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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

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, Registrant's securities began trading on the OTCQB marketplace maintained by the OTC Markets Group, Inc. under the symbols "SMNR" and "SMNRW".

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of voting stock held by non-affiliates of Denali Capital Acquisition Corp., our predecessor, computed by reference to the price at which the common equity was last sold as of June 30, 2025 (the last trading day of the registrant's second fiscal quarter of 2025) was $0.5 million.

The number of shares of Registrant's Common Stock outstanding as of February 25, 2026 was 230,209,142.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement relating to the 2026 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

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SEMNUR PHARMACEUTICALS, INC.

In this Annual Report on Form 10-K (the "Annual Report") , 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 Annual Report 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 Annual Report 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 Annual Report 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. 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.

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 Annual Report 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 Annual Report 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 Israel;
- 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 Annual Report 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 to 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

Item 1. Business.

Our Company

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 (10 mg, dexamethasone sodium phosphate viscous gel), if approved, has the potential to become the first U.S. Food and Drug Administration ("FDA") approved non-opioid novel injectable corticosteroid gel formulation for patients with moderate to severe 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.

Semnur was founded in 2013 and we have invested substantial efforts and financial resources on building our intellectual property portfolio and infrastructure. We have conducted pharmacokinetic ("PK") and toxicology studies, including a Phase 1 PK bridging study, Phase 2 repeat dose study, and a pivotal Phase 3 study. We were acquired by Scilex Holding Company ("Scilex") on March 18, 2019, pursuant to, and in connection with the transactions contemplated by, an Agreement and Plan of Merger between Scilex, us, Sigma Merger Sub, Inc., Scilex's then wholly owned subsidiary ("Sigma Merger Sub"), Fortis Advisors LLC, solely as representative of the holders of our equity (the "Semnur Equityholders' Representative"), and Sorrento Therapeutics, Inc. ("Sorrento"), for limited purposes (as amended, the "Semnur Merger Agreement"). We expect to continue to make investments in research and development, clinical trials and regulatory affairs to develop our product candidate, SP-102.

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 ESI, 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 ESI 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.

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. The primary endpoint of change in average daily Numeric Pain Rating Scale ("NPRS") pain in the affected leg over four weeks demonstrated meaningful and statistically significant result over placebo, least square (LS) mean treatment difference (standard error [SE]) of -0.52 (0.163) units [95% confidence interval [CI]: -0.84, -0.20] compared to placebo (P=0.002).

Most of the secondary endpoints at four weeks also demonstrated statistically significant results, supporting the primary outcome. For the key secondary endpoint of mean change in Oswestry Disability Index ("ODI") from baseline, the LS mean treatment difference (SE) for SP-102 was -3.38 (1.388) units [95% CI: -6.11, -0.65] compared to placebo (P=0.015). SP-102 treatment resulted in a -8.88 point reduction from baseline, which exceeds the established minimal clinically important difference of -8.

Based on the results of this study, 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) 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. Based on such guidance, we designed an open-label multi-center safety and efficacy trial, which we had expected to commence in the first half of 2024 and in which we would seek to enroll approximately 700 patients with moderate-to-severe LRP requiring an epidural steroid injection. In that trial, we expected to administer SP-102 in up to three injections during a six-month observation period. In February 2024, we had a Type D meeting with the FDA to preview the design of such 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. Based on this feedback, we have instead designed a Phase 3 CLEAR-2 trial, which is expected to be a randomized, active comparator and placebo-controlled, multi-center, safety and efficacy study of SP-102 in subjects with moderate to severe LRP enrolling approximately 700 patients to receive an open-label initial injection, and randomizing approximately 200 subjects to the second phase of repeat injection. The primary and key secondary endpoints of the CLEAR-2 trial are consistent with those used in the CLEAR-1 trial, including (i) average daily NPRS pain in the affected leg over four weeks following the initial injection of SP-102 and (ii) Oswestry Disability Index at four weeks following injection of SP-102 or placebo. We have also optimized certain secondary endpoints to capture additional potential clinical benefits of SP-102.

We initiated our second Phase 3 in September 2025 and, given our experience from conducting the Phase 3 CLEAR-1 study, we expect to be able to complete the trial by 2027 and submit our 505(b)(2) NDA to the FDA for approval. If approved, and given SP-102's fast-track designation, this would position us to achieve our targeted commercial launch of SP-102 in 2028. Except as described above, as of the date of this Annual Report, we have not yet pursued any additional substantive development of SP-102.

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.

Our Strategy

Our vision is to become the leading pain management company delivering novel non-opioid and non-addictive treatments to provide safe, effective and durable relief of multiple pain conditions. To accomplish this, the principal elements of our strategy are the following:

- **Develop SP-102 as a novel epidural injection for the first approved treatment of sciatica.** We are developing SP-102 to address the limitations associated with the available corticosteroid epidural injectable products that are used off-label. Many of these products contain potentially neurotoxic preservatives and particulates and are administered over 12 million times annually despite a warning on the label of serious neurologic complications, including loss of vision, stroke, paralysis and death. These products carry warnings required by the FDA that the safety and efficacy of epidural administration has not been established. SP-102 has received fast track designation from the FDA and, if approved, could become the first FDA-approved epidural steroid product with long-term patent protection, which we also believe would create significant barriers to entry. 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. Due to the novelty of our formulation as well as the associated patents and trade secrets, future potential competitors could be required to conduct extensive preclinical studies and costly comparative clinical trials. A full six-month data analysis was completed in February 2022 and we have completed a pivotal Phase 3 study with final

results received in March 2022, which results reflect achievement of primary and secondary endpoints. We have extensive clinical and preclinical data (including those obtained from multiple Phase 2 clinical trials) with the novel viscous gel formulation of SP-102. The Phase 3 study results were published in PAIN® Journal in June 2024 and we also presented the pivotal Phase 3 trial results at the American Society of Interventional Pain Physicians annual meeting in Las Vegas, Nevada in May 2022.

- **SP-102 may be the first FDA approved ESI indicated for sciatica.** Based on the Phase 3 results, we anticipate being able to show advantages of SP-102 compared to existing steroid formulations. We anticipate that SP-102 may have longer duration of clinical benefit compared to generic dexamethasone formulation. The currently used off-label dexamethasone formulation does not have proven efficacy. Pain specialists who have used current dexamethasone formulation believe the efficacy lasts for a short period of time. We expect the clinical benefit of SP-102 to last up to approximately 100 days. Clinical benefit lasting approximately 100 days will reduce the number of procedures patients need and save the health care system valuable resources. Other steroid formulations currently used are suspension steroid formulations. Suspension steroids can cause serious safety concerns such as paraplegia, stroke, paralysis and death, as reflected in FDA class label warning. We expect SP-102 to have proven tolerability based on data from our preclinical and clinical trials. Our reimbursement team will file for a separate J code for SP-102. Once a product receives a special J code, customers will be reimbursed for the product. We have experienced account executives who will follow the process to file for the special J code prior to the launch, which we expected to be granted within two to three quarters after launch. We believe this will facilitate faster uptake in revenue for SP-102 following FDA approval.

- **Capitalize on the potential market as back pain affects most adults, causes disability for some, and is a common reason for seeking healthcare.** In the United States, opioid prescriptions for low back pain have increased, and opioids are now the most commonly prescribed drug class. According to the British Medical Journal 2015, more than half of regular opioid users report back pain. Rates of opioid prescribing in the United States and Canada are two to three times higher than those in most European countries. If approved, SP-102 could become the first FDA-approved ESI product for sciatica. We believe an FDA-approved therapy for the treatment of sciatica could potentially benefit from first-to-market advantage if it can be shown to reduce or delay the need for expensive and potentially risky interventions, such as spinal surgery, and to decrease the use of opioids.

- **Expand our product portfolio by developing or acquiring non-opioid assets that leverage our existing research and development infrastructure.** We are continuously evaluating opportunities to leverage our research and development experience to develop non-opioid therapeutics for pain management indications that are not adequately served with existing treatment options. Plans for expansion of our product portfolio include investing in early and late-stage research programs to develop our pipeline and capabilities by selectively acquiring highly differentiated technologies, investing in technologies to prepare for commercialization, evaluating strategic partnerships to improve patient experience or enable greater patient access, and opportunistically pursuing strategic partnerships and collaborations to maximize the value of our pipeline and platform technologies. We also seek to in-license non-opioid therapeutics that can both complement our existing product portfolio and benefit from our existing research and development infrastructure.

- **Leverage the robust and integrated commercial infrastructure and dedicated sales force and sales management, marketing, medical affairs, managed care capabilities, manufacturing and general administration functions of our parent company, Scilex, to commercialize our current and future product candidates, if approved.** Scilex has successfully launched three commercial non-opioid pain management products in the past five years by using its in-house sales force and an outsourced sales force, who typically bring strong, proven experience promoting a broad scope of pain management products, as our current and future product candidates are commercialized. Scilex's three marketed non-opioid pain products have given the Scilex team the opportunity to interact with the key physician audiences for SP-102, while promoting ZTlido®, one of Scilex's commercial products, and building rapport with the future prescribers as Scilex looks to partner with us for SP-102's commercial launch. Scilex's sales representatives leverage their established relationships with pain management healthcare professionals ("HCPs") to call on over 6,000 target pain specialists, neurologists, and select health care providers, and we believe these same call points that are providing treatment for sciatica could benefit

from SP-102, if approved. Scilex launched ZTlido in the fourth quarter of 2018 with an integrated internal commercial organization and we believe that Scilex's differentiated and focused team, combined with its competitive national accounts strategy and active direct marketing and medical efforts have driven, and will continue to drive, accelerated sales growth for Scilex products and in the future can drive market uptake for our pain product candidates, including SP-102. As of December 31, 2025, we have 12 contractors and consultants, in addition to three full-time employees from Scilex dedicated to our product candidate, SP-102. In connection with the closing of the Business Combination, we entered into a Transition Services Agreement (the "Transition Services Agreement") with Scilex, pursuant to which we can 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. During the transition period and leveraging Scilex's infrastructure, we will be able to develop our own infrastructure with Scilex's continued support and as we enter the final stages of development and pre-launch commercialization planning, we plan to increase the number of full-time employees to strengthen our research and development, general administrative, manufacturing, regulatory and commercial functions. The term of the Transition Services Agreement is three years from the closing of the Business Combination, which we believe is sufficient time for us to develop our commercial infrastructure and other business functions. See the section titled "*Risk Factors — Risks Related to Our Relationship with Scilex*" elsewhere in this Annual Report. Our financial statements for the fiscal years ended December 31, 2025 and 2024 reflect charges for these services on an allocation basis. As a result, our historical 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. Upon completion of the Phase 3 CLEAR-2 trial by 2027, we will commence the preparation work for the mass production of SP-102. Leveraging Scilex's commercial infrastructure, upon approval by the FDA, we intend to initiate negotiations with national insurance companies, as well as Medicare and Medicaid, to secure inclusion of SP-102 in their programs. In addition, we plan to enter into a distribution agreement with a major third-party logistic provider for warehousing and distribution of SP-102 as it approaches the NDA approval stage. Utilizing Scilex's experience and support, we have established cross-functional launch teams and developed a detailed launch playbook to guide the efforts towards a successful product launch. For a brief summary of the launch activities and timelines, please refer to the section titled "*Business — Sales and Marketing*" elsewhere in this Annual Report.

- **Leverage our management team's experience to further develop and commercialize our current and future product portfolio.** Leverage our management team's experience to further develop and commercialize our current and future product portfolio. Our management team has held senior positions at leading biopharmaceutical companies, including Allergan, Inc., Bristol-Myers Squibb Company, Teva Pharmaceuticals Industries Ltd., Novartis Pharmaceuticals Corporation, Ardelyx, Inc., Pfizer Inc., Johnson and Johnson, Cephalon, Inc., Roche AG, PDL BioPharma, Inc., Xenoport, Inc. and Chiron Corp. Our team has substantial experience in rapidly progressing new drug products to clinical proof of concept, completing successful pivotal registration programs and successfully commercializing products.

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.

Our Management Team

Our management team has extensive experience in the pain and neurology center marketplace and a track record of successfully commercializing pain management and central nervous system products, which helps us in aiming to ensure that our current and future product candidates, pipeline programs, and partnerships in the marketplace are consistently of the highest quality.

Our management team is led by our Chief Executive Officer and President, Jaisim Shah, with strategic guidance from our Executive Chairman, Henry Ji, Ph.D. They collectively have over 60 years of global biopharmaceutical and biotechnology experience.

Jaisim Shah has over 30 years of industry success in leading product development and commercializing innovative therapies and creating companies, with documented success in development and commercialization of

some of today's most recognized pharmaceutical brands. He is a seasoned life science executive and board director with extensive accomplishments at Scilex, Bristol-Myers Squibb, Roche, PDL Biopharma, Pfizer, and start-ups such as Elevation. Mr. Shah has served as our Chief Executive Officer and President since our inception in 2013. He also previously served as Scilex's President, Chief Executive Officer from March 2019 through August 2025, and a board member of Scilex from March 2019 through September 2025 and as a member of the board of directors of Scilex Pharmaceuticals, Inc., Scilex's wholly owned subsidiary ("Scilex Pharma"), from November 2016 through August 2025. Mr. Shah served as Chief Business Officer of Elevation Pharmaceuticals where he focused on financing, business strategy, mergers and acquisitions, and business development. He led the sale of Elevation to Sunovion Pharmaceuticals in 2012. At Facet Biotech and PDL BioPharma, he served from 2000 to 2009 as Chief Business Officer and also held the position of senior vice president of marketing and medical affairs. During this time, he completed numerous licensing/partnering and strategic transactions including with Roche, Bristol-Myers Squibb, Otsuka, and Biogen Idec. His leadership in marketing and portfolio management, including leading the commercial enterprise, helped the company make large improvements to meet its profitability potential. At Bristol-Myers Squibb, as vice president of global marketing from 1997 to 2000, Mr. Shah received the "Presidents Award" for completing one of the most significant collaborations in the company's history. He has played a key role in the formulation of long-range plans and pre-launch and launch strategies for brands such as Abilify®, Pegasys®, and Rituxan/MabThera®, each of which have generated well over $1 billion in sales.

Dr. Ji is the holder of several issued and pending patents in the life science research field. Our Chief Financial Officer, Stephen Ma, has more than 15 years of finance and operational expertise across pharmaceuticals and venture-backed biotechnology companies. Our research efforts are guided by highly experienced scientists and experts. Our management team contributes a diverse range of experiences from leading biopharmaceutical companies, including Allergan, Inc., Bristol-Myers Squibb Company, Teva Pharmaceuticals Industries Ltd., Novartis Pharmaceuticals Corporation, Ardelyx, Inc., Johnson and Johnson, Pfizer Inc., Cephalon, Inc., Roche AG, PDL BioPharma, Inc., Xenoport, Inc. and Chiron Corp. With this leadership, we believe we are well positioned to achieve our vision of becoming the leading pain management company delivering novel non-opioid and non-addictive treatments aiming to provide safe, effective and durable relief of multiple pain conditions.

In addition, we are supported by impressive teams across all levels of the organization. We hire and develop world-class talent from diverse backgrounds in biopharma, academia, technology and finance to ensure we have all of the capabilities to design and deliver first-class pain management therapies.

Our Product Candidate — SP-102

SP-102 is a pivotal Phase 3, novel, injectable viscous gel formulation of a widely used corticosteroid for epidural injections to treat sciatica. No ESIs are currently approved by the FDA.

Sciatica Market Overview

A particularly debilitating complication of back pathology is sciatica, which is a condition caused by mechanical compression of the nerve root, or by the effects of inflammatory mediators arising from a degenerative disc that results in inflammation and damage to the nerve roots. This nerve root compression in the lumbar segment of the spine causes shock-like or burning LBP combined with pain radiating down along the sciatic nerve through the buttocks and down one leg, sometimes reaching the foot. This often severe and debilitating leg pain is usually associated with symptoms of neuropathy-like numbness and tingling. The estimated lifetime incidence of sciatica ranges from 13% to 40% of the U.S. population, and about one-third of these cases will develop symptoms lasting over a year. According to a report by Decision Resources Group, it was estimated that over 4.8 million patients would suffer from sciatica in the United States in 2024.

Market Opportunity for SP-102

The applicable assumed market for SP-102 is the U.S. ESI Market, with an average market growth rate of 3.6% through 2027 (as estimated by Syneos Health as part of its consulting assignment with Scilex in 2021 and Scilex internal market research, which takes into account Scilex's anticipated promotional activities), with lower growth thereafter. Projections for SP-102 revenues assume receipt of regulatory approval in 2027 with commercial launch in 2028, a market size of approximately 12.0 million ESI procedures annually (based on Syneos Health's analysis of prescription claims data), an average growth rate of 3.6% year-over-year through 2027 and lower growth thereafter, a maximum market share of approximately 33% of the U.S. ESI market (based on Syneos Health's analogue assessment of other similar products in the applicable market and primary market research with healthcare professional specialists as well as Scilex's assessment of the competitive landscape and that there are currently no

FDA-approved ESI therapies for sciatica). Based on the independent market research conducted by Syneos Health in 2020 and 2021, given the potential substantial utilization of SP-102, by the 5th year of launch, sales of SP-102 in sciatica are projected to reach $1.5 billion to $2.0 billion annually. As of the date of this Annual Report, SP-102 has not received regulatory approval. As disclosed elsewhere, we expect commercial launch in 2028 but there is no guarantee that we will be able to commence a commercial launch of SP-102 in 2028 or ever, as any such launch would be subject to regulatory approval, which we may not receive.

Current Treatment Landscape and Limitations of Existing Treatments

As the U.S. population ages, the incidence of sciatica and the need for interventions are expected to continue to increase. For example, from 2000 to 2018, ESIs in Medicare beneficiaries increased by more than 125%.

