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

FORM 10-K

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

For the fiscal year ended: December 31, 2024

☐ **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 001-39852

Scilex Holding Company

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**92-1062542**
(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)**

(650) 516-4310

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.0001 per share	SCLX	The Nasdaq Stock Market LLC
Warrants to purchase one share of common stock, each at an exercise price of $11.50 per share	SCLXW	The Nasdaq Stock Market LLC

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 Section 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 (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

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

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

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

Indicate by check mark whether the registrant 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 Act). ☐ Yes ☒ No

Based upon the closing sale price of the registrant's common stock on June 30, 2024 (the last trading day of the registrant's second fiscal quarter of 2024), as reported on the Nasdaq Capital Market, the aggregate market value of the voting stock held by non-affiliates of the registrant was approximately $233.12 million. Solely for purposes of this disclosure, shares of common stock held by executive officers and directors of the registrant as of such date have been excluded because such persons may be deemed to be affiliates.

As of March 25, 2025, the registrant had 243,312,885 shares of common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2025 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, 2024, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SCILEX HOLDING COMPANY
ANNUAL REPORT ON FORM 10-K
FISCAL YEAR ENDED DECEMBER 31, 2024
TABLE OF CONTENTS

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SCILEX HOLDING COMPANY

As used in this Annual Report on Form 10-K, unless the context requires otherwise, references to the "Company", "Scilex", "we", "us", "our", and similar terms refer to Scilex Holding Company, a Delaware corporation formerly known as Vickers Vantage Corp. I ("Vickers"), and its consolidated subsidiaries. References to "Legacy Scilex" refer to the private Delaware corporation that is now our wholly owned subsidiary and named Scilex, Inc. (formerly known as "Scilex Holding Company").

On November 10, 2022, we consummated the previously announced business combination pursuant to the Agreement and Plan of Merger, dated as of March 17, 2022 (as amended, the "Merger Agreement"), by and among Vickers, Vantage Merger Sub Inc. ("Merger Sub"), a wholly owned subsidiary of Vickers, and Legacy Scilex. 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 Vickers and Legacy Scilex was effected through the merger of Merger Sub with and into Legacy Scilex with Legacy Scilex surviving as Vickers's wholly owned subsidiary. In connection with the Business Combination, Vickers changed its name from Vickers Vantage Corp. I to Scilex Holding Company.

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 on Form 10-K 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 on Form 10-K including, without limitation, in the sections titled "*Business*" and "*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 on Form 10-K 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, 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 under the heading "Risk Factors" in this Annual Report on Form 10-K. 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 on Form 10-K may include, but are not limited to, statements about:

- our ability to maintain the listing of our Common Stock on the Nasdaq Capital Market;
- 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;
- 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 global economic and political developments, including the conflicts in Ukraine and Israel; and
- other factors detailed under the section of this Annual Report on Form 10-K 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.

The Company

We are an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain. 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 commercial products are: (i) ZTlido® (lidocaine topical system) 1.8%, a prescription lidocaine topical product approved by the U.S. Food and Drug Administration (the "FDA") for the relief of neuropathic pain associated with postherpetic neuralgia ("PHN"), which is a form of post-shingles nerve pain; (ii) ELYXYB®, a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults; and (iii) GLOPERBA®, the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults, which launched in June 2024. In addition, we have three product candidates: (i) SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) ("SEMDEXA™"), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica for which we have completed a Phase 3 study; (ii) SP-103 (lidocaine topical system) 5.4% ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of acute pain and for which we have completed a Phase 2 trial in acute low back pain ("LBP"); and (iii) SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) ("SP-104"), a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia, for which Phase 1 trials were completed. We believe our currently approved products and future product candidates, if approved by the FDA, could uniquely address what we believe are the significant unmet needs of the targeted populations and become the preferred treatment option for their respective indications.

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 Scilex 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 not only responded to the global demand for safer, more effective pain relief solutions, but also made substantial progress in demonstrating the rapid onset and enhanced safety of our products.

Our Products

We launched our first commercial product, ZTlido® (lidocaine topical system) 1.8% in October 2018. ZTlido possesses novel delivery and adhesion technology designed to address many of the limitations of current prescription lidocaine patches by providing significantly improved adhesion and continuous pain relief throughout the 12-hour administration period. ZTlido is a single-layer, drug-in-adhesive topical delivery system comprised of an adhesive material containing 36 mg lidocaine, which is applied to a pliable nonwoven cloth backing and covered with a polyethylene terephthalate film release liner. ZTlido is commercially manufactured for us by Oishi Koseido Co., Ltd. ("Oishi") in Japan. We license the rights to ZTlido from and rely exclusively on Oishi and Itochu Chemical Frontier Corporation ("Itochu") pursuant to the Product Development Agreement (the "Product Development Agreement") dated as of May 11, 2011, by and among Scilex Pharmaceuticals Inc., our wholly owned subsidiary ("Scilex Pharma"), Oishi and Itochu, and the Commercial Supply Agreement (the "Commercial Supply Agreement"), dated as of February 16, 2017, by and among Scilex Pharma, Oishi and Itochu. We have exclusive worldwide rights to Oishi's proprietary formulation and manufacturing technologies except with respect to Japan. In 2024, there were more than 206 million prescription lidocaine patches sold in the United States, according to Symphony Healthcare.

We launched our second commercial product, ELYXYB® in April 2023. We acquired the rights to certain patents, trademarks, regulatory approvals, data, contracts, and other rights related to ELYXYB® (celecoxib oral solution) and the commercialization thereof in the United States and Canada from BioDelivery Sciences International, Inc. and Collegium Pharmaceutical, Inc. in February 2023. ELYXYB® is a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults. We filed a New Drug Submission to Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for the approval of ELYXYB® for acute treatment of migraine with or without aura in Canada.

We launched our third commercial product, GLOPERBA, in June 2024. We acquired certain rights to GLOPERBA and the exclusive license to use the trademark "GLOPERBA®", pursuant to a License and Commercialization Agreement we entered into with RxOmeg Therapeutics LLC (a/k/a Romeg Therapeutics, LLC) ("Romeg"), dated as of June 14, 2022, which agreement was subsequently amended on January 16, 2025 (such agreement, as so amended, the "Romeg License Agreement"). GLOPERBA is an FDA-approved, liquid, oral medication for the treatment of gout in adults. Gout is a painful arthritic disorder affecting an estimated 9.2 million people in the United

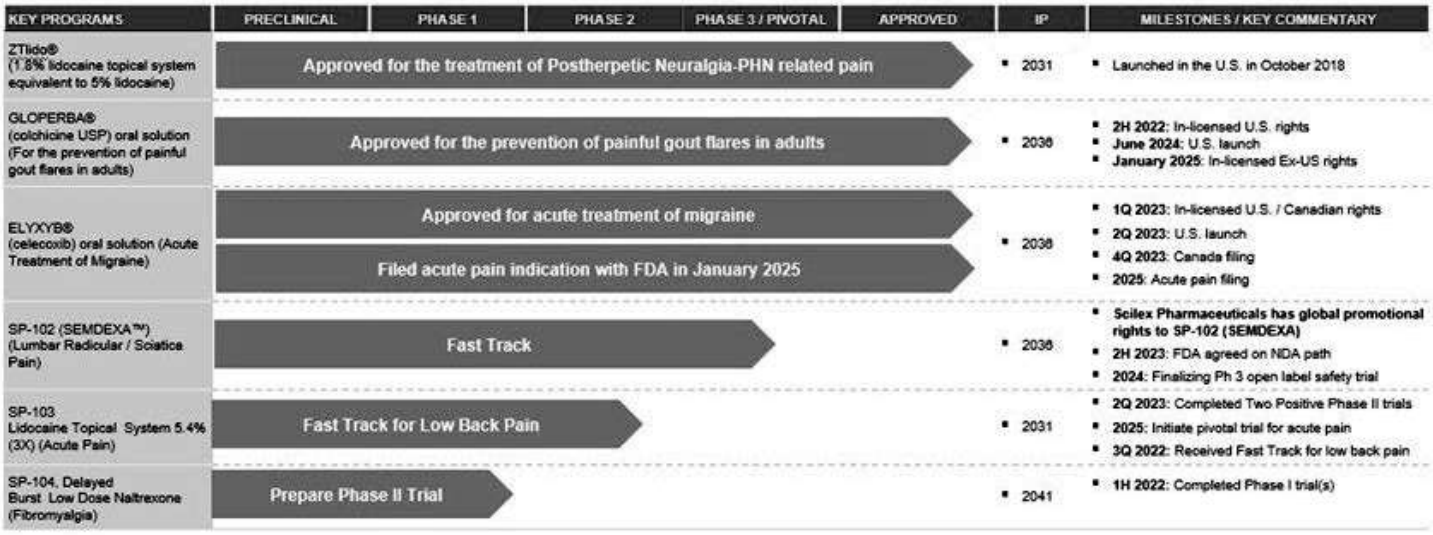
States. Gout pain can be excruciating and is a form of inflammatory arthritis that develops in some people who have high levels of uric acid in their blood. It can cause sudden severe episodes of pain and can be disabling with tenderness, warmth and swelling. Non-steroidal anti-inflammatory drugs, colchicine and corticosteroids are used a majority of time as the first line to treat acute gout. The U.S. is observed to have a high prevalence of gout, owing to lifestyle issues such as high alcohol intake, obesity, and smoking. We commercialized GLOPERBA in June 2024 and believe we are well positioned to market and distribute the product. We have a direct distribution network to national and regional wholesalers and pharmacies throughout the U.S. For more information, please see the section titled "*Business — Material Agreements — Romeg License and Commercialization Agreement.*"

Our Product Candidates

We acquired SP-102 from Semnur Pharmaceuticals, Inc. ("Semnur") in March 2019 and 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 steroid injections ("ESI"), which are administered over 12 million times annually in the United States. SEMDEXA™ has been granted fast track designation by the FDA and, if approved, could become the only FDA-approved ESI for the treatment of sciatica. 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 2022. We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute LBP associated with muscle spasms. SP-103 was safe and well tolerated. Increase of lidocaine load in topical system by three times, compared with approved ZTlido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. SP-103 received FDA Fast Track status in LBP. We will continue to analyze the SP-103 Phase 2 trial data along with an investigator study of ZTlido in patients with chronic neck pain completed in the second half of 2023, which also has shown promising top-line efficacy and safety results. SP-103, if approved, could become the first FDA-approved lidocaine topical product for the treatment of acute pain. We are developing SP-104 as a novel delayed-release formulation of low-dose naltrexone hydrochloride for the treatment of fibromyalgia, which remains a largely unmet medical need given the low response rates of commercially available therapies. Naltrexone is routinely used off-label to treat fibromyalgia. There are no low-dose formulations commercially available in the United States. Our patented formulation is designed to overcome undesirable effects of immediate release naltrexone, such as hyperalgesia, dysphoria, nausea, anxiety and insomnia.

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 for each of our product candidates.

The following chart illustrates completed and anticipated milestones for our current commercial products and novel product candidates.



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:

- **Maximize the commercial potential of ZTlido®.** We have assembled an integrated commercial organization using a dedicated sales force and sales management team, marketing and managed care capabilities to support continued

uptake of ZTlido. We leverage a sales force of over 70 people, targeting over 10,000 primary care physicians, pain specialists, neurologists, rheumatologist, and palliative care physicians who we believe treat the majority of PHN patients. Additionally, we are utilizing direct-to-patient marketing strategies to expand awareness and utilization of ZTlido. Our managed healthcare account executives have extensive experience in negotiating contracts and have already achieved significant uptake by adding ZTlido to key formularies such as CVS Caremark/Aetna Commercial, Cigna HealthCare (commercial and Medicare plans), Express Scripts (commercial), United Healthcare Commercial, Optum Rx Select Commercial, Anthem Blue Cross Blue Shield ("BCBS"), BCBS Louisiana and Kansas, Lifetime/Excellus BCBS, MedImpact, CareFirst, Elixir Commercial and Medicaid in California, Florida, Idaho, and North Dakota.

