as hacking, social engineering, phishing and fraud. Threats can come from a variety of sources, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, and insiders. In addition, certain types of attacks could harm us even if our systems are left undisturbed. For example, certain threats are designed to remain dormant or undetectable, sometimes for extended periods of time, or until launched against a target and we may not be able to implement adequate preventative measures. Further, there has been an increase in such activities due to the increase in work-from-home arrangements. The risk of cyberattacks could also be increased by cyberwarfare in connection with the ongoing conflict between Russia and Ukraine, war in Iran and other conflicts and instability in the Middle East and instability in Venezuela, or other future conflicts, including potential proliferation of malware into systems unrelated to such conflicts. Any future breach of our operations or those of others in the cryptocurrency industry, including third-party services on which we rely, could materially and adversely affect our financial condition and results of operations.

Our custodially-held cryptocurrencies may become part of the custodian's insolvency estate if one or more of our custodians enters bankruptcy, receivership or similar insolvency proceedings.

Initially, we plan to hold all of our cryptocurrency in custody accounts at either a U.S.-based, institutional-grade custodian that has demonstrated a record of regulatory compliance and information security or offshore third party managed custody accounts, which the Company will control. As we further execute on our strategy, we may expand our holdings to multiple similar custodians.

If our custodially-held cryptocurrencies are considered to be the property of our custodians' estates in the event that any such custodians were to enter bankruptcy, receivership or similar insolvency proceedings, we could be treated as a general unsecured creditor of such custodians, inhibiting our ability to exercise ownership rights with respect to such cryptocurrencies and this may ultimately result in the loss of the value related to some or all of such assets. A series

of recent high-profile bankruptcies, closures, liquidations, regulatory enforcement actions and other events relating to companies operating in the digital asset industry, the closure or liquidation of certain financial institutions that provided lending and other services to the digital assets industry, and the filing and subsequent settlement of a civil fraud lawsuit have highlighted the counterparty risks applicable to owning and transacting in digital assets. These bankruptcies, closures, liquidations and other events have likely negatively impacted the adoption rate and use of cryptocurrencies. Additional bankruptcies, closures, liquidations, regulatory enforcement actions or other events involving participants in the digital assets industry in the future may further negatively impact the adoption rate, price, and use of cryptocurrencies, limit the availability to us of financing collateralized by such assets, or create or expose additional counterparty risks. Any loss associated with such insolvency proceedings is unlikely to be covered by any insurance coverage we maintain related to our cryptocurrencies. Even if we are able to prevent our cryptocurrencies from being considered the property of a custodian's bankruptcy estate as part of an insolvency proceeding, it is possible that we would still be delayed or may otherwise experience difficulty in accessing our cryptocurrencies held by the affected custodian during the pendency of the insolvency proceedings. Any such outcome could have a material adverse effect on our financial condition and the market price of our listed securities.

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

Except as previously reported in our Current Reports on Form 8-K, we did not undertake any unregistered sales of our equity securities during the quarter ended September 30, 2026.

We did not repurchase any of our equity securities during the quarter ended September 30, 2026.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the fiscal quarter ended September 30, 2026, 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.

Item 6. Exhibits.

Exhibit Number	Description	Form	File/Reg. No.	Exhibit	Filing Date
2.1#	Agreement and Plan of Merger, dated as of August 30, 2024, by and among Denali Capital Acquisition Corp., Denali Merger Sub Inc. and Semnur Pharmaceuticals, Inc.	S-4	333-283019	Annex A-1	August 12, 2025
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated as of April 16, 2025, by and among Denali Capital Acquisition Corp., Denali Merger Sub Inc. and Semnur Pharmaceuticals, Inc.	S-4	333-283019	Annex A-2	April 21, 2025
2.3	Amendment No. 2 to Agreement and Plan of Merger, dated as of July 22, 2025, by and among Denali Capital Acquisition Corp., Denali Merger Sub Inc. and Semnur Pharmaceuticals, Inc.	S-4	333-283019	Annex A-3	July 23, 2025
3.1	Restated Certificate of Incorporation of Semnur Pharmaceuticals, Inc.	8-K	001-41351	3.1	September 26, 2025
3.2	Certificate of Designations of Semnur Pharmaceuticals, Inc.	8-K	001-41351	3.2	September 26, 2025
3.3	Bylaws of Semnur Pharmaceuticals, Inc.	8-K	001-41351	3.3	September 26, 2025
10.1	Term Sheet, dated July 3, 2026, by and between Semnur Pharmaceuticals, Inc. and iHolding Group LLP.	10-Q	001-41351	10.1	August 10, 2026
31.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		Filed herewith		
31.2	Certification of Stephen Ma, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.		Filed herewith		
32.1	Certification of Henry Ji, Ph.D., Principal Executive Officer, and Stephen Ma, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		Furnished herewith		
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.		Filed herewith		
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Document.		Filed herewith		
104	Cover Page (formatted as Inline XBRL and contained in Exhibit 101).		Filed herewith		

Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601. The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Semnur Pharmaceuticals, Inc.

Date: November 4, 2026

By: */s/ Henry Ji, Ph.D.*
Henry Ji, Ph.D.
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 4, 2026

By: */s/ Stephen Ma*
Stephen Ma
Chief Financial Officer, Chief Operating Officer,
Senior Vice President and Secretary
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Henry Ji, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Semnur Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

/s/ *Henry Ji, Ph.D.*
Henry Ji, Ph.D.
Chief Executive Officer and President
(Principal Executive Officer)

Dated: November 4, 2026

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
Pursuant to Rule 13a-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Stephen Ma, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Semnur Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

/s/ *Stephen Ma*
Stephen Ma
Chief Financial Officer, Chief Operating Officer, Senior Vice President and Secretary
(Principal Financial and Accounting Officer)

Dated: November 4, 2026

Exhibit 32.1

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned, in his or her capacity as the principal executive officer and principal financial officer of Semnur Pharmaceuticals, Inc. (the "Company"), as the case may be, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 that, to the best of his or her knowledge:

1. This Quarterly Report on Form 10-Q for the period ended September 30, 2026 (this "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

2. The information contained in this Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by this Quarterly Report.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission ("SEC") or its staff upon request.

This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of this Quarterly Report), irrespective of any general incorporation language contained in such filing.

Date: November 4, 2026

/s/ *Henry Ji, Ph.D.*

Henry Ji, Ph.D.
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 4, 2026

/s/ *Stephen Ma*

Stephen Ma
Chief Financial Officer, Chief Operating Officer, Senior Vice President and Secretary
(Principal Financial and Accounting Officer)