Although there are numerous etiologies of sciatica, and therapies may differ based on the etiology, pain management interventions for sciatica are usually multi-modal. Among the pain management interventions, ESI is considered to be efficacious and has been widely used by physicians across multiple specialties, including anesthesiology, physical medicine and rehabilitation and pain medicine. However, there is no ESI therapy approved by the FDA for sciatica to date, and particulate formulations of glucocorticoids have been associated with severe adverse events.

Patients with sciatica have a wide range of invasive and non-invasive treatment options. Surgical intervention options include vertebroplasty, spinal laminectomy, discectomy, microdiscectomy, foraminotomy, intradiscal electrothermal therapy, nucleoplasty, radiofrequency denervation, spinal fusion and artificial disc replacement. These options are generally the last line of treatment because they can result in prolonged recovery time, may not be successful in reducing pain or addressing the underlying cause, and may result in permanent loss of flexibility. For these reasons, less invasive interventions are usually implemented first. Less invasive interventions may include (i) nonpharmacological therapies such as physical therapy, stretching exercises, spinal manipulations or chiropractic therapy, traction, acupuncture, transcutaneous electrical nerve stimulation, and biofeedback; (ii) oral pharmaceutical therapies such as NSAIDs, muscle relaxants, opiates, antidepressants, and anticonvulsants; and (iii) injectable pharmaceutical therapies such as off-label use of ESIs or nerve blocks.

ESIs for various back pain syndromes are one of the most common procedures performed in the United States and lumbosacral radicular ESI procedures represent 88% of total ESI procedures. ESIs are used when a patient's pain is inadequately controlled with oral pain medications, topical systems or interventions such as physical therapy. ESIs have demonstrated efficacy in reducing pain, restoring function, reducing the need for other health care and avoiding back surgery. However, in addition to not being FDA-approved for the treatment of sciatica, currently-used ESIs also present various risks and challenges.

When administering an ESI, many physicians use a particulate steroid (including methylprednisolone acetate, triamcinolone acetonide, or betamethasone sodium phosphate or betamethasone sodium acetate) instead of a non-particulate steroid (dexamethasone sodium phosphate) because early studies suggested that the duration of pain relief was longer with the particulates and fewer repeat injections were required, even though dexamethasone is considered an otherwise potent and therapeutically beneficial therapy. Particulate in injectable products is defined as extraneous undissolved particles present in injectable solution products. An example of such particulate is precipitate of insoluble drug product form, or suspended drug product particle. These steroid particles or their aggregates have at least two mechanisms for neurological damage: (1) they can act as emboli if injected into an artery and are of sufficient size to block small terminal arterioles supplying the brain or spinal cord; and (2) several particulate steroids have an immediate and massive effect on microvascular perfusion because of formation of red blood cell aggregates. These emboli can cause rare but catastrophic neurologic injuries including stroke and spinal cord injury that can result in increased pain, severe permanent disability or death. In addition, fungal meningitis has occurred from the injection of steroids manufactured in a compounding pharmacy that did not adhere to sterility standards.

The FDA has been evaluating serious neurologic events with ESIs since 2009, and in 2014, the FDA required a class warning on the currently off-label use of injectable corticosteroids to include information about the risk of serious neurologic events with ESIs. The warning on product labels for all injectable glucocorticoids states that the product is to be used for intramuscular or intravenous purposes only, and specifically includes a warning for serious neurologic adverse reactions with epidural administration. These serious neurologic events have been reported with and without the use of fluoroscopy. The class warning also includes a statement that safety and effectiveness of epidural administration of these corticosteroids have not been established.

Certain third-party payors have also provided limited coverage of ESIs to date. Based on coverage criteria established by different health care plans and certain Medicare Administrative Contractors, an ESI is considered medically necessary and therefore reimbursable only when certain specific criteria are met.

Our Solution

We are developing SP-102 to address problems associated with currently available corticosteroid products that are used in practice but not approved for epidural injection or the treatment of sciatica. SP-102 is a Phase 3 sterile dexamethasone sodium phosphate viscous gel formulation of 10 mg dexamethasone at a 5 mg/mL concentration in a pre-filled glass syringe for delivery via an epidural injection. SP-102 allows for the use of the potent dexamethasone and provides for longer residency time at the site of injection through the use of a viscous excipient in lieu of particulates. The product is also formulated without the use of preservatives and packaged in a pre-filled syringe, so as to confer greater physician convenience.

Currently-used steroids carry a class warning and are not approved to be administered epidurally for the treatment of sciatica. In fact, there are further warnings that the safety and efficacy of the use of these products following epidural administration has not been established. Their formulations include neurotoxic preservatives, surfactants, suspensions or particulates that carry risks of serious neurologic complications. Unlike currently-used steroids, SP-102 does not contain neurotoxic preservatives, surfactants, suspensions or particulates that carry risk of serious neurologic complications, which we believe may improve tolerability and the extent of pain relief. By using dexamethasone sodium phosphate, the soluble form of the potent dexamethasone, we believe SP-102 may substantially reduce the risk of embolic events in case of inadvertent intra-arterial administration and enable repeat injections. We expect the injectable viscous gel product, SP-102, which uses a biocompatible, biodegradable, novel excipient and is protected by multiple patents and patent applications and trade secrets, to prolong the residence time at the injection site and result in extended local activity. We believe SP-102, if successfully developed and approved, has the potential to reduce the disability related to LRP and help delay or avoid spine surgery.

If approved, SP-102 could become the first FDA-approved ESI product for sciatica. We believe an FDA-approved therapy for the treatment of sciatica could potentially benefit from first-to-market advantage if it can be shown to reduce or delay the need for expensive and potentially risky interventions such as spinal surgery and decrease the use of opioids. SP-102 benefits from our substantial intellectual property portfolio and other technical barriers to entry for potential competitors. Historically, we have purchased our clinical and commercial supply requirements for sodium hyaluronate, one of the excipients for SP-102, from Genzyme pursuant to a supply agreement, which terminated as of May 31, 2024. We are currently in discussions with Sanofi, an affiliate of Genzyme, and are in the process of identifying and certifying new suppliers, in each case to fulfill our future supply requirements for sodium hyaluronate. Our complex manufacturing process, specialized equipment and know-how for sterile viscous product candidates are also key to our competitive edge.

We have completed a pivotal Phase 3 CLEAR trial (NCT03372161), which was designed to evaluate the tolerability and clinical benefit of SP-102 in the proposed indication (i.e., treatment of LRP). The CLEAR clinical trial is a randomized, double-blind, placebo-controlled, multicenter Phase 3 trial that enrolled 401 subjects with LRP at over 40 clinical sites across the United States, with a primary objective to evaluate the analgesic effect on average in the affected leg pain (as measured by the NPRS in the affected leg) following a single epidural transforaminal (TF) injection of SP-102, compared to an intramuscular (i.e., the posterior multifidus muscle) injection of placebo over four weeks. After the primary Week Four analysis period, and if the subject continued to experience leg pain, a repeat injection of open-label SP-102 was made optional at the investigator's discretion.

Clinical Development Overview

We have completed a Phase 3 pivotal study of SP-102. The CLEAR study is a randomized, double-blind, placebo-controlled Phase 3 trial that enrolled 401 patients with sciatica to compare the epidural administration of SP-102 to placebo. We announced final results from this study in March 2022. The Phase 3 study results have been published in PAIN®Journal in June 2024 and we also presented the pivotal Phase 3 trial results at the American Society of Interventional Pain Physicians annual meeting in Las Vegas, Nevada in May 2022.

Preclinical and Clinical Trial and Highlights

SP-102 has been evaluated in a number of preclinical studies and clinical trials as a potential treatment for sciatica. Key findings from the preclinical studies and clinical trials include:

- The introduction of SP-102 into blood vessels did not result in neurological complications in the

UPD003-IS21 preclinical toxicology study;

- SP-102 showed an extended residence time and tolerability in the 1014-1512 and the 1014-2847 preclinical studies;
- Repeat injections of SP-102 showed continued pain reduction with no unexpected adverse events based on preliminary results from the SP-102-03 study; and
- SP-102 showed an extended local activity with epidural administration in the ES-1504 study.

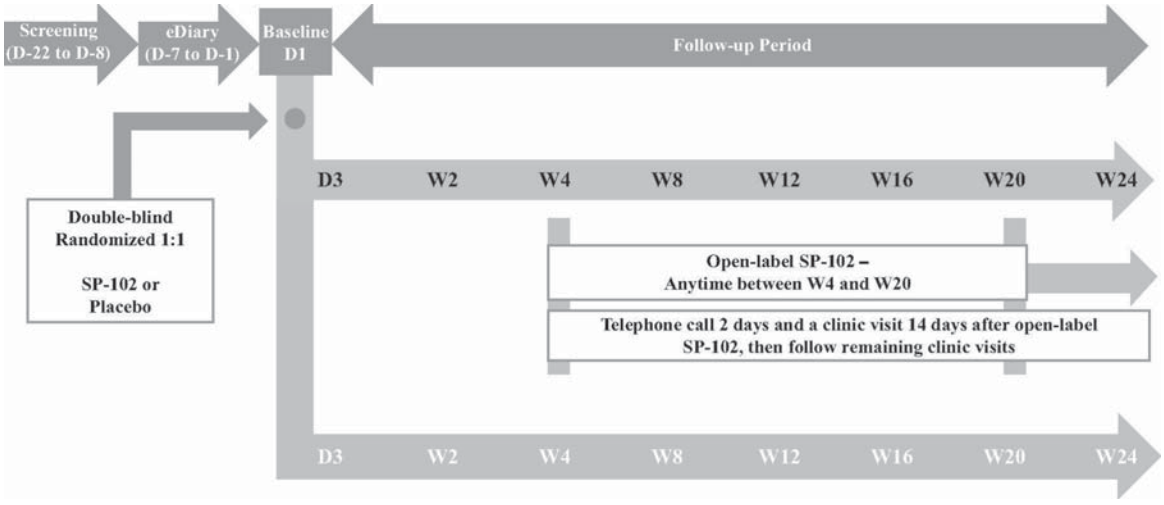
Study Details

Phase 3 Pivotal Clinical Trial — CLEAR

We have completed a pivotal, randomized, double-blind, placebo-controlled Phase 3 trial, CLEAR, that enrolled 401 patients with sciatica at over 40 sites across the United States. The study included an open-label extension where subjects were followed for up to 24 weeks after treatment to evaluate the tolerability of administering SP-102 in a larger patient population. After week four, subjects who met certain pain criteria received open-label SP-102 to investigate the tolerability of repeat injections and the duration of pain relief following injection. This well-controlled, double-blind, randomized trial was designed to demonstrate evidence of the analgesic effect and tolerability of SP-102. The schematic of this Phase 3 trial is demonstrated in the flowchart below.

The primary objective of this study was to evaluate the analgesic effect of SP-102 on average leg pain, measured using the NPRS following a single transforaminal injection. These results were compared to an intra-muscular injection of placebo over a four-week period. The secondary objectives of this study include (i) evaluation of the degree of disability over time as measured by the ODI; (ii) characterization of the change of the subject's radiculopathy symptoms and overall condition, using a combination of PainDETECT, modified Brief Pain Inventory, Clinical Global Impression of Change ("CGIC"), and Patient Global Impression of Change ("PGIC") and (iii) evaluation of the tolerability of a single and repeat SP-102 injection.

Schematic of CLEAR - SP-102 (SEMDEXA) Phase 3 Pivotal Trial



Results of CLEAR - SP-102 Phase 3 PivotalTrial

A full six-month data analysis was completed in February 2022, and we announced final results from the study in March 2022, which results reflect achievement of primary and secondary endpoints. The Phase 3 study results have been published in PAIN® Journal (Miller et al 2024) and we also presented the pivotal Phase 3 trial results at the American Society of Interventional Pain Physicians annual meeting in Las Vegas, Nevada in May 2022.

The Phase 3 CLEAR trial summary results, which results reflect achievement of primary and majority of secondary endpoints, are as follows:

- For the intent-to-treat ("ITT") population, the primary endpoint of change in average daily NPRS pain in the affected leg over four weeks following the initial injection of SP-102 demonstrated least square ("LS") mean treatment difference (standard error ("SE")) of -0.52 (0.163) units [95% confidence interval ("CI"): -0.84, -0.20] compared to placebo (P=0.002). The change from baseline to Week Four in the mean daily average NPRS pain score (standard deviation ("SD")) in the affected leg was -1.81 (1.896) for SP-102 versus -1.29 (1.814) in the placebo group. The calculated standardized effect size (Cohen's D calculated as the group mean difference divided by the pooled standard deviation) associated with the ITT population is 0.28. A statistically significant difference in the mean daily average NPRS pain change between SP-102 and placebo was observed at Week One with a mean change from baseline of -1.49 (1.519) for SP-102 and -1.02 (1.472) for placebo (P=0.002), which was maintained through Week Four. These highly significant differences between SP-102 and placebo were also observed following sensitivity analyses for fixed effects.

- Likewise for the ITT population, most of the secondary endpoints at four weeks also demonstrated statistically significant results. For the key secondary endpoint of mean change in ODI from baseline, the LS mean treatment difference (SE) for SP-102 was -3.38 (1.388) units [95% CI: -6.11, -0.65] compared to placebo (P=0.015). SP-102 treatment resulted in a -8.88 point reduction from baseline, which exceeds the minimal clinically important difference of -8 established in a reported pain study.

- Additional secondary endpoints with statistically significant results for the ITT population include worst pain in affected leg at Week Four (P=0.004) and over four weeks (P=0.001), current pain in the affected leg (P=0.009), average pain in lower back (P=0.035), Brief Pain Inventory-Short Form ("BPI-SF") for pain severity (P=0.003) and pain interference (P=0.049), PGIC (P<0.001) and CGIC (P<0.001), with the proportion of patients achieving a response at 30% (P=0.002).

- The time to repeat injection (50th quantile [95% CI]) for the ITT population was 84 (71, 100) days for SP-102 versus 58 (50, 69) days for placebo (P=0.001).

Additional analyses were performed with the modified ITT population ("mITT"), the population with fluoroscopically confirmed needle placement. The primary endpoint group mean difference, associated standardized effect size (Cohen's D), and statistical significance were improved for the mITT population (i.e., -1.08 (0.171), Cohen's D = 0.68, P<0.001), which were initially observed at Week One and improved through Week Four. Similarly, the mITT population was observed to have improved with mostly highly statistically significant outcomes for SP-102 over placebo for the secondary endpoints. In contrast to the ITT population, the mITT population was observed to have statistically significant PainDETECT (a tool to detect neuropathic pain components) for SP-102 over placebo (P=0.037) as well as number of subjects experiencing a 50% reduction in pain in the affected leg (P<0.001).

- For the mITT population, the time to repeat injection (50th quantile [95% CI]) was 99 (78, 129) days for SP-102 versus 57 (49, 67) days for placebo.

- There were no SAEs related to SP-102 or its administration procedure. There were no AEs leading to death, and no AEs of special interest ("AESIs") (i.e., paraplegia, hematoma, or infection at the injection site). There were four (1.4%) subjects experiencing SAEs and one (0.3%) subject experiencing an AE leading to early withdrawal after receiving SP-102. Two (1.0%) subjects experienced an SAE, with one (0.5%) subject experiencing an AE leading to early withdrawal and one patient death following placebo. The fatal SAE was considered unrelated to the placebo or study procedure, as were the SAEs leading to early withdrawal. In general, a slightly higher proportion of subjects in the SP-102 group had treatment emergent AEs ("TEAEs") than in the placebo group, (60 [29.7%] subjects vs 42 [21.1%] subjects with any TEAE). The most common TEAEs by system organ class (SOC) were nervous system disorders: 20 (9.9%) in the SP-102 group, 16 (8.0%) in the placebo group, and 20 (7.0%) in the SP-102 repeat injection group. The most common TEAEs by preferred term were headache, reported in 13 (6.4%) subjects in the SP-102 group, 11 (5.5%) subjects in the placebo group, and 10 (3.5%) subjects the SP-102 repeat injection group.

- Overall, headaches were more commonly reported in subjects exposed to SP-102 than in subjects not

exposed to SP-102 through 12 weeks (6.5% vs 2.1%). Headaches were generally mild, transient, and associated with the epidural injection. Pain at the site of injection was only reported for subjects receiving SP-102 following the initial injection (2.0%) and repeat injection (0.7%). Otherwise, TEAEs occurring ≥2% of subjects were low and balanced between SP-102 and placebo. TEAEs occurring with an incidence ≥2% remained low following the repeat injection.

- There were no meaningful differences observed in physical examinations, vital signs, or laboratory parameters between treatment groups.

The data from the primary endpoint analyses is graphically presented below. Summary tables are also provided for primary and secondary endpoints.

Mean Change From Baseline in NPRS Average Pain Score (Standard Error) in the Affected Leg (ITT Population)

SP-102 vs Placebo Weeks 1,2,3,4: p = 0.002, 0.005, 0.003, 0.003. Overall treatment Effect (Mean SP-102 vs Placebo difference): Diff = -0.52, SE= 0.163, p =0.002. Error Bars: 95% Confidence Limits.