- **Commercialize and successfully continue launch of ELYXYB® for migraine in the U.S.** We will utilize our current commercial infrastructure comprised of our sales, marketing and managed health care functions to promote ELYXYB for acute migraine to healthcare providers ("HCPs") in the U.S. market. There is a good degree of overlap between the current Scilex sales force HCP targets and HCPs who prescribe medications for acute migraine, allowing for efficient dual promotion of ELYXYB and ZTlido. The principal elements of the ELYXYB strategy are the following:
    - Educate the market on the need for and value of a novel and differentiated option for the treatment of acute migraine, where a high degree of unmet medical need already exists. We will leverage our in-person sales field forces, medical affairs teams, and omni-channel HCP engagement campaigns to drive awareness of ELYXYB features and benefits.
    - Broaden access to ELYXYB. Our managed healthcare account executives will negotiate contracts with key payer and pharmacy stakeholders to achieve uptake to key formularies.

- **Commercialize and successfully continue launch of GLOPERBA® for gout in the U.S.** We will utilize our current commercial infrastructure comprised of our sales, marketing, and managed health care functions to promote GLOPERBA® for gout to approximately 3,000 HCPs in the U.S. market. We anticipate a good degree of overlap between the current HCPs that we target and HCPs who prescribe colchicine for gout, allowing for efficient dual promotion of GLOPERBA and ZTlido. The principal elements of the GLOPERBA strategy are as follows:
    - Educate the market on the need for and value of simplified and precise colchicine dose adjustments to allow individualized, patient-by-patient therapy. Scilex will leverage its in-person sales forces, medical affairs teams, and omni-channel HCP engagement campaigns to drive awareness of GLOPERBA's features and benefits. In addition, target providers, rheumatologists and primary care physicians treating various comorbidities, will be provided with tools to help them identify and prescribe GLOPERBA to appropriate patients.
    - Increase access to GLOPERBA for subsets of patients in prophylactic treatment of gout, specifically those with comorbidities and GI intolerance. Our managed healthcare account executives will negotiate contracts with key payer and pharmacy customers to achieve uptake of key formularies.

- **Develop and commercialize SEMDEXA™ as a novel epidural injection for the first approved treatment of sciatica.** We are developing SEMDEXA 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. SEMDEXA 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 SEMDEXA 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 6-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 pre-clinical data (including those obtained from multiple Phase 2 clinical trials) with the novel viscous gel formulation of SP-102. 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.

- **Pursue clinical development of SP-103 for the first approved topical treatment in patients with acute pain.** We are developing SP-103 as a triple-strength lidocaine topical system for the treatment of acute pain, to be used where we believe a high-dose strength and superior adhesive qualities of a topical system may provide a greater therapeutic benefit than currently available therapies. SP-103 is designed to use ZTlido's delivery and adhesion technology to deliver a dose of lidocaine that is three times higher than any other approved lidocaine topical products. We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute LBP associated with muscle spasms. SP-103 was safe and well tolerated. The increase of lidocaine load in topical system by three times, compared with approved ZTlido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. SP-103 received FDA Fast Track status in LBP. We will continue to analyze the SP-103 Phase 2 trial data along with an investigator study of ZTlido in patients with chronic neck pain completed in the second half of 2023, which also has shown promising top-line efficacy and safety results. SP-103, if approved, could become the first FDA-approved lidocaine topical product for the treatment of acute pain.

- **Pursue clinical development of SP-104 for the treatment of fibromyalgia, which has very few approved therapies that are marginally effective and have unpleasant side-effects.** We are developing SP-104 for fibromyalgia. Low-dose naltrexone hydrochloride delayed-release capsules are routinely used off-label to treat fibromyalgia and other chronic pain conditions such as complex regional pain. SP-104 addresses the shortcomings of using the high-dose commercial products and pharmacy-compounded products by delivering a low-dose of naltrexone hydrochloride (approximately 11 times less than the commercial product) in a delayed-release formulation that bypasses the stomach and releases the drug in the gut (upper intestine). These product characteristics mitigate against the known safety issues associated with the high-dose commercial products and immediate release pharmacy-compounded products, and the overall reliability issues associated with pharmacy-compounded products. SP-104 has completed two Phase 1 studies to characterize the pharmacokinetics ("PK") and safety of the product.

- **Expand our product portfolio by developing or acquiring non-opioid assets that leverage our novel delivery and adhesion technologies and our existing commercial 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. We also seek to in-license or acquire non-opioid therapeutics that can both complement our existing product portfolio and benefit from our existing commercial infrastructure. In evaluating marketed and clinical-stage expansion opportunities, we intend to pursue therapeutics that address markets served by our established target physician audience and that can be commercialized by our existing sales force.

- **Leverage our management team's experience to further develop and commercialize its 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. ("Teva"), Novartis Pharmaceuticals, Cephalon, Inc., Roche AG, PDL BioPharma, Inc., Xenoport, Inc. and Chiron Corp. Our team has substantial experience in rapidly progressing new drugs 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

We have assembled a management team of experienced biopharma industry veterans, who have deep scientific, business and leadership expertise in the pharmaceutical industry, as well as strong transactional and business development track records.

Our management team is led by our Chief Executive Officer and President, Jaisim Shah, with strategic guidance from our Executive Chairperson, 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 and as a member of our board of directors since the closing of the business combination in November 2022. He has also served as Chief Executive Officer and President of Legacy Scilex and Scilex Pharma since March 2019 and as a member of the board of directors of Scilex

Pharmaceuticals, Inc., our wholly owned subsidiary ("Scilex Pharma"), since November 2016. Mr. Shah has served as Chief Executive Officer and President of Semnur Pharmaceuticals since its inception in 2013. 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. Henry 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, 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 Portfolio

ZTlido

Our marketed product, ZTlido, is a lidocaine topical system approved for the relief of neuropathic pain associated with PHN. ZTlido was strategically designed to address the limitations of current prescription lidocaine patches by providing significantly improved adhesion and continuous pain relief throughout the 12-hour administration period. We launched ZTlido in October 2018 with an integrated commercial organization and we believe its differentiated therapeutic profile, combined with our competitive pricing strategy and our active direct marketing efforts have driven, and will continue to drive, accelerated sales growth and increased market uptake.

Prescription Lidocaine Patch Market Overview

Prescription lidocaine patches are approved by the FDA as a local anesthetic and are generally used as a first-line treatment for the relief of neuropathic pain associated with PHN. PHN is a chronic neuropathic pain syndrome that results as a complication following an infection of herpes zoster, also known as shingles. Herpes zoster symptoms resolve after a few weeks, but the pain caused by the nerve injury and surrounding the affected area can persist for months and sometimes years. According to Evaluate Ltd., there were over 3.5 million people living with PHN conditions in the United States in 2021. Lidocaine patches have also been used in patients with other types of pain, such as diabetic neuropathy, osteoarthritis and pain associated with surgery, cancer or trauma, and often in patients with LBP.

In 2024, there were more than 206 million prescription lidocaine patches sold in the United States, according to Symphony Healthcare. Of this number of prescriptions, there are only six main lidocaine patch manufacturers, which accounted for approximately 90% of the total prescriptions, according to Symphony Healthcare. We believe that the PHN market will continue to expand with the introduction of our lidocaine topical system, ZTlido, which is supported by our commercial organization, by prescribing trends away from opioid use, and by continued growth in the population of patients aged 45 years and older who are at greater risk of suffering from PHN. Unlike Lidoderm, the FDA has not determined that any other products are therapeutically equivalent to ZTlido, and accordingly, a prescription for ZTlido may not be able to be substituted by a generic product.

Current Treatment Landscape and Limitations of Existing Treatments

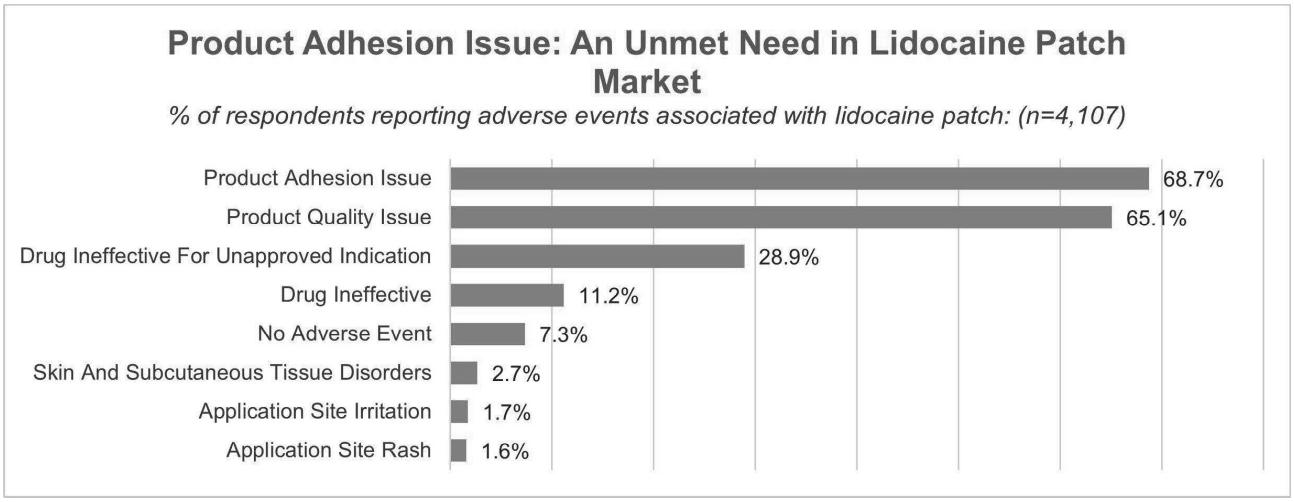
The recommended first-line treatment for the relief of neuropathic pain associated with PHN includes topical lidocaine, gabapentinoids (which have been associated with the potential for abuse as well as numerous adverse events), antidepressants and a multi-modal approach. Topical lidocaine and gabapentinoids are preferred for combination therapies due to their low propensity for drug-to-drug interactions. For example, an eight-week combination use with pregabalin (Lyrica) has been proven to reduce pain in half for patients who had inadequate relief on monotherapy, despite titration of pregabalin to effect. This efficacy boost was achieved without tolerability issues or adding to side effects.

A survey analyzing treatment patterns for neuropathic pain associated with PHN found that recommended first-line therapeutics were used in only 29% of patients examined from 2010 to 2014, while the remaining patients were started on various off-label treatments, including nonsteroidal anti-inflammatory drugs ("NSAIDS") and opioids. These drugs can have adverse effects, especially on elderly patients, which represent the majority of PHN patients. For example, opioids carry a well-characterized risk of abuse and misuse and the potential for serious side effects, such as respiratory depression, constipation and others, including death. According to the Centers for Disease Control and Prevention, over 75% of the 100,306 drug overdose deaths during the 12-month period ending in April 2021 involved opioids. Similarly, tricyclic antidepressants, which can be effective in managing the neuropathic pain associated with PHN, can result in significant systemic side effects and cardiotoxicity, posing risks to the elderly and patients with heart disease, epilepsy or glaucoma. These side effects make topical lidocaine products an attractive first-line treatment option from a safety perspective.

The safety of lidocaine patches is well supported in medical literature. Unlike transdermal medications that are designed to achieve systemic drug levels via absorption through the skin or mucosal membrane, leading to effects away from the application site, topical lidocaine has a local effect at the site of application. Because drug application is localized to the immediate area surrounding the patch, systemic absorption from a topical patch is low, reducing the risk of systemic side effects and lowering the potential for drug interactions relative to other systemic pharmacologic therapies. Due to the low systemic exposure and minimal systemic side effects reported in clinical trials, we believe a topical lidocaine patch is well suited for patients being treated with multiple medications or at a higher risk of side effects, including the elderly or those with chronic conditions. As a localized treatment, lidocaine patches have been used concomitantly with other medications in patients for whom monotherapy is inadequate. Furthermore, we believe medication administered topically rather than orally can improve patient compliance.

While lidocaine patches have certain advantages over the treatment alternatives discussed above, certain patches have limitations that may impact efficacy. For example, poor adhesion of the patch is a leading problem for topical lidocaine patches cited in the FDA Adverse Event Reporting System ("FAERS"). Because the drug is incorporated in the adhesive for these products, patches must maintain adhesion or risk compromising the ability to deliver their full drug dose. As a result, establishing strong adhesion is a key factor for patient compliance and satisfaction. In draft guidance issued in July 2021, the FDA recommended that developers of topical and transdermal delivery systems ("TDSs") conduct studies to characterize the adhesion performance of the product with suggested data requirements. Likewise, the FDA issued a draft guidance in October 2018 outlining the adhesion data requirements for generic TDSs. This guidance, along with Scilex's past experience with regulatory agencies, shows the FDA's interest and the importance of adhesion performance of these products. There are also dermal safety requirements that force developers to carefully balance adhesion performance against dermal safety. ZTlido is the first TDS product approved by the FDA that was able to demonstrate the targeted adhesion performance with an overall benign dermal safety profile.

The following figure depicts data derived from FAERS as of December 31, 2023:



For many of the competing lidocaine patches, a common drawback is the usage of hydrogel technology that limits the overall pharmaceutical efficiency of the product, requiring more total drug to be loaded into the patch to deliver a sufficient amount of drug to achieve a therapeutic effect. For example, Lidoderm has a drug load of 700 mg drug but only delivers 3± 2% of that drug load. Consequently, adhesive thickness must be increased in order to have a drug load sufficient to deliver a therapeutic dose of drug to the skin. As adhesive thickness increases, the product's pliability can be compromised to the extent that the patch loses adhesion as the skin

moves and wrinkles through normal patient activity. The weight of the hydrogel patches (largely due to high water content) further contributes to the challenge in maintaining adhesion.

The greater drug load also poses a risk of accidental exposure. For example, with a bioavailability of 3 ± 2% of the 700 mg drug load for Lidoderm, there is over 650 mg of drug remaining on the patch at the end of the 12-hour administration period, as captured in a bolded warning on the product label. If improperly disposed of, the residual drug poses the potential risk to children, pets and others of accidental exposure to a toxic amount of lidocaine, although we believe the risk with this formulation has not been evaluated.

In addition to prescription lidocaine patches, there are commercially-available OTC topical lidocaine products in the market, but none of these OTC products have been reviewed or approved by the FDA. Notably in 2003, the FDA proposed amending the tentative final monograph for OTC external analgesic drug products to clarify the status of patches (and poultices and plasters), noting that the dosage forms had not been determined to be generally recognized as safe and effective for any analgesia at that time. Therefore, the FDA would likely not consider these OTC products to be compliant with the monograph and do not have legal marketing status.

Our Solution

Our novel adhesion and delivery technology provides significantly improved adhesion compared to Lidoderm, manufactured by Endo Pharmaceuticals, and generic alternatives marketed by Mylan N.V. ("Mylan"), while providing bioequivalent delivery of lidocaine via an efficient drug delivery system. Our product is lighter, thinner and provides for a better patient experience without compromise to dermal safety and with no presentation of dermal sensitization. Below is a comparison of the key advantages of ZTlido to Lidoderm and generic lidocaine patches manufactured by Teva and by Mylan.

Key Advantages of ZTlido vs. Lidoderm and Associated Generics

	Benefits of ZTlido	ZTlido	Lidoderm	Teva's Generic Lidocaine Patch	Mylan's Generic Lidocaine Patch
Adhesion	Unique adhesion technology	Single-layer DIA non- aqueous multi-polymer matrix	Single-layer DIA aqueous base (hydrogel)	Unique adhesion technology	Single-layer DIA non- aqueous multi-polymer matrix
	Superior adhesion*	>90% adhesion (after 12-hours)	<65% adhesion (after 12-hours)	Not studied	<30% adhesion (after 12-hours)
	Labeled for use during moderate exercise and after heat exposure, and while showering and bathing	Labeled that can be used after heat exposure and during exercise, and able to be used while showering and bathing.	Unknown and not labeled for use after heat exposure or during exercise, and labeled to not get wet as it may not stick	Unknown and not labeled for use after heat exposure or during exercise, and labeled to not get wet as it may not stick	Unknown and not labeled for use after heat exposure or during exercise, and labeled to not get wet as it may not stick
Drug Delivery Efficiency	Reduced drug load	36 mg/patch 1.8% strength	700 mg/patch 5% strength	700 mg/patch 5% strength	140 mg/patch 5% strength
	Bioavailability	~48% (in-house studies)	3 ± 2% (per label)	3 ± 2% (per label)	11 ± 4% (per label)
	Reduced residual drug after use	16-17mg (in-house studies)	665 mg (per label)	665 mg (per label)	At least 115 mg (per label)
Ease of Use	Perforated release liner for ease of removal	Yes	No	No	No

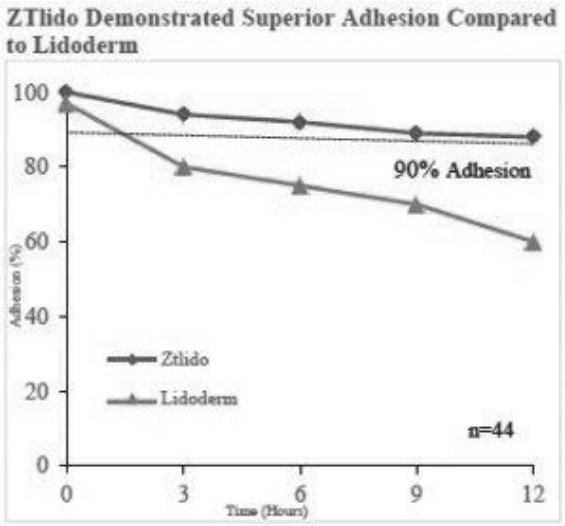
Note: DIA = Drug-in-adhesive

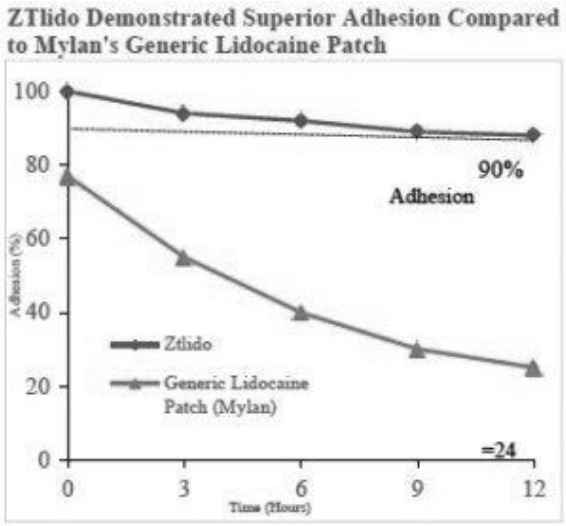
* Source: A Scilex-sponsored head-to-head comparative adhesion study (SCI-LIDO-ADH-003)

ZTlido has been strategically designed to address poor adhesion, a leading complaint associated with other currently marketed topical lidocaine products. ZTlido uses an advanced hot-melt technology, which uses premixing and hot-melt mixing of various excipients and lidocaine, followed by current Good Manufacturing Practices ("cGMP") compliant coating, lining, cutting and filling processes. In clinical studies, the technology provided significantly improved adhesion over Lidoderm® (a branded, prescription 5% lidocaine patch

product) ("Lidoderm") and Mylan's generic lidocaine patch at 12 hours after application. In a head-to-head study of 44 subjects, ZTlido showed statistically significant adhesion at all-time points compared to Lidoderm. Further, ZTlido maintained greater than 90% mean adhesion over the labeled 12-hour administration period while Lidoderm fell below this benchmark within 3 hours. ZTlido also showed superior adhesion when compared to Mylan's generic lidocaine patch. In this head-to-head study, ZTlido maintained greater than 90% mean adhesion throughout the labeled 12-hour administration period, while Mylan's generic product had a mean adhesion score of only 80% immediately after application, which progressively worsened over time. The formulation components are also carefully selected to achieve the target adhesion profile without creating dermal sensitization and maintaining a benign irritation profile.

In two separate studies, adhesion performance of ZTlido was compared to Lidoderm (with 44 subjects) and to Mylan's generic lidocaine patch (with 24 subjects), as depicted in the diagrams below. Both studies were performed with healthy volunteers using a standard clinical adhesion protocol where adhesion could not be enhanced (i.e., no reinforcement, pressing or reattaching). The level of adhesion was measured immediately after application (Time 0), and at 3, 6, 9 and 12 hours after application. ZTlido was the only lidocaine product to achieve over 90% adhesion over 12 hours after application in these studies. Maintaining 90% adhesion was a requirement for ZTlido's NDA approval.





The proprietary adhesive system utilized for ZTlido allows for a more efficient delivery of the drug from the patch to the skin. This was supported by a clinical study in which ZTlido achieved a bioequivalent dose of lidocaine while using a reduced drug load (36 mg for ZTlido versus 700 mg for Lidoderm). The drug delivery efficiency of ZTlido lessens the danger of accidental exposure. After 12 hours after application, ZTlido contains approximately 18 mg of residual lidocaine. In comparison, each Lidoderm patch leaves over 650 mg in the patch at the end of the 12-hour administration period. If improperly disposed of, the residual drug poses a risk of accidental exposure to a toxic amount of lidocaine to children, pets and others, although the risk with this formulation has not been evaluated.

The drug delivery efficiency of ZTlido also enables it to be manufactured as a thinner product relative to Lidoderm and Teva's generic lidocaine patch. We strategically leveraged this property of ZTlido by utilizing a thin patch design with a nonwoven backing cloth that allows for better adhesion of the product. The improved adhesion performance, thinner profile and incorporation of a flexible backing material allows for a product that maintains contact with the skin in contoured areas of the body when encountering torsional strains arising from normal body movements and during contact with clothing and bedding. While Mylan's generic lidocaine patch is also thinner than Lidoderm, it incorporates a film backing material that makes the product inflexible with body movements, contributing to its rapid loss in adhesion.

The adhesion profile of ZTlido allows the product to be used under moderate exercise conditions (tested in 4 sessions of 30-minutes of stationary bike exercise, cumulatively 2 hours) as captured in the ZTlido label. No ZTlido patches fell off during the entire 12-hour administration period. Lidoderm and the associated generics have not produced any public data on the use of their products by active pain patients under such conditions. ZTlido is also labeled to allow patients to shower and bathe while wearing the patch, which is supported by an adhesion or PK study showing that, while some degree of lifting is observed in these environments, the patches were able to be pressed back down or reattached in the cases where the product completely detached, with no clinically meaningful change in PK. In contrast, Lidoderm and the associated generics are labeled with the effects of water exposure being unknown.

Although ZTlido, Lidoderm and the associated generics are all labeled to not be used with heat (e.g., heating pad or blanket), the FDA-approved ZTlido label states that users may apply ZTlido to a treatment site after moderate heat exposure, such as after 15 minutes of heating pad use on a medium setting. This authorized use of ZTlido is of value as heat therapy is widely used in treating pain. In contrast, Lidoderm and the associated generics are not labeled for use with heat.

We believe ZTlido has other favorable features compared to Lidoderm and associated generic lidocaine patches such as the inclusion of a perforated release liner and the absence of cold flow. The perforated release liner allows for easier removal of the liner before application, which we believe provides convenience to patients who have dexterity challenges. In contrast, Lidoderm and generic lidocaine patches incorporate a single-sheet release liner, requiring patients to pick at the corners and edges to breach and remove before application. Cold flow is the propensity of the adhesive to migrate from the edges of the product under normal conditions, either in the product envelope or while on the skin. This can lead to difficulties in removing the product from the envelope and/or movement of the product, while on the skin, away from the intended administration site.

We launched ZTlido in October 2018 with support from an integrated commercial organization using a dedicated sales force and sales management, marketing and managed care capabilities. We market ZTlido through a dedicated sales force of approximately 65 people, targeting over 10,000 primary care physicians, pain specialists, neurologists and palliative care physicians who we believe treat the majority of PHN patients. We are utilizing a multi-channel marketing strategy to expand awareness and utilization of ZTlido. Our managed healthcare account executives have achieved success in adding ZTlido to key formularies, including CVS Caremark/Aetna Commercial, Cigna HealthCare (commercial and Medicare plans), Express Scripts (commercial and most Medicare plans), United Healthcare Commercial, Optum Rx Select Commercial, Anthem BCBS, BCBS Louisiana and Kansas, Lifetime/Excellus BCBS, MedImpact, CareFirst, Elixir Commercial and Medicaid in California, Florida, Idaho, and North Dakota. We believe the benefits of ZTlido, combined with our competitive pricing strategy and our active direct marketing efforts, have driven, and will continue to drive, accelerated sales growth and increased market uptake.