Primary and Secondary Outcomes: NPRS Average Leg Pain In Affected Leg, ODI Total Score, Mean Daily NPRS (worst, current, and lower back), PainDetect, BPI-SF (Change from Baseline to Four Weeks; ITT Population)

	SP-102 N=202	Placebo N=199	LSM (SE)	95% CI	P-value
Endpoint	Mean Change from Baseline[1]	Mean Change from Baseline			
NPRS Average Pain Score in the Affected Leg (primary endpoint)(2)	-1.81 (1.896)	-1.29 (1.814)	-0.55 (0.187)	-0.92, -0.18	0.003
ODI total score(key secondary endpoint)(3)	-8.88 (14.684)	-5.48 (13.083)	-3.38 (1.388)	-6.11, -0.65	0.015
Worst pain in affected leg at Week Four(2)	-1.88 (2.014)	-1.33 (1.946)	-0.57 (0.198)	-0.96, -0.18	0.004
Worst pain in affected leg over Four Weeks(2)			-0.56 (0.173)	-0.90, -0.22	0.001
Current pain in affected leg(2)	-1.8 (2.28)	-1.2 (2.41)	-0.6 (0.23)	-1.1, -0.2	0.009
Average pain in lower back(2)	-0.7 (2.54)	-0.2 (2.48)	-0.5 (0.23)	-0.9, 0.0	0.035
PainDETECT(3	-2.7 (6.47)	-2.5 (6.07)	-0.3 (0.62)	-1.5, 0.9	0.642
Brief Pain Inventory – Short Form score (pain severity)(2)	-1.56 (1.952)	-0.98 (1.928)	-0.59 (0.200)	-0.98, -0.20	0.003
Brief Pain Inventory – Short Form score (pain interference)(3)	-1.16 (2.413)	-0.71 (2.095)	-0.44 (0.221)	-0.87, 0.00	0.049

(1) Baseline NPRS score is the mean of at least five days and no more than seven days of scores from the screening visit until treatment randomization. For the current pain baseline is the last score prior to treatment. Baseline ODI is defined as the last ODI assessment score prior to the first dose on Day 1.

(2) The analysis uses a REML-based MMRM with fixed effects for treatment (SP-102 or placebo), week, site, Pain Catastrophizing Scale group (<30 or ≥30), baseline score, and treatment-by-week interaction.

(3) The analysis uses an ANCOVA model with fixed effects for treatment (SP-102 or placebo), site, Pain Catastrophizing Scale group (<30 or ≥30), and baseline score.

ANCOVA: analysis of covariance; ANOVA: analysis of variance; BPI-SF: Brief Pain Inventory – Short Form; CI: confidence interval; ITT: intent-to-treat (randomized population); LSM: least-squares mean; MMRM: mixed model for repeated measures; NPRS: numeric pain rating scale; REML: restricted maximum likelihood; SE: standard error

Patient Global Impression of Change (PGIC) and Clinical Global Impression of Change (CGIC) – ITT Population

	SP-102 N=202	Placebo N=199
PGIC Responders (number of patients who responded with "very much improved" or "much improved"[1]	71 (35.1%)	39 (19.6%)
Chi-Square	P<0.001	
Logistic regression (odds ratio[95% CI])[2]	2.25 (1.42, 3.54) P<0.001	
CGIC Responders (number of patients assessed as "very much improved" or "much improved"[1]	76 (37.6%)	39 (19.6%)
Chi-Square	P<0.001	
Logistic regression (odds ratio [95% CI])[2]	2.49 (1.58, 3.91) P<0.001	

(1) 7-point scale rating patient's overall improvement. Patient change is rated from "very much improved", "much improved", "minimally improved", "no change", "minimally worse", "much worse" or "very much worse".

(2) Logistic regression models with treatment (SP-102 or placebo), site, and Pain Catastrophizing Scale group (<30 or ≥30) as factors.

CI: confidence interval; ITT: intent-to-treat (randomized population)

Time to Repeat Injection – ITT Population

	SP-102 N=202	Placebo N=199
Number of patients with Repeat Injection of SP-102 (patients who received open-label SP-102 between 4 and 20 weeks after initial injection)	134 (66.3%)	152 (76.4%)
Number of censored patients[1]	68 (33.7%)	47 (23.6%)
Chi-Square	P=0.026	
Time (days)to Repeat Injection		
N	134 (66.3%)	152 (76.4%)
Mean (SD)	67.0 (33.31)	57.8 (31.69)
Median	57.5	43.0
Min, Max	27, 143	26, 148
25th quantile (95% CI)[2]	45 (43, 57)	36 (34, 40)
50th quantile (95% CI)[2]	84 (71, 100)	58 (50, 69)
75th quantile (95% CI)[2]	143 (141, 143)	126 (87, 146)
Comparison to Placebo[3] (Hazard ratio [95% CI]):	0.68 (0.54, 0.86) P=0.001	

(1) Censored patients are the following: (1) patients who do not receive a repeat injection of SP-102 and (2) patients who discontinued the study prior to Week 20 without receiving a repeat injection.

(2) Quartiles are estimated using Kaplan-Meier estimation.

(3) A Cox proportional hazards model was utilized to test the treatment difference while adjusting for site and Pain Catastrophizing Scale (<30 or ≥30).

CI: confidence interval; ITT: intent-to-treat (randomized population); SD: standard deviation

Responder Analysis (Change from Baseline in Mean NPRS, Average Daily Pain in Affected Leg)(1) – ITT Population

	SP-102 N=202	Placebo N=199
30% reduction	88 (43.6%)	57 (28.6%)
Chi-Square	P=0.002	
Logistic regression(2) (odds ratio [95% CI])	1.96 (1.28, 2.98) P=0.002	
50% reduction	58 (28.7%)	41 (20.6%)
Chi-Square	P=0.060	
Logistic regression(2) (odds ratio [95% CI])	1.58 (0.99, 2.52) P=0.055	

(1) Patients that discontinued or have missing scores at Week Four were considered non-responders.

(2) Logistic regression models with treatment (SP-102 or placebo), site, and Pain Catastrophizing Scale group (<30 or ≥30), and baseline averaged daily pain score as factors were used to compare the treatment groups at each week.

CI: confidence interval; ITT: intent-to-treat (randomized population)

Interpreting Clinical Meaningfulness of SP-102 for the Treatment of LRP: a Post-Hoc Analysis of the CLEAR-1 Trial and a Systematic Review of Literature

Analgesic clinical trial studies performed to assess the efficacy of a pharmacological interventions produce results that require interpretation to fully understand their clinical meaningfulness. Commonly, these results are misinterpreted, with the most common source of confusion arising when the magnitude of group differences (typically between active and placebo) are conflated with the determination of the magnitude of improvement within subjects (as assessed by subjects and/or clinicians) that can be considered clinically important. Consequentially, substantial work by researchers, clinicians, and regulatory authorities has been done to establish consensus benchmarks for what constitutes clinically meaningful changes. The analgesic efficacy of SP-102 for the treatment of LRP was evaluated in the pivotal Phase 3 CLEAR-1 clinical trial. The objective of this post-hoc analysis was to interpret the clinical meaningfulness of the magnitude of group mean differences, based on consensus guidelines and benchmarks, of the CLEAR-1 trial by comparing to efficacy data observed for other analgesic products, and to evaluate these effects in the context of overall safety.

Statistical analyses for efficacy endpoints from the CLEAR-1 trial were performed for the ITT population, which included all randomized subjects, and the mITT population, which included only subjects with fluoroscopic verification of successful injection. Group difference efficacy data are presented for the 4-week double-blind period (pre-specified and post-hoc analyses) and safety of single and repeat injections.

A systematic review was conducted and all available clinical trials studies for approved products for chronic low back pain (11 products) and any placebo-controlled trials studies that assessed the efficacy of off-label use of ESIs (4 studies) were collected and the GMDs and standardized effect sizes ("SES") (Cohen's D) were calculated for comparison with the results of the CLEAR-1 trial.

When the group mean difference (mITT: 1.08-point difference; ITT: 0.52) and SES (mITT: 0.68; ITT: 0.28) for the CLEAR-1 Trial are compared with those of other products known to be clinically meaningful analgesics for chronic low back pain, results for the ITT population were similar to those of the majority of other analgesics while the mITT population produced results greater than those of most (median of other products: group mean difference: 0.7- points; SES: 0.32); results were similar when compared against off-label ESIs (median group mean difference: 0.49; SES: 0.29). Similarly, when evaluating secondary endpoints with consensus clinically meaningful cutoffs (NPRS responder analyses, ODI, and Brief Pain Inventory — Pain Interference), statistically significant separation was observed for both populations.

Overall, these results support that SP-102 has a clinically meaningful effect in treating LRP based on assessment of group mean differences and SESs as recommended by consensus guidelines.

Phase 2 Repeat Dose Study — SP-102-03

We conducted an open-label, single-arm, pharmacodynamics ("PD") and tolerability study of repeat epidural injections of SP-102 in patients with sciatica. We conducted this study to characterize repeat dose PD with respect to hypothalamic-pituitary-adrenal suppression using plasma cortisol levels, white blood cell count and blood glucose levels.

The study enrolled 19 subjects, of which 15 received repeat SP-102 epidural injections four to eight weeks after the initial injection. Four of the subjects did not experience recurrent pain and thus did not require a repeat injection. The daily average, current and worst pain in the affected leg and back showed continuous reduction throughout the 28-day observation period for both treatments. Based on a preliminary review of the results, SP-102 injections were generally well tolerated and there were no new unexpected adverse events observed.

Mean Percentage Change in Sciatica-Related Leg Pain as Measured by NPRS

Phase 1 Trial of SP-102 Compared to RLD—ES-1504

We conducted an open-label, single-arm, two-period, fixed sequential-dose study to evaluate the PK, PD and tolerability of SP-102 when administered by epidural injection. SP-102 was compared to intravenous

dexamethasone sodium phosphate injection in subjects with lumbosacral radiculopathy. There were 12 subjects enrolled in this study, all of whom received SP-102 followed by the intravenous dexamethasone sodium phosphate injection (RLD) administered one month later. A RLD is an approved drug product to which new versions are compared to show that they are bioequivalent. The purpose of this study was to establish the pharmaceutical bridge between SP-102 and the RLD. The time to maximum serum concentration ("Tmax") observed with the administration of SP-102 was four hours, compared to 15 minutes observed with intravenous dexamethasone. The PD parameters and tolerability profiles of both products were similar, and SP-102 did not prolong cortisol suppression time. SP-102 also maintained analgesic effects throughout a one-month observation period.

The overall systemic exposure of dexamethasone was similar, whether administered as SP-102 or injected intravenously, with a mean AUCinf of 0.916 µg*h/mL (observed with SP-102) compared to 0.943 µg*h/mL (observed with intravenously administered dexamethasone). Notably, there was a 16-fold increase in the Tmax following epidural injection of SP-102. The median Tmax was 4.00 hours for SP-102 compared to 0.25 hours for the comparison group. All 12 subjects with sciatica showed continuous reduction in back and leg pain during the one-month observation period following a single epidural injection of SP-102.

This study demonstrated that at an equivalent initial dose of dexamethasone, the systemic exposure to dexamethasone following epidural injection of SP-102 did not exceed the exposure following intravenous injection of the RLD. The PD effects, measured as white blood cell count, cortisol levels and glucose levels, as well as the tolerability profile, were similar between the two treatments. SP-102 injections were generally well tolerated and did not result in new unexpected side effects. We believe this trial supports a 505(b)(2) NDA, utilizing the known systemic safety of the FDA-approved RLD dose.

Toxicology Studies - Study Nos. 1014-1512 and 1014-2847

We conducted PK and toxicology studies in two non-rodent animal species to assess SP-102 administered via epidural and intrathecal routes with single and multiple dose regimens. Pharmacokinetically, a prolonged increase in the active dexamethasone metabolite was consistent with the extended residence time of the viscous gel formulation of SP-102 at the site of injection. There were no new unexpected toxicology findings apart from well-characterized toxicity findings commonly observed with administration of dexamethasone sodium phosphate. Based on these studies, we selected the 10mg dexamethasone in 2mL volume dose for our further clinical studies. This selection was endorsed by the FDA during our pre-IND meeting.

Preclinical Toxicology Study - UPD003-IS21

We conducted a preclinical toxicology study designed to simulate the accidental introduction of epidural steroids into arterial blood vessels providing blood supply to the spinal cord, which is a major cause of neurological complications associated with current administration of suspension steroids containing particulates. A 2 mL (10 mg of dexamethasone) injection of SP-102 was injected over one to two minutes into the vertebral artery of large animal species.

Pre- and post-dose angiography showed no remarkable changes and all animals survived for approximately 24 hours until euthanasia. The veterinary animal health report and the pathology report concluded there were no vascular, spinal cord or brain injuries associated with injection into the vertebral artery of the animals.

Hydrodynamic Study - SP-PC002

We conducted a hydrodynamic study of SP-102 in non-rodent animal species, which showed that epidural administration of SP-102 demonstrated an increased local residence half-life and a decreased flow from the injection site.

Hydrodynamic Study - SP-PC002 Epidural Injection Time Course: SP-102 Post-injection in 2 mL SP-102 (DSP 5 mg/mL; 1.25% HA) + 647 mg iohexol vs. Commercial DSP:

Intravascular Injection Study - SEM-005

We conducted a study to evaluate the accidental intravascular injection of SP-102 into the vertebral artery of non-rodent animals. There were no adverse clinical signs associated with the accidental intra-arterial injection of SP-102 following a 24-hour survival period.

Sales and Marketing

We intend to leverage the robust and integrated commercial infrastructure and dedicated sales force and sales

management, marketing, medical affairs and managed care capabilities, manufacturing and general administration functions of our parent company, Scilex, to commercialize our current and future product candidates, if approved. Scilex has successfully launched three commercial non-opioid pain management products in the past five years by using its in-house sales force and an outsourced sales force, who typically bring strong, proven experience promoting a broad scope of pain management products, as our current and future product candidates are commercialized. Scilex's sales representatives leverage their established relationships with pain management HCPs to call on over 6,000 target pain specialists, neurologists, and select health care providers and we believe these same call points that are providing treatment for sciatica could benefit from SP-102, if approved. Scilex's marketing team has expertise in pain management and has already launched three products in the pain market, and we intend to leverage Scilex's marketing expertise to launch SP-102. In connection with the closing of the Business Combination, we entered into the Transition Services Agreement with Scilex, pursuant to which we can utilize certain employees and other service providers of Scilex 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. During the transition period and leveraging Scilex's infrastructure, we will be able to develop our own infrastructure with Scilex's continued support and as we enter the final stages of development and pre-launch commercialization planning, we plan to increase the number of full time employees to strengthen our research and development, general administrative, manufacturing, regulatory and commercial functions. The term of the Transition Services Agreement is three years following the closing of the Business Combination, which we believe is sufficient time for us to develop our commercial infrastructure and other business functions. See the section titled "*Risk Factors — Risks Related to Our Relationship with Scilex*" elsewhere in this Annual Report.

We have created cross functional launch teams and developed a launch playbook to guide us towards a successful launch. The launch will be guided by the playbook activities and timelines briefly summarized below:

- **Patient journey**: Learn how a patient moves through the disease state and how the patient is treated from the early to late stages of the disease.
- **HCP segmentation and profiling**: Understand how to group physicians based on their prescription practices and other behaviors and factors that will influence their prescription practices.
- **Patient segmentation and profiling**: Divide patients with sciatica into groups, according to gender, insurance type, state of disease, and any other factors that will help identify ways to increase SP-102's utilization in each group of patients.
- **HCP and patient research**: HCP research on how physicians treat sciatica, what are the unmet needs, what type of product physicians want to use to treat sciatica, and their expectations from the new product. Patient research provides us with information regarding how satisfied patients are with the current treatments, where the current treatments fall short, and their expectations on the new treatments.
- **Marketing conditioning campaign development**: Determine how to condition the market, including by identifying the current short falls and unmet needs in current treatments, ways to highlight these prior to launch, and the expectations for the new treatments.
- **Product positioning**: Position the product by highlighting physician feedback on the product (e.g., safety, efficacy and length of effectiveness).
- **Branded campaign development and testing**: Develop key messages around the benefits of SP-102.
- **Campaign materials and temporary billing/coding reference guide**: Develop materials for launch and promotion of SP-102 and develop billing codes guidelines for physicians to charge insurance for SP-102.
- **Omnichannel promotion material development**: Develop promotion materials for various channels, ensuring a consistent message, design and tone. These materials could include materials to sales representatives, journal advertisement, direct communication to patient and congress materials.
- **Trade name submission to FDA**: Submit the trade name to FDA prior to filing NDA.
- **OPDP submission strategy**: Submit launch materials to FDA based on the approved prescribing label.

- **Packaging research**: Conduct research on packaging methods with customers, including pharmacists, physicians, nurses, and people who handle the product, to ensure the packaging is convenient for those using SP-102.
- **Baseline/Pre-launch HCP ATU**: Based on product profile messaging, discuss with physicians how they intend to prescribe the product to patients, what key messages resonate with them, and their awareness of SP-102. This is to determine which patients are fit to use the product. This is usually done prior to launch and every six to nine months thereafter for the first two to three years.
- **Quant demand study**: Discuss with physicians anticipated patient demand for, and physician prescription of, SP-102 as well as dosage requirements. This information will help us develop an accurate forecast and plan for sufficient supply of the product.
- **Forecast refresh**: Ongoing analysis of product demand, patient usage, physician feedback, reimbursement levels and other matters that may impact the use of SP-102 and update our forecast accordingly.

Clinical Development and Regulatory

Our clinical development team, which, as discussed above in further detail, consists of dedicated Scilex employees and contractors, includes in-house medical expertise and clinical development experts. The clinical development team works with our CRO to identify sites for clinical trials, support the investigator teams and develop publication plans for our product candidate. Additionally, the clinical development team also works with Key Opinion Leaders, professional societies and patient advocacy groups to educate on and support the appropriate use of pain therapeutics. Our clinical development team is responsible for determining registration or supportive studies, overseeing post-approval studies and supporting investigator-sponsored trials. Our regulatory team includes in-house and consultant regulatory professionals as well as ex-FDA regulatory expert advisors. We contract external regulatory group for publishing and performing submissions to the FDA and other regulatory agencies, including Health Canada.