We plan to support several investigator-initiated research studies to explore the clinical benefits of using ZTlido in patients with carpal tunnel syndrome, neck pain, intercostal neuralgia and other possible indications.

SP-102 (SEMDEXA)

SP-102 (SEMDEXA) 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.

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 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 lumbosacral radicular pain 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 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 2027. 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 Corticosteroid Lumbar Epidural Analgesia Radiculopathy ("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 Numeric Pain Rating Scale ("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.

SP-103 (lidocaine topical system) 5.4%

We are developing SP-103 to be a triple-strength, non-aqueous lidocaine topical system for the treatment of acute pain. SP-103 leverages the same adhesive drug delivery formulation and manufacturing as ZTlido along with comparable backing material, perforated release liner and container-closure system. The increase in drug load is offset by a corresponding decrease in the adhesive diluent.

Our Solution

Our triple-strength SP-103 is an investigational, non-aqueous lidocaine topical system undergoing clinical development in acute pain. If approved, we believe that SP-103 could become the lidocaine topical product for acute pain indications. This program builds on the learning from ZTlido because both products share the same superior adhesion and superior drug delivery formulation and manufacturing technology. We are developing SP-103 to deliver a dose of lidocaine that is at least three times higher than any approved lidocaine topical products (including the approved ZTlido, which has a drug load of 36 mg lidocaine). We manufacture SP-103 to have a drug load of 108 mg lidocaine in a similar superior adhesion as ZTlido, along with comparable backing material, perforated release liner and container-closure system.

SP-103 has demonstrated delivery of three times the level of drug of ZTlido, and consequently delivers three times the level of drug of Lidoderm and associated generics by extrapolation. SP-103 has been granted fast track designation by the FDA in LBP. We believe SP-103, if successfully developed and approved, may be able to address the limitations of prescription lidocaine patches in treating acute pain by delivering a higher dose of lidocaine to the application site, but with systemic exposure of the drug remaining well below established safety thresholds. SP-103 has three times the drug load of ZTlido (108 mg versus 36 mg) in the adhesive system and can potentially deliver three times the level of the drug within a targeted area, with the convenience of a single topical system. This level of dosage for SP-103 is comparable to the maximum approved daily dosage of ZTlido, or three topical systems for up to 12 hours during a 24-hour period. By contrast, delivering higher levels of drug with other lidocaine patches is encumbered by the underlying hydrogel technology that constrains the level of drug that can be loaded into the adhesive of those products. The level of drug product in such patches can be increased only with a thicker adhesive layer, which can result in a loss of adhesion performance and flexibility. Further, increasing product dimensions can allow delivery of the drug over a larger area, but does not increase drug delivery to a localized area under the topical system.

We believe the acute pain market presents an attractive commercial opportunity due to the large patient population, lack of any approved drugs and high level of unmet medical need. We believe developing and commercializing a topical non-opioid product targeting this segment of the pain population represents a commercially attractive strategy.

Potential Additional Markets

Neuropathic Pain Market Overview

Neuropathic pain is triggered as a consequence of a disease or lesion to the somatosensory nervous system, altering its structure and function. It is maladaptive, meaning that the pain can be felt in the absence of a stimulus, and responses to innocuous and noxious stimuli are pathologically amplified. Neuropathic pain affects around 7-10% of the general population.

Common causes of the condition include postsurgical and post-traumatic nerve damage or nerve pressure, vascular malformations, alcoholism, metabolic diseases such as diabetes, cancer, viral infections, and neurological diseases such as multiple sclerosis. Chronic neuropathic pain may also be associated with an underlying condition such as diabetic neuropathy or cancer, and with treatments such as chemotherapy.

Neuropathic pain often manifests as a burning sensation, with the affected regions becoming sensitive to even a slight touch. The symptoms of neuropathic pain include burning and sensations of electric shock, sleep disturbance, depression and anxiety, numbness, pins and needles, and difficulty in sensing temperatures.

Neuropathic Pain: Current Treatment Landscape and Limitations of Existing Treatments

Recommended first-line treatment for the relief of neuropathic pain associated with PHN includes topical lidocaine, gabapentinoids (which have been associated with the potential for abuse as well as numerous adverse events), antidepressants and a multi-modal approach. Topical lidocaine and gabapentinoids are preferred for combination therapies due to their low propensity for drug-to-drug interactions. For example, an eight-week combination use with pregabalin (Lyrica) has been proven to reduce pain in half for patients who had inadequate relief on monotherapy, despite titration of pregabalin to effect. This efficacy boost was achieved without tolerability issues or adding to side effects.

According to the Centers for Disease Control and Prevention, over 75% of the 100,306 drug overdose deaths during the 12-month period ending in April 2021 involved opioids. Similarly, tricyclic antidepressants, which can be effective in managing the neuropathic pain associated with PHN, can result in significant systemic side effects and cardiotoxicity, posing risks to the elderly and patients with heart disease, epilepsy or glaucoma. These side effects make topical lidocaine products an attractive first-line treatment option from a safety perspective. The safety of lidocaine patches is well supported in medical literature. Unlike transdermal medications that are designed to achieve systemic drug levels via absorption through the skin or mucosal membrane, leading to effects away from the application site, topical lidocaine has a local effect at the site of application. Because drug application is localized to the immediate area surrounding the patch, systemic absorption from a topical patch is low, reducing the risk of systemic side effects and lowering the potential for drug interactions relative to other systemic pharmacologic therapies. Due to the low systemic exposure and minimal systemic side effects reported in clinical trials, we believe a topical lidocaine patch is well suited for patients being treated with multiple medications or at a higher risk of side effects, including the elderly or those with chronic conditions. As a localized treatment, lidocaine patches have been used concomitantly with other medications in patients for whom monotherapy is inadequate. Furthermore, we believe medication administered topically rather than orally can improve patient compliance.

While lidocaine patches have certain advantages over the treatment alternatives discussed above, certain patches have limitations that may impact efficacy. For example, poor adhesion of the patch is a leading problem for topical lidocaine patches cited in the FAERS. Because the drug is incorporated in the adhesive for these products, patches must maintain adhesion or risk compromising the ability to deliver their full drug dose. As a result, establishing strong adhesion is a key factor for patient compliance and satisfaction. In draft guidance issued in July 2021, the FDA recommended that developers of topical and TDSs conduct studies to characterize the adhesion performance of the product with suggested data requirements. Likewise, the FDA issued draft guidance in October 2018 outlining the adhesion data requirements for generic TDSs. This guidance, along with Scilex's past experience with regulatory agencies, shows the FDA's interest and the importance of adhesion performance of these products. Since SP-103 uses the same technology as ZTlido, we anticipate that SP-103 will have similar superior adhesive properties.

Acute & Chronic LBP Market Overview

The safe and effective treatment of acute and chronic LBP addresses a high unmet need and creates large market opportunities. LBP affects about 70% of people in resource-rich countries at some point in their lives. Acute and chronic LBP can be self-limiting, however. One year after an initial episode, as many as 33% of people still have moderate intensity pain and 15% have severe pain. Acute LBP has a high recurrence rate with 75% of those with a first episode having a recurrence. Although acute episodes may resolve completely, they may increase in severity and duration over time. Americans spent approximately $134.5 billion in 2016 on treating LBP and neck pain, which was the highest expenditure among 154 conditions studied by the Department of Institute for Health Metrics and Evaluation at the University of Washington.

Acute & Chronic LBP: Current Treatment Landscape and Limitations of Existing Treatments

According to the Centers for Disease Control and Prevention, in 2018, 28.0% of men and 31.6% of women aged 18 years old and older had lower back pain in the past three months. The percentage of women who had lower back pain increased as age increased. Among men, the percentage increased with age through age 74 years and then decreased. Women in the age groups 18 - 44, 45 - 64, and 75 years and older were more likely to have lower back pain in the past three months than were men in the same age groups, but percentages were similar between men and women in the age group 65-74 years. Although most patients recover quickly with minimal treatment,

proper evaluation is imperative to identify rare cases of serious underlying pathology. Certain red flags should prompt aggressive treatment or referral to a spine specialist, whereas others are less concerning. Serious red flags include significant trauma related to age (i.e., injury related to a fall from a height or motor vehicle crash in a young patient, or from a minor fall or heavy lifting in a patient with osteoporosis or possible osteoporosis), major or progressive motor or sensory deficit, new-onset bowel or bladder incontinence or urinary retention, loss of anal sphincter tone, saddle anesthesia, history of cancer metastatic to bone and suspected spinal infection. Without clinical signs of serious pathology, diagnostic imaging and laboratory testing often are not required. Although there are numerous treatments for nonspecific acute LBP, most have little evidence of benefit. Patient education and medications such as nonsteroidal anti-inflammatory drugs, acetaminophen and muscle relaxants are beneficial.

SP-104 (4.5mg, low-dose naltrexone hydrochloride delayed-release capsules)

We are developing SP-104 for the treatment of fibromyalgia. Low-dose naltrexone hydrochloride delayed-release capsules are routinely used off-label to treat fibromyalgia and other chronic pain conditions such as complex regional pain.

Fibromyalgia Market Overview

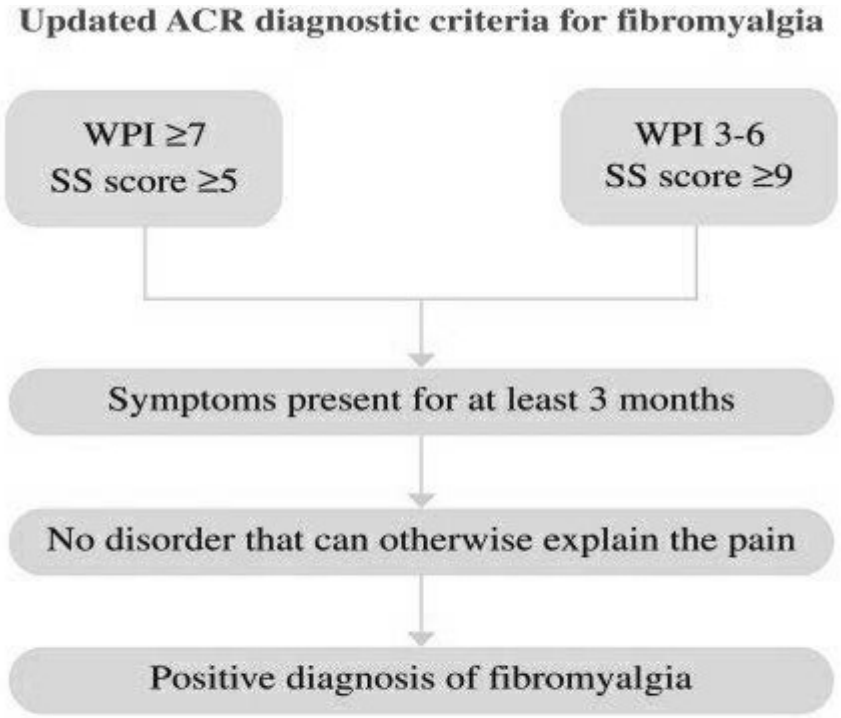
Fibromyalgia affects an estimated 10 million people in the United States and an estimated 3% to 6% of the world population. While it is most prevalent in women, it also occurs in men and children of all ethnic groups. Fibromyalgia is the second most common disorder that rheumatologists encounter, seen in 15% of evaluated patients. Approximately 8% of patients cared for in primary care clinics have fibromyalgia. Prominent fibromyalgia researchers and specialists estimate the economic burden of fibromyalgia in the United States to be between $12 billion to $14 billion each year and the condition accounts for a loss of 1% to 2% of the national overall productivity.

Potential Complications of Fibromyalgia

The following is a non-exhaustive list of complications of fibromyalgia:

- extreme allodynia with high levels of distress;
- opioid or alcohol dependence;
- marked functional impairment;
- severe depression and anxiety;
- obesity and physical deconditioning; and
- metabolic syndrome.

Although fibromyalgia is frequently grouped with arthritis-related conditions, there is no apparent inflammation or damage to the joints, muscles or other tissues. The diagnostic criteria for fibromyalgia are detailed in the chart below.



ACR: American College of Rheumatology; SS: symptom severity; WPI: widespread pain index.

Adapted from Buskila D & Sarzi-Puttini P.Isr Med Assoc J. 2008:10(1):77-8.

See also: https://www.changepain.ie/en-ie/pain-insights/key-pain-conditions/fibromyalgia

Currently approved products for pain in fibromyalgia, including duloxetine, pregabalin and milnacipran, have limited efficacy. Responders applying such products can only demonstrate a 27% to 40% reduction of symptoms, which is far below the commonly accepted threshold of 50% to prove efficacy in treating fibromyalgia. In light of this, we believe new treatments with higher efficacy are needed to improve management of fibromyalgia.

Our Solution

SP-104 has key clinical data supporting its use in fibromyalgia. There are investigational trials that support use and development of SP-104 for fibromyalgia. Currently there are no low-dose formulations (i.e., less than 5 mg) available. Physicians currently use the commercially available high-dose tablets (50 mg) and have compounding pharmacies aliquot lower doses for patients. Pharmacy-compounding is inherently inaccurate and does not involve analyses to confirm that the aliquoted product has the target level of drug, and there is no assurance as to content uniformity within a batch as well as other quality attributes critical for pharmaceutical product performance. This approach can lead to errors in dosing and challenges with titration. The commercial products and pharmacy-compounded products also allow for the immediate release of the drug in the stomach, which can lead to compliance challenges due to severe side effects. Common side effects for naltrexone include hyperalgesia, dysphoria, insomnia and anxiety. All these issues culminate into patient compliance issues and result in the eventual abandonment of an otherwise viable therapy to treat this debilitating disease.

Our SP-104 uses delayed burst release technology that bypasses the stomach and releases the drug in the gut (upper intestine). When taking SP-104 at night before bed, peak drug levels are achieved at night during sleep, allowing the patient to avoid conscious perception of hyperalgesia and other side effects. The combination of the delayed-release and administration at night may also maximize efficacy as most endorphin/ enkephalin release is during sleep, which maximizes the product's potential to elicit compensatory response.

We are committed to developing SP-104 for fibromyalgia. Phase 1 studies are designed to characterize the PK and safety profile of SP-104. If successful, we believe SP-104 can become a pivotal treatment for management of fibromyalgia, which represents a large commercial opportunity with high unmet demands.

Commercialization and Market Access

Sales & Marketing

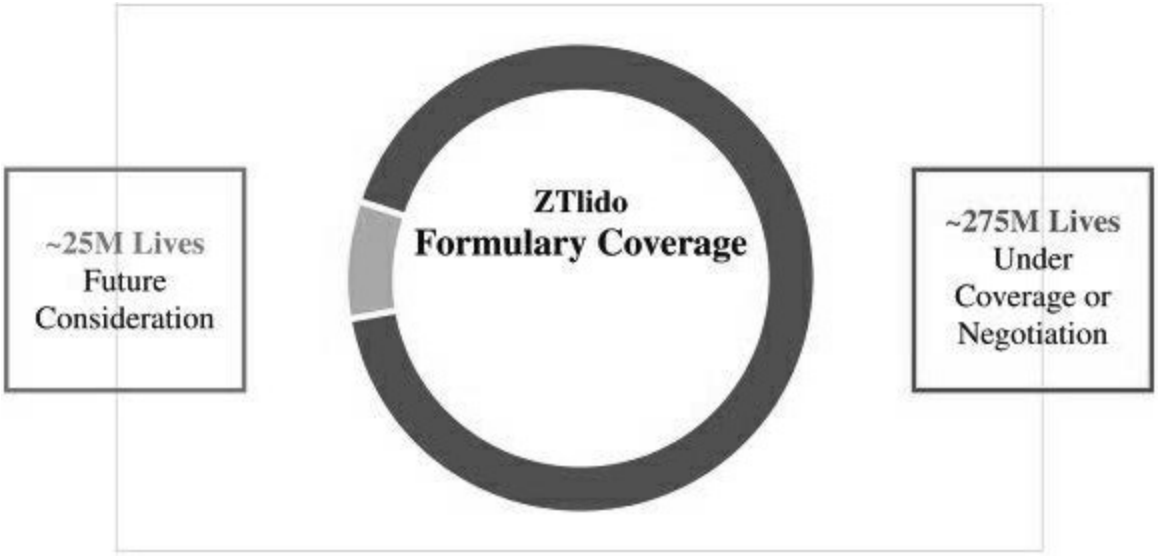
We have built a robust and integrated commercial infrastructure using a dedicated sales force and sales management, marketing and managed care capabilities, to maximize the potential of our three current marketed products, ZTlido, ELYXYB and GLOPERBA, and to commercialize our product candidates, if approved. We are focused on achieving accelerated sales growth and increased market uptake for ZTlido in the topical lidocaine product market, where we believe we have the only actively promoted product, ELYXYB in the migraine market, and GLOPERBA in the grout market. Our dedicated sales force of over 70 people has broad experience in pain management and is exclusively focused on promoting ZTlido, ELYXYB and GLOPERBA. Our sales representatives leverage their established relationships to call on over 10,000 target pain specialists, neurologists, select primary care providers and palliative care physicians who Scilex believes treat the majority of PHN patients and migraine patients. We believe these same call points provide treatment for the sciatica, acute LBP, and acute pain patients that could benefit from SEMDEXA and SP-103, if approved. Our sales representatives typically have over 10 years of experience in promoting a broad scope of pain management products that Scilex intends to leverage as our product candidates are commercialized.

As of December 31, 2024, ZTlido had gained approximately 9.2% market share of the lidocaine patch prescription market across the territories we cover in the United States. The total prescriptions of ZTlido for the year ended December 31, 2024 grew by approximately 2.4% over the year ended December 31, 2023, according to Symphony Healthcare's national prescription data. Our experienced sales representatives and managers are supported by our marketing team, whose members have successfully launched over 20 products with large pharmaceutical, biotechnology and specialty pharmaceutical companies. Our marketing team has developed a multi-channel marketing strategy to promote the continued uptake of ZTlido by highlighting its significantly improved adhesion and continuous pain relief throughout the 12-hour administration period. We are also promoting ZTlido with a marketing campaign that engages patients seeking relief for neuropathic pain associated with PHN through social media and medical and consumer journals. Further, our marketing function is supported by an experienced analytics team that leverages its experience in forecasting and analytics to draw insights from healthcare databases to inform our marketing strategy. As part of our broader commercial strategy, our marketing analytics team is conducting market research to support the launch of SP-102, SP-103 and SP-104, if any of these candidates is approved. We believe that our sales force, supporting commercial infrastructure and established relationships with our targeted physician audience will provide a strategic advantage in pursuing potential partnerships to commercialize other non-opioid pain management therapeutics.

Market Access

We have established a patient-centric market access function with robust capabilities across the market access continuum, including payor sales, contracting and marketing strategies, supplemental patient assistance programs and responsible drug pricing to support patients' access to ZTlido. Our team of managed healthcare account executives has demonstrated experience in establishing products on formularies and have currently prioritized and targeted select payor accounts representing approximately 275 million of the over 300 million lives, with the remaining 25 million to be considered in the future. Currently, ZTlido is covered for over 200 million lives in the United States and coverage continues to improve. As of January 2023, we have secured coverage for ZTlido on CVS Caremark/Aetna Commercial, Cigna HealthCare (commercial and Medicare plans), Express Scripts (commercial and most Medicare plans), United Healthcare Commercial, Optum Rx Select Commercial, Anthem BCBS, BCBS Louisiana and Kansas, Lifetime/Excellus BCBS, MedImpact, CareFirst, Elixir Commercial and Medicaid in California, Florida, Idaho, and North Dakota. We continue to negotiate coverage with large payors and pharmacy benefit managers in all books of business.

ZTlido Formulary Coverage - Over 90% of Lives Covered or In Negotiation



We utilize an outside vendor to administer a patient assistance program directed at patients with commercial insurance or those paying out-of-pocket. With the co-pay assistance program, qualifying patients do not have to pay any co-payment for their ZTlido prescription. We utilize an external vendor and train the sales force to work proactively with clinician office managers in completing required forms for prior authorization for ZTlido.

Clinical Development Overview

ZTlido

Clinical Trial Highlights

We have evaluated ZTlido in over 600 subjects in clinical trials to support marketing approval and promotional campaigns for the relief of neuropathic pain associated with PHN in the United States. Our studies sought to investigate the bioequivalence of ZTlido compared to Lidoderm, adhesion performance and the dermal safety and tolerability of ZTlido under a range of application times and settings. Based on these studies, we concluded that ZTlido:

- demonstrated bioequivalence to Lidoderm in study SCI-LIDO-PK-002A;
- showed greater than or equal to 90% adhesion in over 90% of the subjects at the end of the 12-hour administration period in study SCI-LIDO-ADH-001;
- showed superior adhesion to Lidoderm and Mylan's generic lidocaine patch in studies SCI-LIDO-AHD-002 and SCI-LIDO-ADH-003;
- was not meaningfully impacted by heat or exercise in study SCI-LIDO-HEX-001;
- was able to be used under showering and bathing conditions in study SCI-LIDO-ADH-004; and
- did not show clinically meaningful dermal irritation in study SCI-LIDO-DERM-001.

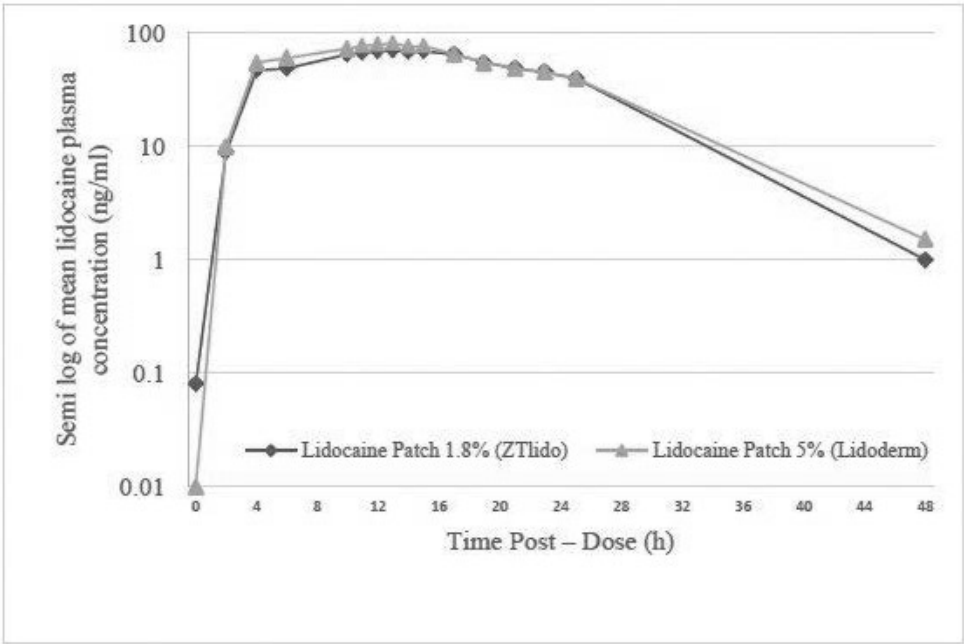
ZTlido Study Details

Pivotal Bioequivalence Study - SCI-LIDO-PK-002A

We conducted a comparative single-dose PK study between ZTlido and Lidoderm designed as a two-way cross-over in 54 healthy subjects. In this trial design, each subject received a single dose of three ZTlido or three Lidoderm patches followed by a washout period and the administration of the other product. The purpose of this study was to establish bioequivalence between the products, which was determined by the statistical comparability of Cmax and AUC as shown in the figure below.

This was considered the pivotal clinical trial for ZTlido, as it provided the pharmaceutical bridge between the two products and showed that ZTlido had comparable safety and efficacy to Lidoderm. As a result of successfully establishing the pharmaceutical bridge, no stand-alone clinical efficacy studies were required by the FDA to determine ZTlido's analgesic effects for ZTlido's approval.