Manufacturing and Supply Chain

We currently contract with third parties for the manufacture, assembly, testing, packaging and storage of our product candidate. Our technical team has extensive pharmaceutical development, manufacturing, analytical, quality and distribution experience and is qualified and capable of managing manufacturing and supply chain operations. Our Quality System, Standard Operating Procedures and contract manufacturing organizations ("CMOs") comply with cGMP and regulatory requirements. We selected our CMOs for specific competencies having met our development, manufacturing, quality and the FDA regulatory requirements. These CMOs manufacture our clinical supplies and commercial batches. We currently have no plans to build our own manufacturing or distribution infrastructure.

As clinical trial development progresses forward, we will continue to explore both internal capabilities as well as deepening and expanding external relationships to ensure we meet our manufacturing requirements.

SP-102 is a Phase 3 sterile dexamethasone sodium phosphate injectable viscous gel drug product containing dexamethasone sodium phosphate equivalent to 10 mg dexamethasone in a pre-filled glass syringe with a 2 mL deliverable volume. SP-102 also contains sodium hyaluronate, which is a novel, biocompatible, viscosity- enhancing excipient and is listed in the European Pharmacopeia. Historically, we have purchased our clinical and commercial supply requirements for sodium hyaluronate, one of the excipients for SP-102, from Genzyme pursuant to a supply agreement, which terminated as of May 31, 2024. We anticipate that our current supply of sodium hyaluronate will be sufficient to satisfy our clinical and commercial supply requirements for sodium hyaluronate for at least 12 months following our expected commercial launch of SP-102 in 2028. We are currently in discussions with Sanofi, an affiliate of Genzyme, and are in the process of identifying and certifying new suppliers, in each case to fulfill our future supply requirements for sodium hyaluronate. SP-102 is manufactured by a single-source manufacturer, which supports the clinical development, including the completed Phase 3 clinical trial of SP-102. In March 2022, we announced final results of the Phase 3 clinical trial, satisfying the primary and key secondary endpoints. The manufacturing process is proprietary and includes trade secrets.

We plan to engage our existing contract manufacturer, Lifecore, for the commercial production of SP-102, if approved. See the section of this Annual Report titled "*Business — Material Agreements — Lifecore Master*

Services Agreement" for additional information regarding the manufacturing of our SP-102 product.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. The large size and expanding scope of the pain management market makes it an attractive therapeutic area for biopharmaceutical businesses. Our potential competitors include pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of these companies have drug product pipelines, readily available capital, and established research and development organizations.

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 ESIs indicated for the treatment of sciatica, we are aware of certain non-steroid product candidates in development. SP-102, if approved, will compete with various opioid pain medications, 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 the 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 drug products as well as drug products 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.

The key competitive factors affecting the success of SP-102 are likely to be its clinical benefit, durability, tolerability, price, intellectual property protection, and the availability of reimbursement from government and other third-party payors.

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. As of December 31, 2025, the transaction has not closed and accordingly, shares have not been issued and funds have not been received. As the transaction did not close on or before December 31, 2025, the nonbreaching party has an option to terminate the PIPE SPA without

liability.

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

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 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. As of December 31, 2025, the transaction has not closed and accordingly, shares have not been issued and funds have not been received. As the transaction did not close on or before December 31, 2025, the nonbreaching party has an option to terminate the Semnur/Biconomy SPA without liability.

Promissory Notes

As of December 31, 2025, we have promissory notes totaling $3.5 million, 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, Legacy Semnur 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, Legacy Semnur 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.

The foregoing is a summary of the material terms of the Lifecore Master Services Agreement and the amendments thereto in the forms filed as exhibits to this Annual Report. You should read the form of the agreement and its amendments for a complete understanding of all of their respective terms.

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"),

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 NDA 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.

The foregoing is a summary of the material terms of the Legacy Semnur Merger Agreement (including the amendment thereto) in the forms filed as exhibits to this Annual Report. You should read the Legacy Semnur Merger Agreement (including the amendment thereto) for a complete understanding of all of their respective terms.

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 royalties 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 Investor is not related to Jaisim Shah, our Chief Executive Officer, and Jaisim Shah has no direct or indirect material interest in the Shah Assignment Agreement.

The foregoing is a summary of the material terms of Shah Assignment Agreement in the form filed as an exhibit to this Annual Report. You should read the Shah Assignment Agreement for a complete understanding of all of its terms.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our novel adhesion and delivery technology, inventions, improvements and product candidates that are important to the development and implementation of our business. Our patent portfolio is intended to cover our product candidates, their methods of use and processes for their manufacture, and any other inventions that are commercially important to our business. We also rely on trade secret protection of our confidential information and know-how relating to our novel adhesion and delivery technology, platforms and product candidates.

Generally, patents are granted a term of 20 years from the earliest claimed non-provisional filing date. In certain instances, the patent term can be adjusted to recapture a portion of delay by the U.S. PTO in examining the patent application or extended to account for term effectively lost as a result of the FDA regulatory review period, or both. We cannot provide any assurance that any patents will be issued from our pending or future applications or that any patents will adequately protect our product or product candidates.

Our patent portfolio, consisting of owned and/or licensed IP as of December 31, 2025 contains approximately seven issued and unexpired U.S. patents and two pending U.S. patent applications. Our portfolio also includes certain foreign counterparts of these patents and patent applications including in most major international markets.

With respect to our product candidate SP-102, the patents and patent applications that we own include formulations and methods of treatment. The patents are U.S. Pat. Nos. 10,500,284, 10,117,938, and 11,020,485, all of which expire in 2036. We continue to seek to maximize the scope of our patent protection for all our programs.

We believe that we have certain know-how and trade secrets relating to our technology and product candidate. We rely on trade secrets to protect certain aspects of our technology related to our current and future product

candidate. However, trade secrets can be difficult to protect. We seek to protect our trade secrets, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, service providers, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Trademarks, Trade Secrets and Other Proprietary Information

We file trademark applications and pursue registrations in the United States and abroad when appropriate. We own pending trademark applications for "SEMNUR PHARMACEUTICALS" and "SEMDEXA" in the United States.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, we rely on trade secret protection and confidentiality agreements to protect our interests. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we will own all inventions conceived by the individual in the course of rendering services to us.

SP-102 benefits from our substantial intellectual property portfolio and other technical barriers to entry for potential competitors. Historically, we have purchased our clinical and commercial supply requirements for sodium hyaluronate, one of the excipients for SP-102, from Genzyme pursuant to a supply agreement, which terminated as of May 31, 2024. We are currently in discussions with Sanofi, an affiliate of Genzyme, and are in the process of identifying and certifying new suppliers, in each case to fulfill our future supply requirements for sodium hyaluronate. Our complex manufacturing process, specialized equipment and know-how for sterile viscous product candidates are also key to our competitive edge. We believe that our competitors will be required to conduct lengthy and costly preclinical and clinical trials to establish products with comparable tolerability profiles and clinical benefit to SP-102.

Government Regulation and Product Approval

Government authorities in the United States at the federal, state and local levels, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, pricing, reimbursement, sales, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are marketing and developing. SP-102 and any other product candidate that we develop must be approved by the FDA or otherwise authorized for marketing before they may be legally marketed in the United States and by the corresponding foreign regulatory agencies before they may be legally marketed in foreign countries. The processes for obtaining marketing approvals, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the FDCA and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process or after approval, may subject an applicant or its products to a variety of administrative or judicial sanctions, such as imposition of a clinical hold, the FDA's refusal to approve pending applications, withdrawal of an approval, inspection scrutiny, issuance of untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, or reimbursements, restitution, disgorgement of profits or other civil or criminal penalties. The process required by the FDA before a drug product may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to GLPs or other applicable regulations;

- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- approval by an IRB covering each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the laws and regulations pertaining to the conduct of human clinical trials, collectively referred to as GCP requirements to establish the safety and efficacy of the proposed drug product for its proposed indication;
- submission to the FDA of an NDA or other marketing application, for a proposed new drug product, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacturing and quality controls, as well as proposed labeling for the drug candidate;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection ("PAI") of the manufacturing facility or facilities where the drug substance, drug product, packaging components and device are produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, manufacturing, methods and controls are adequate to preserve the drug product's identity, strength, quality and purity;
- potential FDA audit of the preclinical study and clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA prior to any commercial marketing, sale, distribution or shipment of the drug product.

Before testing novel compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage, also referred to as preclinical studies. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug product candidate. The conduct of the preclinical studies must comply with federal laws and requirements including GLPs. The IND sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, and any available clinical data or literature, to the FDA as part of the IND. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. Some preclinical studies may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug product candidate at any time before or during clinical trials due to safety concerns, non-compliance, or for additional reasons. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy subjects or patients with the target disease under the supervision of qualified investigators, generally physicians not employed by the trial sponsor. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, subject selection and exclusion criteria, dosing procedures, and the parameters to be used to collect data and to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND, and timely safety reports must be submitted to the FDA and investigators for suspected adverse reactions that are serious and unexpected and other safety-related findings. Clinical trials must be conducted in accordance with applicable statutes, the FDA's regulations and GCP requirements. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to and signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until it is completed. In some instances, additional oversight boards, such as a data safety monitoring board, are required to evaluate interim data and determine whether a study should continue or be modified or terminated.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign

clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with GCP, including review and approval by an independent ethics committee (IEC) and informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary. Information about many clinical trials is required to be publicly reported on www.ClinicalTrials.gov or similar databases.

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

- ***Phase 1***. The drug product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted only in patients having the specific disease.
- ***Phase 2***. The drug product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule for patients having the specific disease.
- ***Phase 3***. The drug product is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the safety and efficacy of the product for potential approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA. In some cases, the FDA may approve a drug product based on the results of a single adequate and well-controlled Phase 3 trial for excellent design and which provided highly reliable and statistically strong evidence of important clinical benefit. The FDA's decision to approve a drug product using the results of a single adequate and well-controlled Phase 3 trial depends both on the quality and quantity of the evidence and considers trial design, trial endpoints, and statistical methodologies, as well as the availability of other confirmatory evidence or reliance on a previous finding of effectiveness of an approved drug when scientifically and legally permissible.

The Company's planned NDA application for SP-102 will not seek approval based on the results of a single adequate and well-controlled Phase 3 trial. The Company initiated Phase 3 CLEAR 2 trial in September 2025 (as described in more detail elsewhere in this Annual Report under the section titled "*Business — Our Company*").

Post-approval studies, also referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the status of drug product development and results of the clinical trials must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for suspected adverse reactions that are serious and unexpected (including increased rate of occurrence of such adverse reactions), findings from other studies that suggest a significant risk in humans exposed to the drug product, or any findings from tests in laboratory animals that suggests a significant risk for human subjects or patients. Phase 1, Phase 2 and Phase 3 clinical trials may not yield positive results, or may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug product has been associated with unexpected serious harm to study subjects.

During the development of a new drug product, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, the end of Phase 3 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end of Phase

2 meeting to discuss their Phase 2 clinical results and present their plans for the Phase 3 clinical trials or manufacturing process validation and testing and their pre-NDA meeting to discuss the data that they believe will support approval of the new drug product.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug product as well as validate a process for commercial manufacturing the drug product in accordance with cGMP requirements. The commercial manufacturing process must be capable of consistently and continuously producing quality batches of the drug product candidate and, among other things, the manufacturer must develop appropriate methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug product candidate does not undergo unacceptable deterioration over its shelf life.

FDA Review and Approval Processes

The results of product development, preclinical studies and clinical trials for the claimed indications are incorporated into an NDA requesting approval to market the product. The application may include both negative or ambiguous results of preclinical trials as well as positive findings.

In addition, proposed labeling and descriptions of the manufacturing process and controls, analytical tests conducted on the chemistry of the drug product, proposed labeling and other relevant information are required to be submitted to the FDA as part of an NDA. The submission of an NDA is subject to the payment of substantial user fees and a waiver of such fees may be obtained under certain limited circumstances.

The FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for the specified indication(s), and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the product's safety and efficacy to the satisfaction of the FDA. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of 10 months from the date of "filing" of a standard, original NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accepting an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

After the NDA is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with cGMP requirements. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA conducts its own analysis of the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of an NDA by the FDA is extensive and time-consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

During the drug product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure the safe use of the drug product. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without a REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

Before approving an NDA, the FDA will generally inspect the facilities at which the product is to be manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. If the FDA determines that the application, manufacturing process or manufacturing

facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug product with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 trial or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, referred to as Phase 4 testing, which involves clinical trials designed to further assess a product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA administers a number of different programs that enable the agency and sponsors in various ways to expedite the development or agency review of a new drug product. Among these, the FDA has a fast track designation that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. New drug products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. As an example of the modified processes available to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug product designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of other NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require that a sponsor of a drug product receiving accelerated approval perform additional adequate and well-controlled post-marketing clinical trials. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product approved under the accelerated approval pathway. FDA has issued draft guidance that proposes criteria it will evaluate to determine if a trial is underway, including whether enrollment in the trial has been initiated. Since the FDORA amendments, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires as a condition for accelerated approval pre-use submission of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval

do not change the standards for approval but may expedite the development or approval process.

The Food and Drug Administration Safety and Innovation Act established a category of drug products referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek the FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug product if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work with the sponsor to expedite the development and review of such drug product.

With passage of the 21st Century Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Pediatric Trials

Under the Pediatric Research Equity Act, a marketing application for a drug or biological product for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor submit an initial Pediatric Study Plan ("PSP") within 60 days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The FDA and the sponsor must reach agreement on the PSP. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct or a justification for not including certain required information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may grant deferrals for the development and submission of pediatric data or full or partial waivers after the initial submission of a PSP.

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown risks or problems with a product may result in labeling changes, restrictions on the product or even complete withdrawal of the product from the market. After approval, most changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug product manufacturers and other entities involved in the manufacture and distribution of approved drug products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. In addition, the FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences or quality issues with the product, providing the FDA with updated safety and efficacy information, satisfaction of post-approval requirements or commitments, product sampling and distribution requirements, tracking and tracing requirements and complying with FDA promotion and advertising requirements. These promotion and advertising requirements include, among other things, standards for direct-to-consumer advertising, prohibitions against promoting drug products for uses, or in patient populations, that are not described in the drug product's approved labeling, which is

known as "off-label use," rules for conducting industry-sponsored scientific and educational activities, and promotional activities involving the internet. Failure to comply with post-approval requirements can have negative consequences, including adverse publicity, enforcement letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties. Although physicians may prescribe legally available drug products for off-label uses, manufacturers may not market or promote such off-label uses. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant, manufacturer or product to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-approval clinical trials, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Hatch-Waxman Amendments

Section 505 of the FDCA describes three types of NDAs that may be submitted to request marketing authorization for a new drug product, the first being a 505(b)(1) NDA. A 505(b)(1) NDA is an application that contains full reports of investigations of safety and effectiveness. A 505(b)(2) NDA likewise contains full reports of investigations of safety and effectiveness relevant to a product, but where at least some of the information required for approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. This regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product (the "listed drug"), or published literature, in support of its application. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product candidate for all or some of the labeled indications for which the listed product has been approved, or for any new indication sought by the 505(b)(2) applicant.

Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an abbreviated new drug product application ("ANDA"). An ANDA generally provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form, and with the same labeling and route of administration as the listed drug product and has been shown to be bioequivalent to the reference listed drug product. ANDA applicants are required to conduct bioequivalence testing to confirm chemical and therapeutic equivalence to the branded reference drug product. Generic versions of drug products can often, and sometimes must, be substituted by pharmacists under prescriptions written for the branded reference drug product.

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Upon approval, each of the patents listed by the NDA sponsor is published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA at least one of the following (1) no patent information on the drug product that is relied upon by the ANDA or 505(b)(2) NDA (known as the reference drug product) has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the drug product for which the ANDA or 505(b)(2) NDA is submitted. This last certification is known as a Paragraph IV Certification. If the NDA holder for the reference drug product or patent owner(s) asserts a patent challenge to the Paragraph IV Certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the Paragraph IV Certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug product sponsor's or patent owner's decision to initiate patent litigation.

In addition to, and distinct from the patent protection provisions, the Hatch-Waxman Amendments establish periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug product. For example, the holder of an NDA may obtain five years of exclusivity upon approval of a new drug product containing a new chemical entity that has not been previously approved by the FDA. The Hatch-Waxman Amendments also

provide three years of marketing exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for drug products that include the innovation that required the new clinical data, but generally allows the approval for non-protected characteristics and labeling.

Third-Party Payor Coverage, Pricing and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, sales of a product will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for the product. Third-party payors include government payor programs at the federal and state levels, including Medicare and Medicaid, managed care providers, private health insurers and other organizations. In the United States, the principal decisions about reimbursement for new drug products are often made by the Centers for Medicare and Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS). CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for products exists among third-party payors. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication, and which can change over time. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs, in order for the company's products to be considered as a formulary option. Nonetheless, product candidates may not be considered by individual payors to be medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that a preferred formulary position or an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drug products. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as our products and the product candidates that we are developing and could adversely affect our net revenue and results. See the discussion below under "*U.S. Healthcare Reform*", and regarding the Inflation Reduction Act for further information.