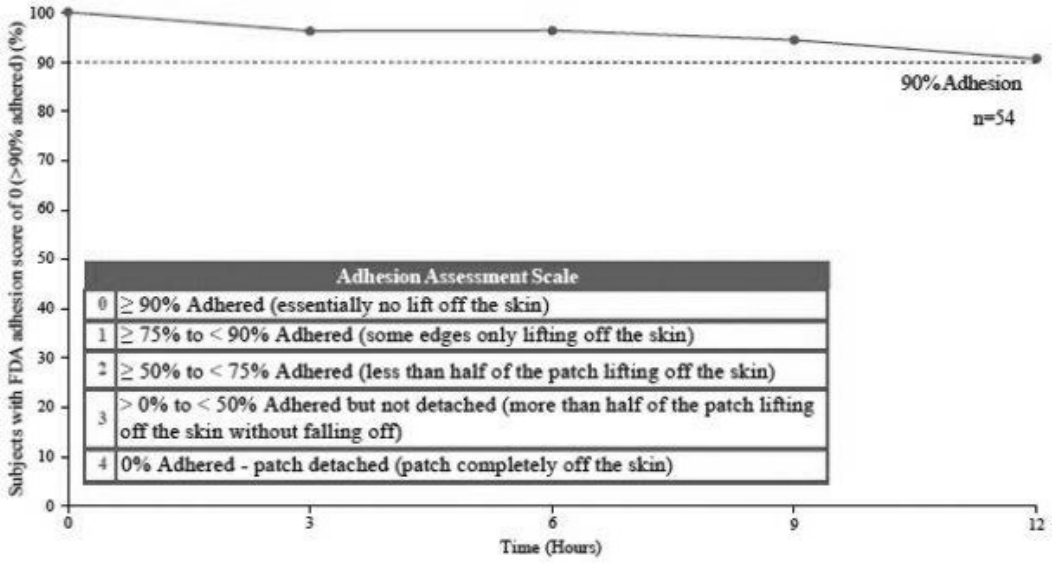
Mean Lidocaine Plasma Concentration Time Profiles - Semilog Scale



Pivotal Adhesion Study - SCI-LIDO-ADH-001

We conducted an open-label, single-treatment, single-period, single-application adhesion performance study in 54 healthy, human subjects to assess the adhesion performance of ZTlido over the 12-hour administration period of the product. The study also investigated whether ZTlido met an FDA established adhesion performance benchmark of greater than or equal to 90% adhesion in greater than or equal to 90% of subjects in the study at the end of the administration period. At the end of the 12-hour administration period, over 90% of the subjects (49 out of the 54 subjects) maintained greater than or equal to 90% adhesion, with no adverse events reported during the study.

ZTlido Maintained Greater Than 90% Adhesion Over the 12-Hour Time Period



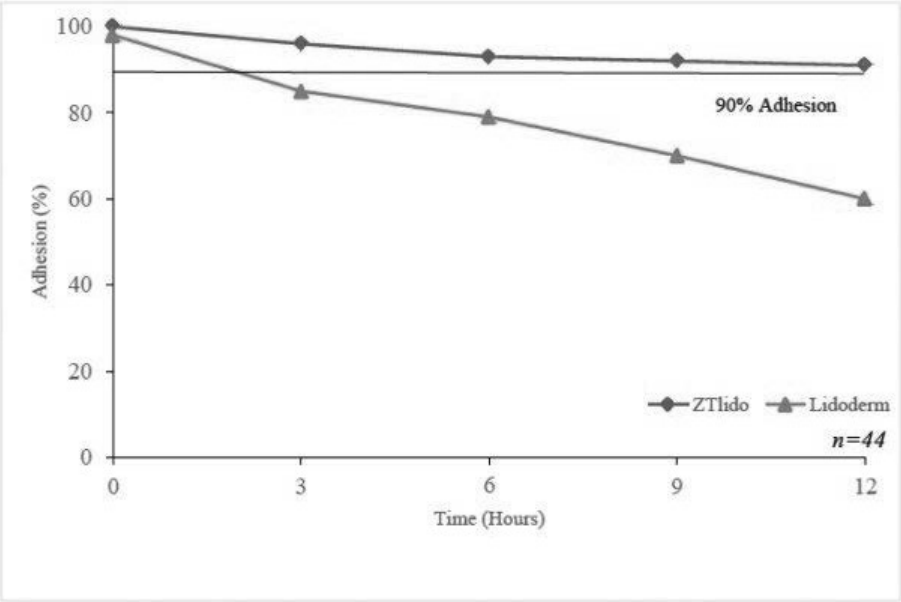
This study was considered the pivotal adhesion study for marketing approval and is summarized in the product label.

Head-to-Head Adhesion Study versus Lidoderm - SCI-LIDO-ADH-002

We conducted an open label, single-treatment, three-period, single-application adhesion performance study in 44 healthy, human subjects to evaluate the adhesion performance of ZTlido compared to the adhesion performance of Lidoderm over a 12-hour administration period.

In this study, ZTlido demonstrated significantly superior mean adhesion scores compared to Lidoderm at 3, 5, 9 and 12 hours after application. ZTlido maintained a mean percent adhesion performance greater than 90% over the 12-hour administration period, while Lidoderm fell below 90% mean adhesion within three hours.

ZTlido Demonstrated Superior Adhesion Compared to Lidoderm

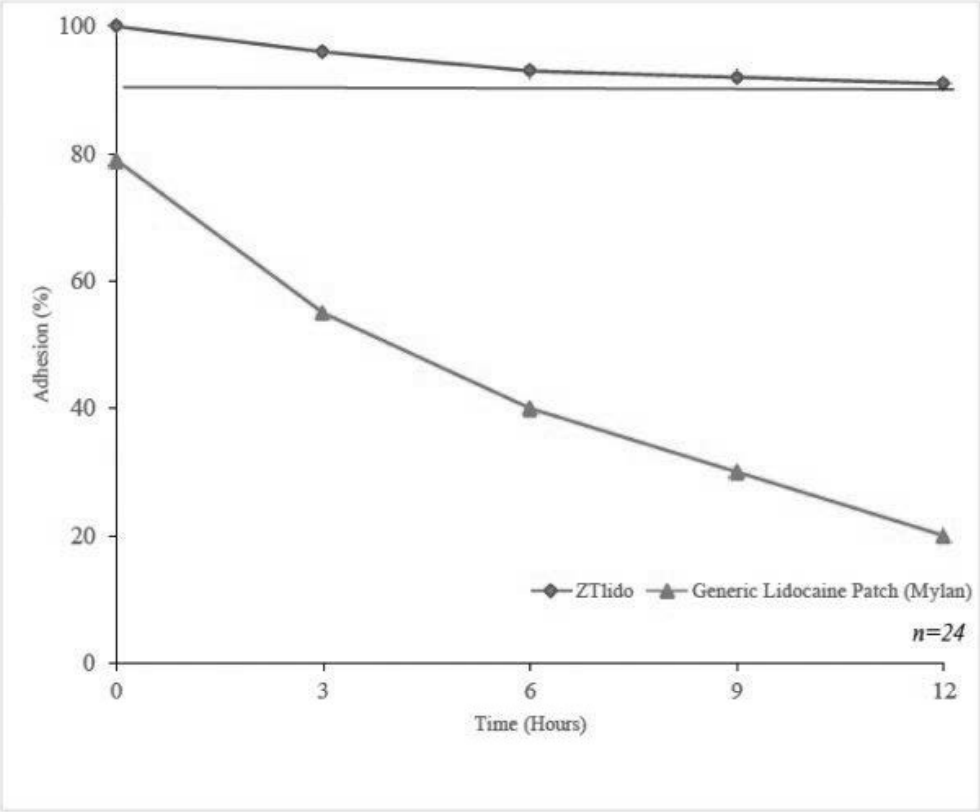


Head-to-Head Adhesion Study versus Mylan's Generic - SCI-LIDO-ADH-003

We conducted an open-label, single-treatment, two-period, single-application adhesion performance study in 24 healthy, human subjects to evaluate the adhesion performance of ZTlido compared to the adhesion performance of a generic lidocaine patch 5% manufactured by Mylan over a 12-hour administration period. The purpose of this study was to compare the adhesion performance of ZTlido against a topical lidocaine product involving a non-aqueous formulation. We selected Mylan's generic lidocaine patch as a comparator because it has similar product characteristics, including a non-aqueous polymer drug-in-adhesive system allowing for a thinner patch and a lower drug load as compared to Lidoderm.

In this study, ZTlido demonstrated significantly superior adhesion performance compared to Mylan's generic lidocaine patch. ZTlido maintained a mean adhesion greater than 90% over the 12-hour administration period, while the generic product had a mean adhesion score of only 80% immediately after application, which declined to a mean adhesion score of 27% at 12 hours after application.

ZTlido Demonstrated Superior Adhesion Compared to Mylan's Generic Lidocaine Patch



PK and Adhesion Study under Exercise and Heat Conditions - SCI-LIDO-HEX-001

We conducted an open-label, randomized, three-treatment, three-sequence, three-period, cross-over, PK and adhesion performance study of three ZTlido topical systems applied to separate areas in 12 healthy, human subjects during physical exercise, exposure to heat and under normal conditions, respectively. The three treatment periods were as follows:

- Treatment A sought to assess the PK and adhesion performance of ZTlido under physical exercise conditions. In this treatment period, subjects were instructed to perform exercise for 30 minutes on a stationary bike achieving a heart rate of 108 beats per minute, with continuous heart monitoring during exercise. Subjects were instructed to perform exercise immediately after the application of the topical system and at 2.5, 5.5 and 8.5 hours following the application of the topical system.

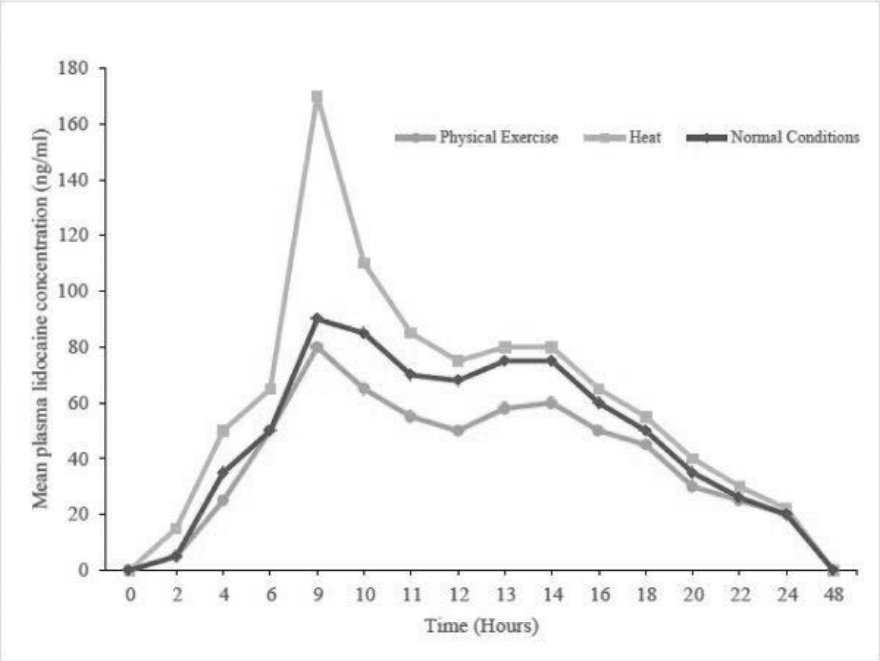
- Treatment B sought to assess the PK and adhesion performance of ZTlido under heat conditions. In this treatment period, a heating pad adjusted to the medium setting was applied for 20 minutes immediately after application of the topical system and at 8.5 hours following the application of the topical system.

- Treatment C sought to assess the PK and adhesion performance of ZTlido under normal conditions. In this treatment period, topical systems were applied to the mid-lower back and worn for 12 hours.

In treatment A, adhesion and PK performance were not compromised by exercise, as reflected in the product label. In treatment B, heat had an effect on PK but had no effect on adhesion. In Treatment C, normal PKs were observed and greater than 90% of subjects showed greater than 90% adhesion. No meaningful irritation was observed across all treatments across all time points in any of the subjects.