Different pricing and reimbursement schemes exist in other countries. In the European Economic Area ("EEA") (which is currently comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein), governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some countries in the EEA operate positive and negative list systems under which some medicinal products are selected for coverage (positive list) and others are explicitly listed as excluded from reimbursement (negative list). To obtain reimbursement or pricing approval, some of these EEA countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product to currently available therapies. Other EEA countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drug products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border

imports from low-priced markets exert a commercial pressure on pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our products.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Affordable Care Act (the "ACA") was enacted, which is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, and which substantially changes the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (1) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (2) prescribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drug products that are inhaled, infused, instilled, implanted or injected, (3) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (4) established annual nondeductible fees on manufacturers of certain branded prescription drug products, apportioned among these entities according to their market share in certain government healthcare programs, (5) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drug products to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drug products to be covered under Medicare Part D, (6) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (7) expanded the entities eligible for discounts under the 340B Public Health Service Act program, (8) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research, and (9) established a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug product spending.

Since its enactment, there have been judicial, Congressional and Administrative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, legislation affecting the implementation of certain taxes under the ACA has been signed into law. The TCJA included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Further, the Bipartisan Budget Act of 2018 (the "BBA"), among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owned by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is unclear how additional healthcare reform measures of the Trump or subsequent administrations or other efforts, if any, to modify or invalidate the ACA or its implementing regulations, or portions thereof, will impact our business. For example, on July 4, 2025, legislation commonly referred to as the One Big Beautiful Bill Act was signed into law, which reduced funding to federal healthcare programs and imposed additional requirements to be eligible for healthcare, which may result in decreased access to healthcare, particularly in Medicaid programs. Any health care reform measures will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or other policy or the impact of potential legislation or other policy on us.

Other legislative and administrative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. For example, the Budget Control Act of 2011, among other things, in connection with subsequent legislation, reduced Medicare payments to providers, on average, by 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the

statute, including the BBA, will remain in effect through 2032. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may impact the ability of relevant agencies to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On August 16, 2022, former President Biden signed into law the Inflation Reduction Act of 2022, which among other things, contains two specific provisions affecting pricing for drug products and biologics. The first provision allows for CMS to negotiate prices for certain single-source drug products and biologics reimbursed under Medicare Part B and Part D, beginning with 10 high-cost drug products paid for by Medicare Part D starting in 2026, followed by 15 Part D drug products in 2027, 15 Part B or Part D drug products in 2028, and 20 Part B or Part D drug products in 2029 and beyond. The legislation subjects drug product manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering 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. The legislation also caps Medicare beneficiaries' annual out-of-pocket drug product expenses at $2,000. The second provision imposes a requirement that pharma manufacturers provide a rebate to Medicare, if the manufacturer increases price at a rate higher than the measured inflation rate. Medicaid has had a rebate program for several years, but Medicare did not. The intent is to limit price increases. The new rebate applies to drug products covered by Medicare under Part B or Part D. Various industry stakeholders, including pharmaceutical companies, have lawsuits pending against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. HHS has generally won the substantive disputes in these cases, but certain of these cases continue to be appealed. The current Administration has also issued public statements and other executive orders about its commitment to lowering the cost of prescription drugs and has sought additional voluntary agreements to reduce drug pricing from certain pharmaceutical manufacturers. At the state level, legislatures are increasingly passing legislation and implementing 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. In some cases, states appear interested in public policy designed to encourage drug product importation from other countries and bulk purchasing. In January 2024, the FDA authorized Florida's Agency for Health Care Administration's drug importation program, which is the first step toward Florida facilitating importation of certain prescription drugs from Canada. Authorization of other state programs may follow as other states have submitted importation program proposals. The Trump Administration has publicly supported such state-directed importation programs, and FDA has taken steps to facilitate such states in initiating such 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.

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

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services (*e.g.*, the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. For example, various activities, including but not limited to sales, marketing and

scientific/educational grant programs, must comply with the anti-fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the federal False Claims Act and similar state laws, each as amended. Failure to comply with such requirements could potentially result in substantial penalties to us. Even if we structure our programs with the intent of compliance with such laws, there can be no certainty that we would not need to defend against enforcement or litigation, in light of the fact that there is significant enforcement interest in pharmaceutical companies in the United States, and some of the applicable laws are quite broad in scope.

The federal Anti-Kickback Statute prohibits any person, including a pharmaceutical manufacturer (or a party acting on its behalf), from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other.

The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain business arrangements from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from federal Anti-Kickback Statute liability. The government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that 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 (discussed below) or the civil monetary penalties statute, which imposes fines against any person who is determined to have presented or caused to be presented claims to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute, and some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payor, not only the Medicare and Medicaid programs in at least some cases, and do not contain safe harbors.

The federal False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment of government funds, or knowingly makes, uses, or causes to be made or used a false statement material to a false or fraudulent claim, or knowingly conceals or knowingly and improperly avoids, or decreases an obligation to pay money to the government. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claims laws analogous to the False Claims Act. Some of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price ("AMP"), improper promotion of off-label uses (*i.e.*, uses not expressly approved by the FDA in a drug product's label), and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance.

The healthcare fraud provisions under the U.S. federal Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("HIPAA") impose criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, or falsifying or covering up a material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We may be subject to, or our marketing activities may be limited by, data privacy and security law and regulation promulgated by both the U.S. federal government and the U.S. states in which we conduct our business. For example, under HIPAA, the U.S. Department of Health and Human Services imposes upon "covered entities" (broadly, healthcare providers, health plans and healthcare clearinghouses) and their respective "business associates" (individuals or entities that create, receive, maintain or transmit protected health information on behalf of a covered entity) the HIPAA Privacy and Security Rules which include privacy obligations; requirements to implement appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information; and breach response notification obligations. Although we are neither a covered entity nor business associate, and therefore not subject to the HIPAA Privacy and Security Rules, we must monitor developments with these requirements for changing obligations that may apply to us. The FTC also requires companies to take appropriate steps to keep consumers' personal information secure and to make accurate statements regarding how they secure personal information under their custody or control, such as in a privacy notice. The FTC also expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of personal information it holds, the size and complexity of its business, and the cost of available tools to improve data security and reduce vulnerabilities. Individually identifiable health information, which we process, is considered sensitive data that merits stronger safeguards. Violations of the foregoing FTC requirements may constitute unfair or deceptive acts or practices under Section 5(a) of the Federal Trade Commission Act (the "FTC Act"). While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to bring enforcement actions based on the FTC's interpretation of public privacy statements. Further, events that we cannot fully control, such as data breaches, may also result in civil penalties, FTC enforcement or enforcement by U.S. state attorneys general or other regulators. Various U.S. states have implemented privacy laws and regulations that regulate the use and disclosure of health information and other personal information. For example, the CCPA, established a privacy framework for covered businesses by, among other items, expanding the definition of personal information, establishing new data privacy rights for consumers who are California residents, imposing rules on the collection of personal information from minors, and creating a statutory damages framework for violations of the CCPA, including for failure to implement reasonable security procedures and practices to prevent data breaches. Penalties for violations of the CCPA include civil penalties and may result in related legal claims. The CPRA, most provisions of which became operative on January 1, 2023, introduced significant amendments to the CCPA and established and funded a dedicated California privacy regulator, the California Privacy Protection Agency. Several other states have implemented similar consumer privacy laws that took effect in the past year or will take effect in the near future. Further, Washington's My Health My Data Act, taking effect July 1, 2024, imposes requirements specific to consumer health data. The foregoing U.S. state privacy laws impose many similar obligations as the CCPA on our processing of personal information. Other U.S. states are considering similar privacy legislation, and industry organizations regularly adopt and advocate for new standards in these areas. The uncertainty, ambiguity, complexity, and potential inconsistency surrounding the implementation and interpretation of the CCPA and other enacted or forthcoming U.S. state privacy laws exemplify the vulnerability of our business to the evolving regulatory environment related to the privacy, security and confidentiality of personal information and protected health information. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

Our activities outside of the U.S. implicate local, state, provincial, and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. Such laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers, or to remediate issues caused by such breaches. Compliance with these laws is challenging, constantly evolving, time consuming, and requires a flexible privacy framework and substantial resources. Compliance efforts will likely be an increasing and substantial cost in the future.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drug products, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition to this federal requirement, a number of individual states and foreign jurisdictions require detailed reporting and often public disclosures concerning transfers of value to physicians, other health care providers and family members. Effective January 1, 2022, these reporting obligations were extended to include transfers of value made to certain non-physician providers such as physician

assistants and nurse practitioners.

Compliance with such requirements may require investment in infrastructure to ensure that tracking is performed properly, and some of these laws result in the public disclosure of various types of payments and relationships.

Several states have enacted legislation requiring pharmaceutical companies to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, or register their sales representatives, as well as prohibiting pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and prohibiting certain other sales and marketing practices. These laws may affect our sales, marketing and other promotional activities by imposing administrative burdens on us. If we fail to track and report as required by these laws or otherwise comply with these laws, we could be subject to the penalty provisions of the pertinent state and federal authorities.

Where our activities involve foreign government officials, they may also potentially be subject to the FCPA. If we seek to have a product paid for with federal funds under the Medicaid programs or Medicare Part B, various obligations, including government price reporting, are required under the Medicaid rebate provisions of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, each as amended, which generally require products to be offered at substantial rebates/discounts to such programs and certain purchasers. Government price reporting may also be required with respect to average sales price, which serves as the basis of reimbursement under Medicare Part B. In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Many of our current as well as possible future activities are potentially subject to federal and state consumer protection and unfair competition laws. We must also comply with laws that require clinical trial registration and reporting of clinical trial results on the publicly available clinical trial databank maintained by the National Institutes of Health ("NIH") at www.ClinicalTrials.gov. We are subject to various environmental, health and safety regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous substances. From time to time, and in the future, our operations may involve the use of hazardous materials.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts, integrity oversight and reporting obligations to resolve allegations of non-compliance, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to HCPs.

U.S. Marketing Exclusivity

Hatch-Waxman Exclusivity. Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's NDA. If the new drug product is a new chemical entity subject to an NDA, the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug product is a new chemical entity if the FDA has not previously approved any other new drug product containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. This definition is currently under FDA review. During the exclusivity period, the FDA may not accept for review an ANDA or a Section 505(b)(2) NDA submitted by another company for another version of such drug product where the applicant does not own or have a legal right of reference to all the data required for approval. However, such an application may be submitted after four years if it contains a certification of patent invalidity or

non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, such as new indications, dosages or strengths of an existing drug product. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drug products containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to any existing exclusivity period or patent term. This six-month exclusivity may be granted by the FDA based on the completion of a pediatric clinical trial in accordance with provisions of the FDCA.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, pricing and reimbursement, anti-bribery, advertising and promotion, data privacy and security and any commercial sales and distribution of our future products.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials.

In the EEA, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with the EU Clinical Trials Directive 2001/20/EC (the "Clinical Trials Directive") and the related national implementing provisions of the relevant individual EEA country's requirements, the clinical trial described in that CTA may proceed.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (the "Clinical Trials Regulation") was adopted. The Clinical Trials Regulation entered into force on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EEA countries, repealing the prior Clinical Trials Directive. The new Clinical Trials Regulation allows a sponsor to start and conduct a clinical trial in accordance with the Clinical Trials Directive during a transitional period of one year after the application date, i.e. January 31, 2022. The transition period for the trials ongoing at the moment of applicability will be a maximum of three years after the date of application of the Clinical Trials Regulation. Clinical trials authorized under the current Clinical Trials Directive before January 31, 2023 can continue to be conducted under the Clinical Trials Directive until January 31, 2025. The new Clinical Trials Regulation is intended to simplify and streamline the approval of clinical trials in the EEA. The main characteristics of the regulation include: a streamlined application procedure through a single entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided into two parts.

For other countries outside of the EEA, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origins in the Declaration of Helsinki.

In the EEA, medicinal products can be commercialized only after obtaining a Marketing Authorization ("MA"). There are several procedures for requesting marketing authorization which can be more efficient than applying for authorization on a country-by-country basis. There is a "centralized" procedure allowing submission of a single marketing authorization application to the EMA. If the EMA issues a positive opinion, the European Commission will grant a centralized marketing authorization that is valid in all EEA countries.

The "centralized" procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The

"centralized" procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EEA.

There is also a "decentralized" procedure allowing companies to file identical applications to several EEA countries simultaneously for product candidates that have not yet been authorized in any EEA country and a "mutual recognition" procedure allowing companies that have a product already authorized in one EEA country to apply for that authorization to be recognized by the competent authorities in other EEA countries. Under the "decentralized" procedure, an identical dossier is submitted to the competent authorities of each of the EEA countries in which the MA is sought, one of which is selected by the applicant as the Reference Member State ("RMS"). If the RMS proposes to authorize the product, and the other EEA countries do not raise objections, the product is authorized in all the EEA countries where the authorization was sought. Before granting the MA, the EMA or the competent authorities of the EEA countries make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

In many countries outside the United States, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of a MA. Many EEA countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EEA countries will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some EEA countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EEA country, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA countries. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EEA countries, although the HTA Regulation, which aims to harmonize the clinical benefit assessment of HTA across the EEA, will apply from January 12, 2025. If we are unable to maintain favorable pricing and reimbursement status in EEA countries that represent significant markets, our anticipated revenue from and growth prospects for our products in the EEA could be negatively affected.

Outside the United States, interactions between pharmaceutical companies and physicians are also governed by strict laws, such as national anti-bribery laws of EEA countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

In the EEA, the advertising and promotion of our products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with a marketing authorization approval. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EEA. Other applicable laws at the EEA level and in the individual EU Member States also apply to the advertising and promotion of medicinal products, including laws that prohibit the direct-to-consumer advertising of prescription-only medicinal products and further limit or restrict the advertising and promotion of our products to the general public and to health care professionals. Violations of the rules governing the promotion of medicinal products in the EEA could be penalized by administrative measures, fines and imprisonment.

In addition to data privacy and security regulations in the United States, we may be subject to, or our marketing activities may be limited by, data privacy and security regulations in the EEA, Switzerland, or the United Kingdom ("UK"), where the legislative and regulatory landscape continues to evolve. There has been increased regulator attention to privacy and data security issues that could potentially affect our business, including through legislation

such as the EEA GDPR (as defined below) and UK GDPR, which each imposes strict obligations on the processing of personal data, including the transfer of personal data from the EEA, Switzerland, or UK to third countries that the European Commission has determined does not ensure an adequate level of protection, such as the United States. If we violate the GDPR, we may face significant penalties of up to EUR 10,000,000 or 2% of our total worldwide annual turnover, or for more serious violations, up to EUR 20,000,000 or 4% of our total worldwide annual turnover.

The GDPR and other EEA and UK data privacy and security regulations generally restrict the transfer of personal data from the EEA, UK and Switzerland, to the United States and certain other third countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards on which companies may rely to import or export personal data from had been the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the U.S. Department of Commerce. However, the EU-U.S. Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union (the "CJEU") in a case known as "Schrems II." Following this decision, the Swiss Federal Data Protection and Information Commissioner (the "FDPIC") announced that the Swiss-U.S. Privacy Shield does not provide adequate safeguards for the purposes of personal data transfers from Switzerland to third countries that are deemed as not providing adequate protection, including the United States. While the FDPIC does not have authority to invalidate the Swiss-U.S. Privacy Shield regime, the FDPIC's announcement casts doubt on the viability of the Swiss-U.S. Privacy Shield as a compliance mechanism for Swiss-U.S. data transfers.

The CJEU's decision in Schrems II also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission's Standard Contractual Clauses, can lawfully be used for personal data transfers from Europe to the United States or other third countries that are not the subject of an adequacy decision of the European Commission. While the CJEU upheld the adequacy of the Standard Contractual Clauses in principle in Schrems II, it made clear that reliance on the Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. Use of the Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred data. In the context of any given transfer, where the legal regime applicable in the destination country may or does conflict with the intended operation of the Standard Contractual Clauses and/or applicable European law, the decision in Schrems II and subsequent draft guidance from the European Data Protection Board (the "EDPB") would require the parties to that transfer to implement certain supplementary technical, organizational and/or contractual measures to rely on the Standard Contractual Clauses as a lawful "transfer mechanism." However, the draft guidance from the EDPB on such supplementary technical, organizational and/or contractual measures appears to conclude that any combination of such measures may not be sufficient to allow effective reliance on the Standard Contractual Clauses in the context of transfers of personal data "in the clear" to recipients in countries where the power granted to public authorities to access the transferred data goes beyond that which is "necessary and proportionate in a democratic society"—which may, following the CJEU's conclusions in Schrems II on relevant powers of United States public authorities and commentary in draft EDPB guidance, include the United States in certain circumstances (e.g., where Section 702 of the U.S. Foreign Intelligence Surveillance Act applies). Further, the UK Information Commissioner's Office has provided for separate international data transfer mechanisms for restricted transfers of data from the UK: an international data transfer agreement (the UK equivalent of the EU Standard Contractual Clauses) ("IDTA") and an international data transfer addendum (which amends the EU Standard Contractual Clauses for purposes of international data transfers from the UK to countries without an essentially equivalent data protection framework) (the "Addendum"). Both the IDTA and the Addendum came into force in March 2022.

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.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions or criminal prosecution.

Employees and Human Capital Resources

As of December 31, 2025, we have 10 full time employees, including three employees who have M.D.s or Ph.D.s As a majority owned subsidiary of Scilex, we have been dependent upon the services provided by Scilex's employees, including the equivalent of three Scilex employees and 12 Scilex contractors providing full time services to us as of December 31, 2025. We expect that those employees of Scilex will devote a portion of their time to our business and affairs on an ad hoc basis as necessary to manage and conduct our operations. As of December 31, 2025, Scilex has 28 full-time employees, including three employees who have M.D.s or Ph.D.s. Within that workforce, four employees were primarily engaged in research and development, seven were primarily engaged in sales and marketing and 17 were primarily engaged in general management and administration. None of Scilex's employees are represented by labor unions or covered by collective bargaining agreements.