The impact of heat and exercise on PK is presented in the figure below. It was observed that heat had an effect on Cmax, but the drug returned to normal levels after removal of heat and there was no clinically meaningful observed effect on AUC. Heat did not appear to have a deleterious or catastrophic effect on topical system performance, either as a dose-dump (i.e., immediate and complete release of all drug from the product), or as reduced drug delivery (i.e., much lower systemic exposure). There was no significant effect on PK observed with exercise when compared to subjects under normal conditions.

ZTlido Demonstrated Consistent PK Performance under Exercise and Heat Conditions*



* Defined as no clinically meaningful changes by meeting bioequivalence criteria

Dermal Sensitization and Irritation Study - SCI-LIDO-DERM-001

We conducted a provocative dermal sensitization and irritation human clinical trial, also referred to as a repeat insult topical system test, intended to elicit the worst-case dermal safety of ZTlido by extended wearing of the product over multiple days. In this trial, we compared the sensitization potential, and the overall irritation profiles of ZTlido and Lidoderm in 218 normal and healthy subjects. We used a 7-point scale where a score of 0 indicated no irritation and a score of 7 was considered a strong reaction spreading beyond the application site.

In this study, results showed that the adhesion quality of ZTlido did not compromise dermal safety. The study reported that ZTlido did not show potential for dermal sensitization and showed an overall benign irritation profile. Both ZTlido and Lidoderm had a mean irritation score well below 1, which is defined as barely perceptible erythema. This study allowed for the ZTlido label to adopt the same local tolerance language as labeled for Lidoderm.

Photoallergy and Phototoxicity Studies - SCI-LIDO-PHOT0-001 and SCI-LIDO-PHOTO-002

We conducted a 6-week randomized study, SCI-LIDO-PHOTO-001, to evaluate the potential of ZTlido and its comparator, Lidoderm, to induce a photoallergic skin reaction in 54 healthy volunteers. In this study, we observed that ZTlido was not photoallergic.

We conducted a 4-day, randomized study, SCI-LIDO-PHOTO-002, to evaluate the irritation potential of ZTlido and its comparator, Lidoderm, when application to skin is followed by light exposure in 32 healthy volunteers, using a phototoxicity patch test. In this study, we observed that ZTlido was not phototoxic.

Post-Approval Studies for ZTlido

Water Stress Study (Shower and Swimming) - SCI-LIDO-ADH-004

We conducted a single-dose study in 24 subjects to examine the adhesion and lidocaine delivery (PK) of ZTlido when it is exposed to two separate water stress conditions of (1) showering (10 minutes) and (2) swimming (15 minutes). The study showed that while some degree of product lifting was observed, the product could be pressed back down or reattached with no further diminished adhesion performance or drug delivery. This study led to a change in the product label indicating that patients may use the product while showering or bathing. This provides significant patient convenience as Lidoderm and the associated generics are labeled to avoid contact with

water such as bathing, swimming or showering, as these products may not stick if they get wet. With ZTlido, patients can engage in these activities within the 12-hour administration period.

Investigator-Sponsored Studies

We plan to support several investigator-initiated research studies to evaluate the clinical benefits of using ZTlido in patients with carpal tunnel syndrome, neck pain, intercostal neuralgia and other possible indications.

SP-102 (SEMDEXA)

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. 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.

Clinical Trial 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:

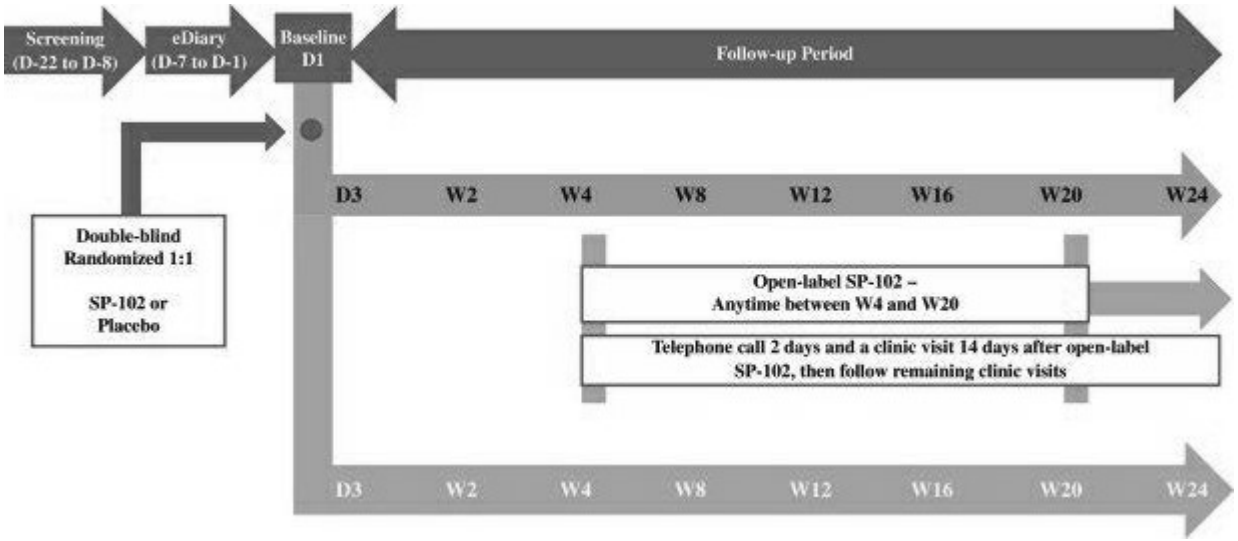
- Repeat injections of SP-102 showed continued pain reduction with no unexpected adverse events based on preliminary results from the SP-102-03 study;
- SP-102 showed an extended local activity with epidural administration in the ES-1504 study;
- SP-102 showed an extended residence time and tolerability in the 1014-1512 and the 1014-2847, preclinical studies; and
- The introduction of SP-102 into blood vessels did not result in neurological complications in the UPD003-IS21 preclinical toxicology study.

SP-102 (SEMDEXA) 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 safety of administering SP-102 in a larger patient population. After week 4, subjects who met certain pain criteria received open-label SP-102 to investigate the safety of repeat injections and the duration of pain relief following injection. This well-controlled, randomized trial was designed to demonstrate evidence of the analgesic effect and safety 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 Oswestry Disability Index; (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, and Patient Global Impression of Change and (iii) evaluation of the safety of a single and repeat SP-102 injection.

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



A full 6-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. 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 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 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), Patient Global Impression of Change ("PGIC") (P<0.001) and Clinical Global Impression of Change ("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 efficacy 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 serious adverse events ("SAEs") related to SP-102 or its administration procedure. There were no adverse events ("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 ("PT") 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.

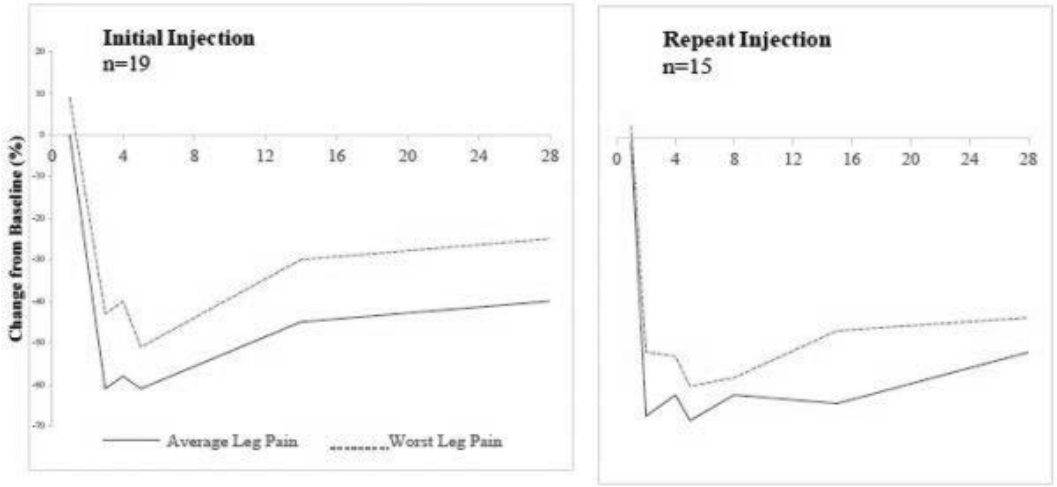
CI: confidence interval; ITT: intent-to-treat (randomized population)

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 (SEMDEXA) Compared to Reference Listed Drug - 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 (Reference Listed Drug ("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 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 time to maximum serum concentration ("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.

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.

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.

SP-103 (lidocaine topical system) 5.4%

SP-103 is an investigational, non-aqueous lidocaine topical system undergoing clinical development in acute LBP. As a higher strength topical lidocaine system, SP-103 will build on the learnings from ZTlido because both products share the same adhesive drug delivery formulation and manufacturing technology. The clinical program involves evaluating the safety and efficacy of SP-103 for the treatment of acute LBP. A Phase 1 study was completed that demonstrated bioequivalent PK between the administration of a single SP-103 and the administration of three commercial ZTlido. The study also showed linear kinetics among multiple applications of SP-103 (i.e., one, two or three patches) over a 12-hour administration period. Adhesion performance was assessed and found to be comparable between SP-103 and ZTlido.

We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute LBP associated with muscle spasms. SP-103 was safe and well tolerated. Increase of lidocaine load in topical system by three times, compared with approved ZTlido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. SP-103 received FDA Fast Track status in LBP. We will continue to analyze the SP-103 Phase 2 trial data along with an investigator study at Johns Hopkins University completed in the second half of 2023, investigating ZTlido in patients with chronic non-radicular neck pain, which also has shown promising top-line efficacy and safety results. While the phase 2 trial in acute LBP had demonstrated an effect in a subpopulation of patients who had acute LBP associated with more severe muscle spasms, the investigator-initiated randomized, crossover, placebo-controlled trial showed substantial reduction of average daily pain in general population of patients with chronic non-radicular neck pain following the application of ZTlido. We therefore plan to prioritize further potential development of SP-103 for the treatment of acute pain. SP-103, if approved, could become the first FDA-approved lidocaine topical product for the treatment of acute pain.

SP-104 (4.5mg, low-dose naltrexone hydrochloride delayed-release capsules)

Two Phase 1 trials have been completed for SP-104 at investigative sites in New Zealand:

- SP-104-01 is a food effect and bridging PK study comparing SP-104 to Naltrexone HCL Tablets conducted on approximately 18 healthy adult subjects. The study is designed to be an open-label, three-period, three-treatment, randomized study to characterize the PK and safety and tolerability of SP-104 under fasting and fed conditions. Subjects are randomly administered a single dose of one of three treatments and followed for PK and safety for a period of time followed by a washout period before receiving one of the other treatments. All subjects receive all three treatments. The study characterize the single-dose clinical studies and ultimately the commercial label. The study also serves as a "pharmaceutical bridge" between SP-104 and the commercial RLD (Naltrexone HCI tablets, USP 50 mg) to support the eventual Section 505(b)(2) NDA. Assuming that the rate and extent of drug exposure for SP-104 will be lower than that observed for the RLD, this study allows us to rely upon the FDA's findings of safety for the RLD instead of having to perform extensive nonclinical animal safety toxicology studies and establish an extensive clinical safety database. Our development program can focus on establishing efficacy of SP-104 in the treatment of fibromyalgia.