In connection with the closing of the Business Combination, we entered into the Transition Services Agreement with Scilex, pursuant to which we can utilize certain employees and other service providers of Scilex 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. 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 that certain senior secured promissory note issued by Scilex to Oramed Pharmaceuticals Inc. ("Oramed") in September 2023 in the principal amount of $101.9 million (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. During the transition period, we plan to engage and increase full-time employees to support our research and development, general administrative, manufacturing, regulatory and commercial functions as we enter the final stage of development and pre-launch commercialization planning. The term of the Transition Services Agreement is three years following the closing of the Business Combination, which we believe is sufficient time for us to develop our commercial infrastructure and other business functions.

Our Corporate History

We were incorporated under the name "Denali Capital Acquisition Corp." 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. On September 22, 2025, in connection with the Business Combination, we changed our jurisdiction of incorporation by deregistering as a Cayman Islands exempted company and continuing and domesticating as a corporation incorporated under the laws of the State of Delaware. On September 22, 2025, we changed our name to "Semnur Pharmaceuticals, Inc."

We are an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we are eligible for exemptions from various reporting requirements 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 and reduced disclosure obligations regarding executive compensation.

Additionally, we are currently a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements.

Website Access to SEC Filings

We file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission ("SEC"). The SEC maintains an Internet website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Semnur. We maintain an Internet website at www.semnurpharma.com. The information contained on our website or that can be accessed through our website does not constitute a part of this report. We make available, free of charge through our Internet website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after we electronically file or furnish this information to the SEC.

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 this Annual Report, including matters addressed in the section of this Annual Report 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 Annual Report 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 consolidated financial statements and the notes to the 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 specialty pharmaceutical 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, 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 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.
- 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, 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 Cryptocurrency

- The Company intends to use the net proceeds of the Biconomy SPA, which as of the date of this Annual Report has not closed and will be paid in Bitcoin, to fund investments in other companies. The price of Bitcoin will likely continue to be highly volatile, which could cause the Company's share price to significantly fluctuate.

- Our cryptocurrency treasury strategy has not been implemented or tested.
- 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.

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

We are a late-stage clinical specialty pharmaceutical 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 years ended December 31, 2025 and 2024, we had net losses of $160.4 million and $4.7 million, respectively. As of December 31, 2025, we had an accumulated deficit of $275.8 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 biopharmaceutical 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 and preclinical and clinical development 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 the 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 December 31, 2025, our cash and cash equivalents were $20 thousand and we had an accumulated deficit of $275.8 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 (as defined below) through an intercompany arrangement between Scilex and Semnur, which arrangement is not currently in place (see section titled "*Legacy Semnur Merger Agreement*" under Note 4 of our consolidated financial statements included elsewhere in this Annual Report for more information);
- 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, are adopted by the physician community;

- our need to expand our research and development activities;
- the costs of acquiring, licensing or investing in businesses, product candidate 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 number of public shares that are redeemed by Denali's public shareholders;
- 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 section titled "*Liquidity and Going Concern*" under Note 1 of our consolidated financial statements included elsewhere in this Annual Report, 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 section titled "*Liquidity and Going Concern*" under Note 1 of our consolidated financial statements included elsewhere in this Annual Report, 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 $275.8 million as of December 31, 2025. These conditions raise substantial doubt about our ability to continue as a going concern. Our 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.

In the past, 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.

Such material weaknesses 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 implemented 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.

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 investigational 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 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 in the delivery of our clinical supplies which could affect the development of SP-102.

Historically, we have purchased our clinical and commercial supply requirements for sodium hyaluronate, one of the excipients for SP-102, solely from Genzyme Corporation ("Genzyme") pursuant to a supply agreement, which terminated as of May 31, 2024. We anticipate that our current supply of sodium hyaluronate will be sufficient to satisfy our clinical and commercial supply requirements for sodium hyaluronate for at least 12 months following our expected commercial launch of SP-102 in 2028. There is no guarantee that we will be able to commence a commercial launch of SP-102 in 2028 or ever, 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 Semnur's written and approved acceptance criteria in its 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 GCPs, 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' 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 GCPs;
- 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 they 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.

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 it, 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 for 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) 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 trial.

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 Jaisim Shah, our Chief Executive Officer and President, Henry Ji, Ph.D., our Executive Chairman, 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 December 31, 2025, we have 10 full-time employees, including three employees who have a M.D. or Ph.D. As a subsidiary of Scilex, we have been dependent upon the services provided by Scilex employees. As of December 31, 2025, Scilex has 28 full-time employees, including three employees who have M.D.s or Ph.D.s. 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 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 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 administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. Although the current 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 continued hostilities between Russia and Ukraine and, more recently, Hamas' attack against Israel and the ensuing conflict.

In addition, Russia's invasion of Ukraine and sanctions against Russia are causing disruptions to global economic conditions. The escalation in October 2023 of the conflict between Israel and Hamas and U.S. military intervention in Venezuela also could cause disruptions to global economic conditions and affect the stability of those regions. It is not possible to predict the broader consequences of these ongoing conflicts. It is also not possible to predict with certainty these ongoing conflicts and additional adverse effects on existing U.S. macroeconomic conditions and financial markets, all of which could impact the business, financial condition, and results of operations of the Company 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.

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 issue 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, their 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 Act provides 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 providing 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 are 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 has 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 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/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. 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, 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 Act 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 cGMPs and GCPs 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, is 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 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 also sets expectations for 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 be 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 that clarified applies to health apps and other similar technologies and includes breach notification requirements, which adds 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 operating results.

International data protection laws, including the EU's and UK's 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 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 2020 (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 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 candidate 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.

Mr. Shah, Dr. Ji, Dr. Chun, Mr. Followwill, Ms. Navani and Dr. Wu serve on our Board of Directors (the "Board of Directors"). Dr. Ji is also one of our executive officers, 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, 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 Scilex common stock, 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 creates, 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 December 31, 2025 and December 31, 2024 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, 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 December 31, 2025, Scilex (together with certain of its subsidiaries) controls approximately 81.9% 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 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 our Series A Preferred Stock, will have 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 its product candidate, if approved;
- the status and cost of our marketing commitments for its product candidate;

- announcements regarding results of any clinical trials relating to our product candidate;
- unanticipated serious safety concerns related to the use of any 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 its 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 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 its 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 its 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 Israel, 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 its 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 its 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.

Future sales, or the perception of future sales, of a substantial number of shares of Common Stock may cause the price of the Common Stock to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our Common Stock, the trading price of our Common Stock could decline and it could impair our ability to raise capital through the sale of additional equity securities. The Common Stock held by Jiandong "Peter" Xu, FutureTech Capital LLC, Huifeng Chang, Lei Huang, Jim Mao, You "Patrick" Sun and Kevin Vassily (the "Sponsor Shares"), except those held by our former directors and officers, and the private warrants issued by Denali in connection with its' IPO (the "Private Warrants"), together with the warrants sold to public investors in connection with the Denali IPO (the "Public Warrants" and, collectively with the Private Warrants, the "Warrants"), are subject to lock-up provisions that restrict the ability to transfer such shares of Common Stock and Private Warrants until one year from the close of the Business Combination, subject to certain exceptions.

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 Semnur may become involved;
- regulatory developments affecting our product candidate, regulatory approvals of its 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 its 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 Semnur does not maintain any bank accounts with Silicon Valley Bank or Signature Bank, Semnur regularly maintains 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 its 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 our 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 its 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 December 31, 2025, 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 in 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 Semnur's ability to use its net operating loss carryforwards attributable to the period prior to the change. Semnur has 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 its stock ownership (some of which shifts are outside its control). As a result, if Semnur earns net taxable income, its ability to use its 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 Semnur.

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 Semnur's ability to utilize its 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 the Company.

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 its 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 its 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 Annual Report, 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 Annual Report, 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

its 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 its legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase its operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for we 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 it may incur to respond to these requirements. The impact of these requirements could also make it more difficult for we 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 its 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 its business, financial condition and results of operations, including its ability to forecast or make sales and collect its 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 its 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 its 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 its 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 its 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 its 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 we 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 its 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 Semnur.

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. Subsequently, 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 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, and 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. 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

As disclosed elsewhere in this Annual Report, on September 23, 2025, we entered into the Biconomy SPA with Biconomy, pursuant to which we agreed to issue and sell, and Biconomy agreed to purchase, an aggregate of 6,250,000 Biconomy Shares, for a purchase price of $16.00 per share, payable in Bitcoin. The closing of the transactions contemplated by the Biconomy SPA has not occurred as of the date of this Annual Report. However, before making an investment decision, you should consider carefully whether such pending transaction has been completed and any other disclosures that we may make from time to time regarding the closing of such transaction and/or our future cryptocurrency financings or treasury strategy.

The Company intends to use the net proceeds from the Biconomy SPA, which as of the date of this Annual Report has not closed and will be paid in Bitcoin, to fund investments in other companies. The price of Bitcoin has been, and will likely continue to be, highly volatile. The Company's operating results and share price may significantly fluctuate, including due to the highly volatile nature of the price of such digital assets and erratic market movements.

We intend to use the net proceeds from the Biconomy SPA, which as of the date of this Annual Report has not closed and will be paid in Bitcoin, to establish the Company's cryptocurrency treasury operations and to fund our

investment in other companies. Digital assets generally are highly volatile assets. In addition, digital assets do not pay interest or other returns and so the ability to generate a return on investment from the net proceeds of any capital raisings will depend on whether there is appreciation in the value of digital assets following our purchases of digital assets with the net proceeds from such capital raisings. Future fluctuations in digital asset trading prices may result in our converting digital assets into cash with a value substantially below what we paid for such digital assets.

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. 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 Russia-Ukraine, Israel-Hamas and Israel-Iran conflicts, 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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity is a critical element of our information security program. Security controls are implemented in a manner that protects the confidentiality, integrity and availability of our information assets without hindering business operations. Management is responsible for the day-to-day administration of our cybersecurity policies, processes, and practices. Our cybersecurity policies, standards, processes, and practices are based on recognized frameworks established by the National Institute of Standards and Technology (the "NIST") and management's knowledge of best practices in the cybersecurity industry. In general, we seek to address material cybersecurity threats through a company-wide approach that addresses the confidentiality, integrity and availability of our information systems or the information that we collect and store, by proactively monitoring for cybersecurity threats and assessing, identifying and managing cybersecurity issues as they occur.

We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. Key elements of our cybersecurity risk management strategy include:

- We require an annual Service Organization Control 2 Type 1 report from all third-party providers attesting to the presence of security processes. Additionally, we require that SaaS/PaaS providers perform risk assessments and manage the security risks associated with their services.
- We have established and maintain a comprehensive incident response plan designed to address our response to a cybersecurity incident. We conduct regular training scenarios to test these plans and ensure personnel are familiar with their roles in a response scenario.
- We provide regular, mandatory training for employees regarding cybersecurity threats as a means to equip our employees with effective tools to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices.
- We use a third party to conduct a periodic assessment of our cybersecurity risk posture and maturity against the NIST Cybersecurity Framework. The results are evaluated by management and the Audit Committee and are used to adjust our cybersecurity policies, standards, processes and practices as necessary.
- The Company studies and evaluates threats in cyber landscape and aims to regularly improve our risk posture by learning from those lessons.

Our Audit Committee receives quarterly presentations and reports on developments in the cybersecurity space, including risk management practices, recent developments, vulnerability assessments, third-party and independent reviews, the threat environment, and information security issues encountered by other public companies.

The Senior Director of IT acts as the Incident Manager and meets regularly with our Incident Response Team, including members of Financial Risk Management, IT Security and Human Resources senior management to discuss the necessary measures to take prior to and during an incident. In the event of an incident, the Incident Manager meets regularly with the executive leadership team and keeps them apprised of the status of any incident during the incident response. Our Board and the Audit Committee also receive prompt and timely information from the Senior Director of IT and executive leadership regarding any cybersecurity risks that meet certain reporting thresholds, as well as ongoing updates regarding any such risk. Finally, the Incident Response Manager briefs corporate leadership

on lessons learned from the incident during or after the recovery phase.

The Senior Director of IT, in collaboration with a team of IT professionals, our legal counsel and Human Resources, are tasked with implementing a program designed to protect our information systems from cybersecurity threats and manage material risks. The Senior Director of IT has served in various roles in information technology and information security for over 20 years. The Senior Director of IT and senior management are informed about and monitor the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real time and report such threats and incidents to the Audit Committee when appropriate.

Risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our Company, including our business strategy, results of operations, or financial condition as of December 31, 2025. For more information, please see the risk factor disclosures included in Item 1A of this Annual Report.

Item 2. Properties.

Our principal executive office is currently located in Palo Alto, California, and consists of approximately 3,000 square feet of leased office space provided at no cost by Scilex. The lease term expires in September 2027. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate additional or alternative space will be available on commercially reasonable terms.

Item 3. 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 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock and Warrants are currently traded on the Pink Limited Market of the OTC Markets under the symbols "SMNR" and "SMNRW," respectively. Investors should be advised that any over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

Holders

As of February 25, 2026, there were 17 holders of record of our common stock and one holder of record of our Public Warrants, which amount does not include participants of The Depository Trust Company or beneficial owners holding shares through nominee names.

Dividend Policy

We have never declared or paid any dividend on shares of our Common Stock. We anticipate that we will retain all of our future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our capital stock will be at the discretion of our Board of Directors. It is the present intention of our Board of Directors to retain all earnings, if any, for use in our business operations and, accordingly, our Board of Directors does not anticipate declaring any dividend in the foreseeable future. Should we decide in the future to do so, as a holding company, our ability to pay dividends on our capital stock and meet other obligations depends upon the receipt of dividends or other payments from our operating subsidiaries, including Legacy Semnur. Further, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we or our subsidiaries incur.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III for information regarding securities authorized for issuance under our equity compensation plans.

Unregistered Sales of Equity Securities

On December 26, 2025 and on December 29, 2025, we issued an aggregate of 468,164 shares of Common Stock pursuant to the cashless exercise of 1,327,878 Public Warrants.

The shares of Common Stock issued upon exercise of the Public Warrants were issued pursuant to the exemption from registration provided by Section 3(a)(9) of the Securities Act.

There were no other unregistered sales of our equity securities during the fiscal year ended December 31, 2025, other than those previously disclosed on our Current Report on Form 8-K.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

Item 7. 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 consolidated financial statements and related notes thereto included elsewhere in this Annual Report. 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 Annual Report, including those set forth in the sections of this Annual Report 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 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 on 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 December 31, 2025, we had cash and cash equivalents of $20 thousand and accumulated deficit of $275.8 million. During the year ended December 31, 2025, we had operating losses of $160.4 million and used $5.9 million of cash in operations. 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 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 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. As of December 31, 2025, the transaction has not closed and accordingly, shares have not been issued and funds have not been received. As the transaction did not close on or before December 31, 2025, the nonbreaching party has an option to terminate the PIPE SPA without liability.

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

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 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. As of December 31, 2025, the transaction has not closed and accordingly, shares have not been issued and funds have not been received. As the transaction did not close on or before December 31, 2025, the nonbreaching party has an option to terminate the Semnur/Biconomy SPA without liability.

Promissory Notes

As of December 31, 2025, we have promissory notes totaling $3.5 million, 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 year ended December 31, 2025, we incurred expenses of $0.9 million 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"),

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 NDA 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 royalties 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

Since 2019, we have operated as a majority owned subsidiary of Scilex. 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 "Transition Services Agreement") 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 Years Ended December 31, 2025 and 2024

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

	Year Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 2,546	$ 1,709	$ 837
General and administrative	157,870	2,981	154,889
Total operating expenses	160,416	4,690	155,726
Loss from operations	(160,416)	(4,690)	(155,726)
Net loss	$ (160,416)	$ (4,690)	$ (155,726)

Research and Development Expenses

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

	Year Ended December 31,		
	-2025	2024	Change
SP-102:			
Contracted R&D	$ 1,420	$ 1,160	$ 260
Personnel	923	492	431
Other	203	57	146
Total research and development expenses	$ 2,546	$ 1,709	$ 837

Total research and development expenses for the year ended December 31, 2025 and 2024 were $2.5 million and $1.7 million, respectively. The increase of $0.8 million was primarily related to increased personnel costs due to an increase in headcount and allocation of expenses from Scilex and an increase in contracted R&D due to increased clinical development activities related to development of SP-102.

General and Administrative Expenses

Total general and administrative expenses for the year ended December 31, 2025 and 2024 were $157.9 million and $3.0 million, respectively. The increase of $154.9 million was primarily related to $140.0 million of consulting expense related to consultant shares issued at Closing and $9.9 million of deferred offering costs written off at Closing. Additionally, there was an increase in personnel-related costs due to an increase in headcount and allocation of expenses from Scilex and an increase in consulting expenses due to services required to manage a public company.

Liquidity and Capital Resources

As of December 31, 2025, we had cash and cash equivalents of $20 thousand and accumulated deficit of $275.8 million. During the year ended December 31, 2025, we had operating losses of $160.4 million and used $5.9 million of cash in operations. 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.

In the twelve months following the Business Combination, we expect our primary sources of liquidity to include our existing cash on hand and continued support from Scilex pursuant to the Transition Services Agreement and we are currently exploring various financing alternatives, including new credit facilities, non-dilutive financing options, such as collaborations with international partners to out-license SP-102, debt financings and royalty financings, and equity financing options, such as standby equity purchase arrangements or private placements.

In connection with the PIPE SPA and the Semnur/Biconomy SPA, we may receive financing of $20.0 million and $100.0 million, respectively.

In connection with the Transition Services Agreement 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.

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 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;
- 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, 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 stockholder 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 support our clinical development to expand approved indications, 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 consolidated financial statements are issued. See Note 1 "*Nature of Operations — Liquidity and Going Concern*" of the notes to our consolidated financial statements included elsewhere in this Annual Report 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 December 31, 2025, we have promissory notes totaling $3.5 million, all of which are due in less than a year.

As of December 31, 2025, we have a long-term related party loan totaling $11.9 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 a senior secured promissory note 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 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):

	Year Ended December 31,		
	2025	2024	Change
Net cash used in operating activities	$ (5,867)	$ (4,891.00)	$ (976)
Net cash provided by financing activities	5,875	4,891	984
Net change in cash and cash equivalents	$ 8	$ —	$ 8

Cash Flows from Operating Activities

Net cash used in operating activities increased by $1.0 million during the year ended December 31, 2025 compared to year ended December 31, 2024. The increase is primarily related to higher expenses primarily due to an increase in headcount, an increase in clinical development activities and an increased in general costs associated with managing a public company.

Cash Flows from Financing Activities

For the years ended December 31, 2025 and 2024, net cash provided by financing activities of $5.9 million and $4.9 million, respectively, was primarily due to proceeds from the the related party loan.

Critical Accounting Estimates

Our accounting policies are more fully described in Note 2 of the consolidated financial statements to this Annual Report. As disclosed in Note 2, the preparation of 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 consolidated financial statements and accompanying notes. Actual results could differ significantly from those estimates. We do not have any critical accounting estimates as of December 31, 2025.

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 as 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 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, we are not required to provide the information specified under this Item 7A of this Annual Report.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15(a)(1) and (a)(2), respectively, of this Annual Report.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's regulations, rules and forms and that such information is accumulated and communicated to our management, including our principal officers, as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. As required by Rule 13a-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Principal Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report. Based on the foregoing, our Principal Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Under the supervision of and with the participation of our Principal Executive Officer and Principal Financial Officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria set forth in the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

This Annual Report does not include an attestation report of our independent registered public accounting firm on our internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm because the JOBS Act permits emerging growth companies such as our company to provide only management's report in the Annual Report.

Inherent Limitations on Effectiveness of Controls

Because of its inherent limitations, ICFR may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Accordingly, our controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our control system are met. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

10b5-1 Trading Plan Activity

During the fiscal quarter ended December 31, 2025, none of our directors or officers (as defined in Section 16 of the Exchange Act) 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) under the Exchange Act or any "non-Rule 10b5-1 trading arrangement," as defined in Item 408(c) of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference from the information contained in the Company's definitive proxy statement relating to the 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report that includes the information required by this Item.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report that includes the information required by this Item.

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

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report that includes the information required by this Item.

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

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report that includes the information required by this Item.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report. To the extent that we do not file the 2026 Proxy Statement by such date, we will file an amendment to this Annual Report that includes the information required by this Item.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Financial Statements

(1) Reference is made to the Index to Consolidated Financial Statements appearing on page F-1 of this Annual Report.

(2) All other schedules not listed above have been omitted because of the absence of conditions under which they are required, or because the required information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date
2.1#	Agreement and Plan of Merger, dated as of March 18, 2019, by and among Scilex Holding Company, Sigma Merger Sub, Inc., Semnur Pharmaceuticals, Inc., Fortis Advisors LLC, solely as the representative of the Equityholders and, solely with respect to Section 1.8(a), Section 3.11 and Article X, Sorrento Therapeutics, Inc.	S-4	333-283019 333-283019-01	2.1	August 12, 2025
2.2	Amendment No. 1 to Agreement and Plan of Merger, dated as of August 7, 2019, by and among Semnur Pharmaceuticals, Inc., Scilex Holding Company, Sigma Merger Sub, Inc., Fortis Advisors, LLC, solely as the representative of the Equityholders and, solely with respect to Section 1.8(a), 3.11 and Article X of the Agreement and Plan of Merger, Sorrento Therapeutics, Inc.	S-4	333-283019 333-283019-01	2.2	August 12, 2025
2.3#	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 333-283019-01	2.3	August 12, 2025
2.4	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 333-283019-01	2.4	August 12, 2025
2.5	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 333-283019-01	2.5	August 12, 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
3.4	Extension Amendment, dated as of April 11, 2025, to the Amended and Restated Memorandum and Articles of Association of Denali Capital Acquisition Corp.	8-K	001-41351	3.1	April 16, 2025
4.1	Specimen Warrant Certificate of Semnur Pharmaceuticals, Inc. (f/k/a Denali Capital Acquisition Corp.).	S-1	333-263123	4.3	April 5, 2022

4.2	Warrant Agreement, dated as of April 6, 2022, between Denali Capital Acquisition Corp. and VStock Transfer, LLC, as warrant agent.	8-K	001-41351	4.1	April 12, 2022
10.1	Letter Agreement, dated as of April 6, 2022, by and among Denali Capital Acquisition Corp., Denali Capital Global Investments LLC and certain security holders named therein.	8-K	001-41351	10.5	April 12, 2022
10.2	Contribution and Satisfaction of Indebtedness Agreement, dated as of August 30, 2024, by and between Scilex Holding Company and Semnur Pharmaceuticals, Inc.	S-4	333-283019 333-283019-01	10.17	April 21, 2025
10.3	Amended and Restated Registration Rights Agreement, dated as of September 22, 2025, by and among Semnur Pharmaceuticals, Inc., Scilex Holding Company and certain security holders.	8-K	001-41351	10.2	September 26, 2025
10.4*	Form of Indemnification Agreement of Semnur Pharmaceuticals, Inc.	S-4	333-283019 333-283019-01	10.11	April 21, 2025
10.5*	2024 Semnur Pharmaceuticals, Inc. Stock Option Plan.	S-4	333-283019 333-283019-01	10.12	August 11, 2025
10.6*	Form of Stock Option Grant Notice and Form of Stock Option Agreement under 2024 Semnur Pharmaceuticals, Inc. Stock Option Plan.	S-4	333-283019 333-283019-01	10.13	August 11, 2025
10.7#	Sponsor Interest Purchase Agreement, dated as of August 30, 2024, by and between Denali Capital Global Investments LLC and Scilex Holding Company.	8-K	001-41351	10.3	September 5, 2024
10.8^	Master Services Agreement—SP-102, dated as of January 27, 2017, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC.	S-4	333-283019 333-283019-01	10.19	August 12, 2025
10.9	Amendment No. 1 to Master Services Agreement, dated as of April 26, 2018, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC.	S-4	333-283019 333-283019-01	10.20	August 12, 2025
10.10^	Amendment No. 2 to Master Services Agreement, dated as of June 6, 2023, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC.	S-4	333-283019 333-283019-01	10.21	August 12, 2025
10.11	Assignment Agreement by and among Shah Investor LP and the Company, dated as of August 6, 2013.	S-4	333-283019 333-283019-01	10.22	August 12, 2025
10.12#	Transition Services Agreement, dated as of September 22, 2025, by and between Scilex Holding Company and the Company.	S-1/A	333-290995	10.14	December 19, 2025
10.13	Stock Issuance Agreement, dated as of July 22, 2025, by and between Semnur Pharmaceuticals, Inc. and the party named therein.	S-4	333-283019 333-283019-01	10.27	August 12, 2025
10.14	Advisory Services Agreement, dated as of June 12, 2025, by and between JW Investment Management Company Limited and Semnur Pharmaceuticals, Inc.	S-4	333-283019 333-283019-01	10.28	August 12, 2025

10.15	Amendment to Advisory Services Agreement, dated as of July 22, 2025, by and between JW Investment Management Company Limited and Semnur Pharmaceuticals, Inc.	S-4	333-283019 333-283019-01	10.29	August 12, 2025
10.16	Securities Purchase Agreement, dated as of August 20, 2025, by and among Denali Capital Acquisition Corp., Semnur Pharmaceuticals, Inc. and the Buyers thereto	8-K	001-41351	10.1	August 22, 2025
10.17	Satisfaction and Discharge of Indebtedness Agreement, dated September 22, 2025, by and between Denali Capital Acquisition Corp. and D. Boral Capital LLC (f/k/a EF Hutton).	8-K	001-41351	10.5	September 26, 2025
10.18	Promissory Note, dated September 22, 2025, issued by Denali Capital Acquisition Corp. to D. Boral Capital LLC (f/k/a EF Hutton).	8-K	001-41351	10.6	September 26, 2025
10.19	Satisfaction and Discharge of Indebtedness Agreement, dated September 22, 2025, by and between Denali Capital Acquisition Corp. and US Tiger Securities, Inc.	8-K	001-41351	10.7	September 26, 2025
10.20	Promissory Note, dated September 22, 2025, issued by Denali Capital Acquisition Corp. to US Tiger Securities, Inc.	8-K	001-41351	10.8	September 26, 2025
10.21	Satisfaction and Discharge of Indebtedness Agreement, dated September 22, 2025, by and between Denali Capital Acquisition Corp., Denali Capital Global Investments LLC and Scilex Holding Company.	8-K	001-41351	10.9	September 26, 2025
10.22	Promissory Note, dated September 22, 2025, issued by Denali Capital Acquisition Corp. to Denali Capital Global Investments LLC.	8-K	001-41351	10.10	September 26, 2025
10.23	Satisfaction and Discharge of Indebtedness Agreement, dated September 22, 2025, by and between Denali Capital Acquisition Corp., Denali Capital Global Investments LLC and FutureTech Capital LLC.	8-K	001-41351	10.11	September 26, 2025
10.24	Promissory Note, dated September 22, 2025, issued by Denali Capital Acquisition Corp. to FutureTech Capital LLC.	8-K	001-41351	10.12	September 26, 2025
10.25	Limited Amendment Letter Agreement, dated September 22, 2025, by and among Denali Capital Acquisition Corp., Semnur Pharmaceuticals, Inc. and the investor listed therein.	8-K	001-41351	10.13	September 26, 2025
10.26	Securities Purchase Agreement, dated September 23, 2025, by and among Semnur Pharmaceuticals, Inc. and the investors listed on the schedule of buyers attached hereto.	8-K	001-41351	10.14	September 26, 2025
10.27	Employment Agreement, dated September 22, 2025, by and between Semnur Pharmaceuticals, Inc. and Jaisim Shah.	8-K	001-41351	10.15	September 26, 2025
10.28	Employment Agreement, dated September 22, 2025, by and between Semnur Pharmaceuticals, Inc. and Henry Ji, Ph.D.	8-K	001-41351	10.16	September 26, 2025
10.29	Employment Agreement, dated September 22, 2025, by and between Semnur Pharmaceuticals, Inc. and Stephen Ma.	8-K	001-41351	10.17	September 26, 2025
19.1	Semnur Pharmaceuticals, Inc. Insider Trading Policy.			Filed herewith	
21.1	List of Subsidiaries of the Registrant.			Filed herewith	
23.1	Consent of Pipara & Co LLP, independent registered public accounting firm of Semnur.			Filed herewith	

24.1	Power of Attorney (included on signature page).	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith
97.1	Semnur Pharmaceuticals, Inc. Clawback Policy.	Filed herewith
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents	
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	

* Indicates management contract or compensatory plan or arrangement.

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.

^ Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because such information is both (i) not material and (ii) information that the Registrant treats as private or confidential. The Registrant hereby undertakes to furnish supplemental copies of the unredacted exhibit upon request by the SEC.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Semnur Pharmaceuticals, Inc.

Date: February 27, 2026 By: /s/ *Jaisim Shah*
Jaisim Shah
Chief Executive Officer and President
(Principal Executive Officer)

Date: February 27, 2026 By: /s/ *Stephen Ma*
Stephen Ma
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints, jointly and severally, each of Jaisim Shah and Stephen Ma, acting alone or together with another attorney-in-fact, as his attorney-in-fact, with full power of substitution and resubstitution, for him in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ *Jaisim Shah* Jaisim Shah	Chief Executive Officer, President and Director (Principal Executive Officer)	February 27, 2026
/s/ *Stephen Ma* Stephen Ma	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2026
/s/ *Henry Ji* Henry Ji, Ph.D.	Executive Chairperson and Director	February 27, 2026
/s/ *Dorman Followwill* Dorman Followwill	Director	February 27, 2026
/s/ *Jay Chun* Jay Chun, M.D., Ph.D.	Director	February 27, 2026
/s/ *Yue Alexander Wu* Yue Alexander Wu, Ph.D.	Director	February 27, 2026
/s/ *Annu Navani* Annu Navani, M.D.	Director	February 27, 2026

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Semnur Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Semnur Pharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows, for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has negative working capital, has suffered losses from operations, has recurring negative cash flows from operations, dependence upon the support from its parent, Scilex Holding Company, and the success of future development and regulatory approval of SP-102. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ PIPARA & CO LLP (6841)

We have served as the Company's auditor since 2025.

New Delhi, India
February 27, 2026

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

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20	$ 12
Prepaid expenses	576	2
Other current assets	—	5,981
Total current assets	596	5,995
Property and equipment, net	750	689
Total assets	$ 1,346	$ 6,684
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,912	$ —
Accrued expenses	739	35
Promissory notes	3,517	—
Total current liabilities	10,168	35
Related party loan	11,928	49,433
Total liabilities	22,096	49,468
Commitments and contingencies (See Note 4)		
Stockholders’ deficit:		
Preferred stock, $0.0001 par value, 45,000,000 shares authorized as of December 31, 2025 and 2024; 5,423,606 and no shares issued and outstanding as of December 31, 2025 and 2024, respectively	1	—
Common stock, $0.0001 par value, 740,000,000 and 200,000,000 shares authorized as of December 31, 2025 and 2024, respectively; 230,209,142 and 200,000,000 issued and outstanding as of December 31, 2025 and 2024, respectively	23	20
Additional paid-in capital	255,026	72,580
Accumulated deficit	(275,800)	(115,384)
Total stockholders' deficit	(20,750)	(42,784)
Total liabilities and stockholders' deficit	$ 1,346	$ 6,684

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 2,546	$ 1,709
General and administrative	157,870	2,981
Total operating expenses	160,416	4,690
Loss from operations	(160,416)	(4,690)
Net loss and comprehensive loss	$ (160,416)	$ (4,690)
Net loss per share, basic and diluted	$ (0.78)	$ (0.02)
Weighted average shares of common stock outstanding, basic and diluted	204,784,615	200,000,000

See accompanying notes to the consolidated financial statements.

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

	Preferred Stock		Legacy Common Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance, January 1, 2024	—	$ —	160,000,000	$ 2	—	$ —	$ 72,598	$ (110,694)	$ (38,094)
Retroactive application of recapitalization	—	—	(160,000,000)	(2)	200,000,000	20	(18)	—	—
Adjusted balance, January 1, 2024	—	—	—	—	200,000,000	20	72,580	(110,694)	(38,094)
Net loss	—	—	—	—	—	—	—	(4,690)	(4,690)
Balance, December 31, 2024	—	—	—	—	200,000,000	20	72,580	(115,384)	(42,784)
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	—	(12,787)	—	(12,787)
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
Issuance of common stock upon cashless exercise of warrants	—	—	—	—	468,164	—	—	—	—
Net loss	—	—	—	—	—	—	—	(160,416)	(160,416)
Balance, December 31, 2025	5,423,606	$ 1	—	$ -	230,209,142	$ 23	$ 255,026	$ (275,800)	$ (20,750)

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2025	**2024**
Operating activities		
Net loss	$ (160,416)	$ (4,690)
Adjustments to reconcile net loss to net cash used for operating activities:		
Stock-based compensation	142,435	660
Changes in operating assets and liabilities:		
Prepaid expenses	(586)	—
Other assets	9,851	—
Accounts payable	2,145	—
Accrued expenses	704	(861)
Net cash used in operating activities	(5,867)	(4,891)
Financing activities		
Proceeds from Business Combination	27	—
Proceeds from related party loan	5,848	4,891
Net cash provided by financing activities	5,875	4,891
Net change in cash and cash equivalents	8	—
Cash and cash equivalents at beginning of period	12	12
Cash and cash equivalents at end of period	$ 20	$ 12
Supplemental disclosure of non-cash investing and financing activities:		
Purchase of equipment through related party loan	$ 61	
Deferred offering costs paid through related party loan	$ 7,602	$ 5,981
Payment of promissory notes through related party loan	$ 961	
Net liabilities assumed in Business Combination	$ 12,914	$ —
Related party loan settled in preferred stock pursuant to Debt Exchange Agreement	$ 54,236	$ —
Related party loan settled in common stock	$ 1,000	$ —
Promissory notes settled in common stock	$ 125	$ —

See accompanying notes to the consolidated financial statements.

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 December 31, 2025, 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 (10 mg, dexamethasone sodium phosphate 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 and Denali.

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 outstanding 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 certain subsidiaries thereof and 40,000,000 Legacy Semnur stock options held by certain Scilex employees, 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.

Immediately prior to the Closing, 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 (iv) 2,072,500 ordinary shares of Denali held by Denali Capital Global Investments LLC (the "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 "*Capital Structure — Consulting Agreements with Stock Remuneration*") and 100,000 shares of Common Stock were issued to Denali underwriters.

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 will also control 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 assets and liabilities of Denali are recognized 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, 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, 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. As of December 31, 2025, the transaction has not closed and accordingly, the shares have not been issued and the funds have not been received. As the transaction did not close on or before December 31, 2025, the nonbreaching party has an option to terminate the PIPE SPA without liability.

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

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 blockchain ("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. As of December 31, 2025, the transaction has not closed and accordingly, the shares have not been issued and the funds have not been received. As the transaction did not close on or before December 31, 2025, the nonbreaching party has an option to terminate the Semnur/Biconomy SPA without liability.

Public Warrants and Private Placement Warrants

Upon completion of the Business Combination, 8,760,000 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 Semnur 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 the Company's Common Stock. As of 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 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 consolidated financial statements.

As of December 31, 2025, the Company had cash and cash equivalents of $20 thousand and accumulated deficit of $275.8 million. During the year ended December 31, 2025, the Company had operating losses of $160.4 million and used $5.9 million of cash in operations. 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 consolidated financial statements are issued.

Forward Stock Split

On August 30, 2024, the Company effected a 160,000-for-1 forward stock split of all outstanding shares of Common Stock which proportionally increased the number of all issued and outstanding shares of Common Stock from 1,000 to 160,000,000 and did not change the par value per share. All equity-related information including per share amounts for all periods presented within these consolidated financial statements have been adjusted retroactively, where applicable, to reflect the forward stock split.

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 our 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 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 we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, these 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 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 include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented. All intercompany balances and transactions have been eliminated in consolidation. Certain prior period amounts in the statement of cash flows have been reclassified to conform to the current period presentation.

Carve-Out Method

As of December 31, 2025, the Company's financial results are included in Scilex's consolidated financial results.

The accompanying 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 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 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 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 year ended December 31, 2025. See Note 8 "*Related Parties*" 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 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 consolidated financial statements were reasonable and appropriate under the circumstances. Nevertheless, the Company's 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 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 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 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, the current U.S. government shutdown 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 Depository Insurance Coverage 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 year ended December 31, 2025, the Company incurred expenses of $0.9 million 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 assesses 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 consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the 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 and cash equivalents. 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.

Deferred Offering Costs

The Company's legal, accounting and other fees directly attributable to the Business Combination were deferred and capitalized within other current assets on the consolidated balance sheets. Total costs deferred and capitalized in relation to the Business Combination as of December 31, 2024 were $6.0 million. Deferred offering costs of $9.9 million were fully expensed upon Closing of the Business Combination within G&A expenses on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

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 years ended December 31, 2025 and 2024.

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 December 31, 2025 and 2024, the Company has accounted for the 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's 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 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 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 Adopted Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update 2023-08, *Intangibles—Goodwill and Other—Crypto Assets (Subtopic 350-60): Accounting for and Disclosure of Crypto Assets* ("ASU 2023-08"), which requires cryptocurrency assets to be measured at fair value on the balance sheet and gains and losses from changes in the fair value of cryptocurrency assets to be recognized on the statement of operations and comprehensive loss in each reporting period. ASU 2023-08 also requires certain interim and annual disclosures with respect to cryptocurrency holdings. The Company adopted ASU 2023-08 for the fiscal year beginning January 1, 2025 and the adoption did not have any impact to the Company's consolidated financial statements as the Company did not have any cryptocurrency holdings at adoption.

In December 2023, the FASB issued Accounting Standards Update 2023-09, *Income Taxes - Improvements to Income Tax Disclosures* ("ASU 2023-09") requiring enhancements and further transparency to certain income tax disclosures, most notably the tax rate reconciliation and income taxes paid. ASU 2023-09 does not change the

recognition or measurement of income taxes under ASC 740. The Company adopted ASU 2023-09 on a prospective basis for the fiscal year ended December 31, 2025 and other than the presentation of additional disaggregated data in the income tax footnote disclosure, there was no material impact on the Company's consolidated financial statements. Prior-period comparative disclosures for the income tax footnote have not been recast to the expanded format required by ASU 2023-09, consistent with the transition guidance in ASU 2023-09.

Recently Issued Accounting Pronouncements

In November 2024, 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.

Note 3. Balance Sheet Components

Prepaid expenses

Prepaid expenses consist of the following (in thousands):

	December 31,	
	2025	2024
Prepaid research & development	$ 436	$ 2
Prepaid insurance	140	—
Total prepaid expenses	$ 576	$ 2

Property and equipment, net

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

	December 31,	
	2025	2024
Construction-in-progress	$ 750	$ 689
Furniture	17	17
Computers and equipment	8	8
Property and equipment, gross	775	714
Less: accumulated depreciation	(25)	(25)
Property and equipment, net	$ 750	$ 689

The Company recognized no depreciation expense for years ended December 31, 2025 and 2024. 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):

	December 31,	
	2025	2024
Accrued research & development	$ 30	$ 8
Accrued professional fees	236	2
Accrued compensation	469	—
Accrued other	4	25
Total accrued expenses	$ 739	$ 35

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 December 31, 2025 and 2024, the Company was not a party to any material legal proceedings with respect to itself or any of its material properties.

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 the Company'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 royalties 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 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 Scilex 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"). Per the terms of the note, the Sponsor Note is payable in six monthly installments of $134 thousand, starting 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"). Per the terms of the note, the FutureTech Note is payable in six monthly installments of $170 thousand, starting on October 1, 2025 and ending on March 1, 2026.

At Closing, Denali and the Denali underwriters entered into a 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"). Per the terms of the notes, the Denali Underwriter Notes are payable in nine monthly installments of $300 thousand, starting on October 1, 2025 and ending on June 1, 2026, with the last monthly payment being $250 thousand.

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

			New Agreements	
Note	Original Issue Date	Existing Denali 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 December 31, 2025, the Company had total current promissory notes of $3.5 million, 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 fourth quarter of 2025 on the Sponsor Note (monthly installments of $134 thousand) and the Denali Underwriter Note for U.S. Tiger Securities, Inc. (monthly installments of $150 thousand). As of December 31, 2025, the Sponsor Note had an outstanding principal balance of $0.8 million and accrued interest of approximately $20 thousand at 10% per annum (calculated monthly). The Company has not recorded the accrued interest as of December 31, 2025. The Company has not received a notice of default and expects to make the payments in March 2026.

Note 6. Capital Structure

As of 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 ("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 December 31, 2025, no dividends were declared.

Common Stock Reserved

As of December 31, 2025, Common Stock reserved for future issuance, on an as converted basis, totaled 67,332,122 shares and includes 7,432,122 shares to be issued upon conversion of outstanding Warrants, 50,000,000 shares to be issued upon exercise of outstanding stock options, 1,250,000 shares to be issued under the PIPE SPA, 6,250,000 shares to be issued under the Semnur/Biconomy SPA and 2,400,000 shares reserved under the 2025 Inducement Plan (as defined in Note 7).

Preferred Stock

As of 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 affecting 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.

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 who 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, 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 were 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") who 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, 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 G&A 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 common stock multiplied by the Exchange ratio) of Common Stock were issued to JW and the associated expense was recognized as G&A expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2025.

On August 20, 2025, the Company entered into the PIPE SPA. As of December 31, 2025, the PIPE transaction has not closed and therefore the cash financing service fee of 7% is not a current obligation.

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 common stock multiplied by the Exchange ratio) of Common Stock.

All such shares are 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 may be sold and the net proceeds may be applied against the outstanding legal fees. The retainer shares not applied against the outstanding legal fees due will be returned to the Company. As of December 31, 2025, it was not probable that any of the retainer shares would be applied against any outstanding legal fees.

Sponsor Support Agreement

Concurrently with the execution of the Merger Agreement, the Sponsor and each of the Company's directors and executive officers entered into a sponsor support agreement with the Company and Semnur (the "Sponsor Support Agreement"), pursuant to which the Sponsor and each of Company's directors and executive officers has agreed to, among other things: (i) vote in favor of the Parent Shareholder Approval Matters (as defined in the Merger Agreement) and in favor of any proposal in respect of an Extension Amendment (as such terms are defined in the Merger Agreement); (ii) vote against (or otherwise withhold written consent of, as applicable) any "Business Combination" (as such term is defined in Denali's organizational documents) or any proposal relating thereto (in each case, other than as contemplated by the Merger Agreement); (iii) vote against (or otherwise withhold written consent of, as applicable) any merger agreement or merger, consolidation, combination, sale of substantial assets, reorganization, recapitalization, dissolution, liquidation or winding up of or by the Company (other than the Merger Agreement and the transactions contemplated thereby); (iv) vote against (or otherwise withhold written consent of, as applicable) any change in the business, management or Board of Directors (other than in connection with the Merger Agreement and the transactions contemplated thereby); and (v) vote against (or otherwise withhold written consent of, as applicable) any proposal, action or agreement that would (a) impede, frustrate, prevent or nullify any provision of the Sponsor Support Agreement or the Merger Agreement or any of the transactions contemplated thereby, (b) result in a breach in any respect of any covenant, representation, warranty or any other obligation or

agreement of Denali or Merger Sub under the Merger Agreement, (c) result in any of the conditions set forth in Article VIII of the Merger Agreement not being fulfilled or (d) change in any manner the dividend policy or capitalization of, including the voting rights of any class of capital stock of, the Company. Under the terms of the Sponsor Support Agreement, the Sponsor also agreed to certain standstill provisions with respect to the ordinary shares and other equity securities of the Company held by the Sponsor.

Stockholder Support Agreement

Concurrently with the execution of the Merger Agreement, Legacy Semnur, Semnur and Scilex (as the then sole stockholder of Semnur) entered into a company stockholder support agreement (the "Stockholder Support Agreement"), pursuant to which Scilex agreed to, among other things: (i) appear at any meeting of Semnur's stockholders related to the transactions contemplated by the Merger Agreement, or otherwise cause its shares of Semnur common stock to be counted as present thereat for the purpose of establishing a quorum; (ii) vote (or execute and return an action by written consent), or cause to be voted at any such meeting of Semnur's stockholders (or validly execute and return and cause such consent to be granted with respect to), all of its shares of Semnur common stock in favor of the Merger Agreement and the Business Combination; (iii) authorize and approve any amendment to Semnur's certificate of incorporation or bylaws that is deemed necessary or advisable by Semnur for purposes of effecting the Business Combination; and (iv) vote (or execute and return an action by written consent), or cause to be voted at any such meeting of Semnur's stockholders (or validly execute and return and cause such consent to be granted with respect to), all of its shares of Semnur common stock against any other action that would reasonably be expected to (a) impede, interfere with, frustrate, delay, postpone or adversely affect the Business Combination, (b) result in a breach of any covenant, representation or warranty or other obligation or agreement of Semnur under the Merger Agreement or (c) result in a breach of any covenant, representation or warranty or other obligation or agreement of Scilex contained in the Stockholder Support Agreement.

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 years ended December 31, 2025 and 2024. Total stock-based compensation recognized consists of an allocation of such shared employees' stock-based compensation expense on the same basis as their salaries and benefits and expense for 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 employee stock purchase plan ("ESPP") using the Black-Scholes option pricing method. The Black-Scholes option pricing method requires the use of subjective assumptions.

The following assumptions were used by Scilex in the Black-Scholes option pricing model to estimate stock-based compensation on the date of grant for stock options granted and ESPP shares issued for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	**2024**
Stock options:		
Expected dividend yield	0.0%	0.0%
Expected volatility	72.5% - 99.1%	72.0% - 119.1%
Risk-free interest rate	3.6% - 4.2%	3.8% - 4.7%
Term of options (in years)	6.3	3.0 - 6.3
Employee stock purchase plan:		
Expected dividend yield	0.0%	0.0%
Expected volatility	112.9%	129.3%
Risk-free interest rate	4.3%	5.4%
Expected life (in years)	0.5	0.5

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

	Year Ended December 31,	
	2025	**2024**
Research and development	$ 205	$ 128
General and administrative	142,230	532
Total stock-based compensation expense	$ 142,435	$ 660

As of December 31, 2025, there was approximately $7.0 million of total unrecognized stock-based compensation expense, which is expected to be recognized over an estimated weighted-average vesting term of 3.1 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.

Equity Incentive Plans

2024 Plan

On August 30, 2024, the Company adopted the 2024 Plan, under which 40,000,000 shares of 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 NSO's 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 of December 31, 2025. 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 December 31, 2025, as the vesting is contingent upon the repayment of the Scilex-Oramed Note.

As of December 31, 2025, the 50,000,000 NSO's have an intrinsic value of $686.8 million and a remaining contractual term of 8.7 years. As of December 31, 2025, no shares remained available for issuance under the 2024 Plan.

2025 Plans

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 Company's 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 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 consolidated balance sheets. These amounts do not carry interest, and are not expected to be settled through transfer of cash or other assets by the Company.

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

	Year Ended December 31,	
	2025	2024
Loans to Scilex Holding Company — stock-based compensation	$ 2,435	$ 660
Loans to Scilex Holding Company — expenses paid by Scilex Holding Company on behalf of the Company	14,472	10,872
Total loans from Scilex Holding Company	$ 16,907	$ 11,532

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 December 31, 2025, the Company had $0.3 million of service fees accrued under the Transition Services Agreement which is included in related party loan on the consolidated balance sheet.

Note 9. Income Taxes

For U.S. federal and state tax reporting purposes, the Company is a member of Scilex's consolidated reporting group. The basis of presentation for these financial statements is on a separate standalone basis as if the Company were not a member of a consolidated group and was operating as an independent entity. Settlements of tax balances that differ from the separate entity computations are treated as either increases or decreases in equity. There were no settlements of tax balances between the entity and the Scilex during the periods presented. Total loss before income taxes for the years ended December 31, 2025 and 2024 did not include a foreign component. There was no income tax expense for the years ended December 31, 2025 and 2024.

The reconciliation between U.S. federal income taxes at the statutory rate and the Company's provision for income taxes are as follows:

	December 31, 2025
U.S. federal taxes at statutory rate	21.0 %
State tax, net of federal tax benefit	1.0
Nontaxable and nondeductible items:	
Business Combination expenses	(6.9)
Other	(0.1)
Change in valuation allowance	(15.0)
Effective income tax rate	— %

	December 31, 2024
U.S. federal taxes at statutory rate	21.0 %
Equity compensation	(3.0)
Change in valuation allowance	(18.0)
Effective income tax rate	— %

The Company files its tax returns on a consolidated or combined basis with Scilex. For purposes of its financial statements, the Company has calculated its income tax amounts, including net operating losses and credit carryforwards, using a separate return methodology and has presented these amounts as if it were a separate taxpayer from Scilex in each jurisdiction for each period the Company has presented. The Company has not determined the amount of tax attributes, including net operating losses and tax credit carryovers, which it would retain if it were to deconsolidate for tax purposes from Scilex. An analysis will be performed at a future date, if necessary.

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The components of the Company's net deferred tax assets and related valuation allowance are as follows (in thousands):

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	$ 38,350	$ 14,517
General business and other credit carryforwards	1,319	1,319
Capitalized research expenditures	619	807
Stock-based compensation	492	—
Intangible assets	641	720
Total gross deferred tax assets	41,421	17,363
Valuation allowance	(41,421)	(17,363)
Total deferred tax assets	—	—
Deferred tax liabilities	—	—
Total net deferred tax assets	$ —	$ —

The Company has evaluated the available evidence supporting the realization of its gross deferred tax assets, including the amount and timing of future taxable income, and has determined that it is more likely than not that the deferred tax assets will not be realized. Due to such uncertainties surrounding the realization of the deferred tax assets, the Company maintains a full valuation allowance against its deferred tax assets as of December 31, 2025 and 2024. Realization of the deferred tax assets will be primarily dependent upon the Company's ability to generate sufficient taxable income prior to the expiration of its net operating losses. The valuation allowance increased by $24.1 million during the year ended December 31, 2025, primarily due to an increase in the deferred tax asset on net

operating losses. The valuation allowance increased by $0.8 million during the year ended December 31, 2024, primarily due to primarily due to an increase in the deferred tax asset on net operating losses

As of December 31, 2025, the Company had $166.2 million of U.S. federal net operating loss carryforwards, of which $10.2 million will begin to expire in 2033 for federal tax purposes and $156.0 million can be carried forward indefinitely. While these federal NOLs do not expire, the Tax Cuts & Jobs Act of 2017 limits the amount of federal net operating loss utilized each year after December 31, 2017, to 80% of taxable income. As of December 31, 2025, the Company had $58.0 million of state net operating loss carryforwards that will begin to expire in 2033.

As of December 31, 2025, the Company had federal research and development income tax credits of $1.2 million which will begin to expire in 2033. As of December 31, 2025, the Company had California research and development income tax credits of $0.6 million that have indefinite life and will not expire.

Internal Revenue Code Section 382 ("Section 382") rules apply to limit a corporation's ability to utilize existing net operating loss and tax credit carryforwards once the corporation experiences an ownership change as defined in Section 382. For the years ended December 31, 2025 and 2024, a formal Section 382 analysis and computation have not been performed. Additionally, since there is a taxable loss in both years, the absence of the Section 382 limitation analysis does not have an impact for the periods presented and there was no impact of such limitations on the Company's income tax provisions.

The Company is subject to taxation in U.S. federal and state tax jurisdictions. All of the Company's tax years will remain open for three years for examination by the federal and state tax authorities from the date of utilizations of net operating loss. There are no active tax compliance audits as of December 31, 2025.

Uncertain Income Tax Positions

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	December 31,	
	2025	2024
Balance at the beginning of the year	$ 354	$ 354
Balance at the end of the year	$ 354	$ 354

As of December 31, 2025 and 2024, the Company had $0.4 million in total unrecognized tax benefits, which have been reflected as a reduction in deferred tax assets. If these were to be recognized, they would affect the effective tax rate, however given the full valuation allowance in the jurisdiction in which the unrecognized tax benefits relate to, the impact on the effective tax rate would be nil.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. No interest or penalties have been recognized as of and for the years ended December 31, 2025 and 2024.

The Company believes that no material amount of the liabilities for uncertain tax positions are expected to reverse within 12 months of December 31, 2025.

Note 10. 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):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (160,416)	$ (4,690)
Denominator:		
Weighted average shares of common stock outstanding, basic and diluted	204,784,615	200,000,000
Net loss per share, basic and diluted	$ (0.78)	$ (0.02)

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:

	Year Ended December 31,	
	2025	2024
Shares subject to outstanding common stock options	50,000,000	50,000,000
Shares subject to outstanding common stock warrants	7,432,122	—
Retainer shares	12,500,000	—
Total	69,932,122	50,000,000