- SP-104-02 is a Phase 1 study of SP-104 conducted on approximately 52 healthy human subjects. The study is designed to be a double-blind, randomized, two-period, two-treatment crossover study to evaluate the safety of SP-104, compared to immediate release naltrexone capsules. The primary purpose of the study is to test the hypothesis that, when taken at night, the delayed release of 4.5 mg Naltrexone mitigates against adverse events known for the drug and could affect patient compliance in maintaining treatment for their fibromyalgia. In a small (n=52) cross-over trial in healthy volunteers comparing SP-104 (naltrexone hydrochloride delayed-release 4.5 mg) to naltrexone hydrochloride immediate release 4.5 mg (the "compared drug"), there were no serious adverse effects, no AEs leading to discontinuation, no meaningful differences in physical examinations, vital signs, or laboratory parameters between treatments, no severe AEs for either treatment. Of the 52 patients receiving at least a single injection of SP-104, there were 21 (40%) patients experiencing at least one TEAE, 14 (27%) patients experiencing at least one treatment-related TEAE, 12 (23%) patients experiencing at least one treatment-related TEAE within 72 hours after first administration of SP-104. Notable AEs of special interest were nausea and headache within 72 hours after first administration of SP-104. SP-104 administered at night before bed resulted in a lower number of subjects with at least one AE ($p = 0.0414$), and an even lower number of subjects with at least one AE within 72 hours after the first administration of SP-140 when compared to the compared drug. There was a lower number of subjects with AEs of special interest within 72 hours after administration of SP-104 (n=9; 12 events) versus the compared drug (n=15; 20 events). Notable AEs of special interest observed within 72 hours after administration of the applicable drug are nausea (SP-104: n=0; the compared drug: n=3) and headache (SP-104: n=6; the compared drug: n=12). The study randomized subjects to one of two treatments followed by a washout period and then receipt of the other treatment, which allows all subjects to act as their own control. The study will support intellectual property, inform on clinical study design and contribute to safety characterization to support market applications.

We completed both studies in the second quarter of 2022. We plan to use data collected from these studies to support an Investigational New Drug application with the FDA, which is expected to enable further clinical development and initiation of a planned multi-center placebo-controlled registration trial in the field of fibromyalgia. The registration trial is designed to be a Phase 3, randomized double-blind, placebo-controlled, parallel group, multicenter study that meets the regulatory requirements of an "adequate and well-controlled" study to establish the efficacy of SP-104 in the treatment of fibromyalgia. Depending on the outcomes, this registration trial alone may be efficient in supporting market approval of SP-104 or an additional Phase 3 study may be required.

Medical Affairs

Our Medical Affairs team includes in-house medical expertise, health economics and third-party payor support. The Medical Affairs team works with our clinical team to identify sites for clinical trials, support the investigator teams and develop publication plans for clinical and real-world ZTlido data and our product candidates. Our Medical Affairs team also works with Key Opinion Leaders, professional societies and patient advocacy groups to educate on and support the appropriate use of pain therapeutics, including topical pain products. Further, our Medical Affairs team provides our sales organization with therapeutic knowledge and product training. The Medical Affairs team and Promotional Review Committee review all promotional materials for scientific accuracy. The Medical Affairs team also develops lifecycle planning and works with our clinical team to determine registration or supportive studies, oversee post-approval studies and support investigator-sponsored trials.

Manufacturing and Supply Chain

We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our product. 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.

ZTlido

ZTlido is a single-layer, drug-in-adhesive topical delivery system comprised of an adhesive material containing 36 mg lidocaine, which is applied to a pliable nonwoven cloth backing and covered with a polyethylene terephthalate film release liner. ZTlido is commercially manufactured for us by Oishi in Japan. We have exclusive worldwide rights to Oishi's proprietary formulation and manufacturing technologies except with respect to Japan. ZTlido is manufactured using premixing and hot-melt mixing of various excipients and lidocaine, followed by cGMP compliant coating, lining, cutting and filling processes. ZTlido is packaged as a carton of 30 topical systems, into individual child-resistant envelopes. See the section of this Annual Report on Form 10-K titled "*Business - Material Agreements - Itochu and Oishi Product Development Agreement*" and "*Business - Material Agreements - Itochu and Oishi Commercial Supply Agreement*" for additional information regarding the manufacturing and supply chain of ZTlido.

Once production is complete, commercial product shipments are sent to the United States, where our exclusive third-party logistics distribution provider, Cardinal Health 105, LLC ("Cardinal Health 105"), ships them to temperature-controlled customer distribution centers, which are generally able to deliver finished product to retail pharmacies on the same day, or within 24 hours. We currently contract with multiple pharmaceutical distributors throughout the United States, including McKesson Corporation ("McKesson"), Cardinal Health 110, LLC ("Cardinal Health 110") and AmerisourceBergen Corporation ("AmerisourceBergen"). Distributors have agreements in place that provide us with access to large retail chains, including CVS, Walgreens, Rite Aid and Walmart, as well as independent pharmacies. In addition to all order fulfillment, Cardinal Health 105 performs the following services on our behalf: customer service, credit checks, invoicing, chargebacks, distributor fee for service, government reporting, customer returns, accounts receivable, inventory control, product security (DSCSA serialization) inquiries and recall assistance. In the years ended December 31, 2020 and 2021 and in the first quarter of 2022, Cardinal Health 105 was our only customer and sales to Cardinal Health 105 represented all of our net revenue for such periods.

As we continue to expand the commercialization of ZTlido, we expanded our direct distribution network to national and regional distributors and pharmacies in the second quarter of 2022. We currently hold wholesaler licenses and commenced selling directly to our main distributor customers as well as pharmacies from the second quarter of 2022. In April 2022, we discontinued our use of "title model" services provided by Cardinal Health 105, but expect that Cardinal Health 105 will continue to perform other third-party logistics services for us.

SP-102 (SEMDEXA)

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 2027. 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 on Form 10-K titled "*Business of Semnur — Material Agreements — Lifecore Master Services Agreement*" for additional information regarding the manufacturing of our SP-102 product candidate.

SP-103

SP-103 contains 5.4% lidocaine (108 mg lidocaine) and is manufactured for clinical supply by Oishi, using the same manufacturing processes as used for ZTlido. If our Phase 2 and Phase 3 trials are successful, we plan to submit the SP-103 manufacturing protocols in a supplemental new drug application.

SP-104

We are developing SP-104, a novel low-dose, naltrexone hydrochloride delayed release formulation for treating fibromyalgia. SP-104 is 4.5 mg, low-dose naltrexone hydrochloride delayed release capsule product in clinical development, for which Phase 1 studies were completed in the second quarter of 2022. It is manufactured by a contract manufacturer, Tulex Pharmaceuticals Inc. ("Tulex"), located in Cranbury, NJ.

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 pipelines, readily available capital, and established research and development organizations.

ZTlido and our product candidate, SP-103, if approved, face and will likely face competition from prescription, generic, and OTC topical lidocaine patches, including Lidoderm, generic lidocaine patches manufactured by Teva, Mylan and Par Pharmaceutical, Inc., and over-the-counter lidocaine patches. Additionally, SP-103, if approved, will likely compete with various opioid pain medications, NSAIDs, muscle relaxants, antidepressants and anticonvulsants, particularly as we seek approval for the treatment of chronic neck pain.

We launched ELYXYB for treatment of acute migraine pain. ELYXYB faces competition from other NSAID products, triptans and newly launched CGRP inhibitors. NSAIDs and triptans are well established for the treatment of migraine.

We launched GLOPERBA, our liquid colchicine formulation, in June 2024. GLOPERBA will face competition from generic colchicine formulations, uric acid lowering products like alopurinol, and other products that are used for the prophylaxis treatment of gout. GLOPERBA is the only liquid colchicine product approved by the FDA.

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.

With respect to our product candidate SP-104, while there are currently no formulations containing naltrexone in clinical development for the treatment of fibromyalgia, we are aware of certain non-opioid therapeutics currently in a late-stage Phase 3 pipeline containing two 505(b)(2) development programs. Therefore, we believe that SP-104 will likely face direct competition from these candidates.

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 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.

The key competitive factors affecting the success of ZTlido, GLOPERBA, ELYXYB, SP-102, SP-103 and SP-104 are likely to be their clinical benefit, durability, tolerability, price, intellectual property protection, and the availability of reimbursement from government and other third-party payors.

Material Agreements

Itochu and Oishi Product Development Agreement

We are party to the Product Development Agreement with Oishi and Itochu (the "Developers"). Pursuant to the Product Development Agreement, the Developers agreed to develop, exclusively for us, lidocaine tape products, including ZTlido and SP-103 (the "Products"). Pursuant to the Product Development Agreement, we obtained the rights to market, sell and distribute the Products in global markets outside of Japan.

In carrying out the development responsibilities, the Developers agreed to, among other things, (1) source and provide the active pharmaceutical ingredient for the Products for manufacturing, (2) develop a stable final dosage form of the Products suitable for regulatory approvals, (3) conduct product development activities necessary to support the filing of applications for regulatory approvals for the Products and (4) conduct manufacturing scale-up activities and preclinical studies for the Products. We are responsible for, among other things, (a) conducting all pivotal human clinical trials for the Products, (b) completing all regulatory filings, correspondence and meetings with the FDA or other applicable governmental authorities with respect to the Products and (c) commercially launching the Products. We maintain the ultimate responsibility and decision-making control with regard to the marketing and pricing of the Products.

The parties agreed to cooperate in good faith to determine whether to seek or maintain patent protection with respect to the Products, the active pharmaceutical ingredient, any associated method of use, method of manufacturing, or any other invention that could reasonably be expected to affect the commercialization or value of the Products. The Developers have the first right to pursue patent protection for any invention by them. All parties will jointly agree on the appointment of the patent representatives in each country outside of Japan.

Until the expiration or termination of the Product Development Agreement, the Developers granted us an exclusive, royalty-free, sublicensable, worldwide license (except with respect to Japan) under its current and future intellectual property rights relating to the Products and the lidocaine in such Products. As consideration for the Developers' development obligations under the Product Development Agreement, we agreed to pay a contingent quarterly royalty between 25% and 35% to the Developers based on the net quarterly profits of the Products. In the event that the net profits of any of the first four calendar quarters after the commercial launch equals a negative amount (a "Net Loss"), we are allowed to carry over such Net Loss to apply against all future calendar quarters until such Net Loss is covered, all calculated in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Under the Product Development Agreement, if our total net profits for ZTlido and SP-103 are equal to or less than five

percent of our net sales of ZTlido and SP-103 for a period of four or more consecutive quarters, the Developers have the right to terminate the Product Development Agreement and the Commercial Supply Agreement. As of the date of this Annual Report on Form 10-K, our net profits for ZTlido and SP-103 have not exceeded five percent of net sales. Accordingly, Oishi and Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of the date of this Annual Report on Form 10-K, neither Oishi nor Itochu has exercised its right of termination. Additionally, if we receive any licensing fees from any third-party sublicensees, we are obligated to pay the same proportions of such licensing fee to the Developers.

The current term of the Product Development Agreement will continue until October 2, 2028, which is the 10th anniversary of the first commercial sale of ZTlido. Afterwards, the agreement will renew automatically for subsequent successive one-year renewal periods unless we or the Developers terminate it upon six months' written notice. In addition, we or the Developers may terminate the Product Development Agreement if (1) the other party is in material breach of the agreement and the breach is not curable, or if the breach is curable and the breaching party has not cured such material breach within 180 days after notice requesting to cure; (2) the FDA determines that the formulation of the Products would not be eligible for FDA approval in the absence of efficacy studies, and the Developers are unable to address the efficacy study requirements despite good faith efforts; (3) the market conditions are such that (a) our total net profits of the Products are equal to or less than five percent of our net sales of the Products for a period of four or more consecutive quarters, or (b) the Products' economic viability is affected significantly as evidenced by documentation and substantial information by any external circumstances deemed detrimental to all parties as agreed to by us and the Developers, and the parties are unable to resolve the concerns under the foregoing clauses (a) and (b) after 30 days of good-faith discussion; (4) the parties fail to reach mutual agreement as to who will conduct the clinical studies and how the costs will be allocated; or (5) we or either one of the Developers are bankrupt or make assignment for the benefit of creditors. Additionally, we may terminate the Product Development Agreement if (i) any of the pivotal human clinical trials for any of the Products fail, or (ii) the FDA issues a "Refusal to File" for any of the Products' regulatory approval application and, after reasonable consultation with the Developers, we believe that it is commercially unreasonable to re-file. The Developers may terminate the Product Development Agreement if we fail to file for regulatory approval for any of the Products within three months of the date on which all required components of the regulatory approval application are received by us.

Under the Product Development Agreement, we and the Developers have agreed, subject to certain exceptions, to indemnify each other against any third-party liabilities arising out of (1) any breach of our respective representations, warranties or obligations under the Product Development Agreement, (2) any failure by either of us to comply with all applicable laws, or (3) our respective negligence or willful misconduct.

The foregoing is a summary of the material terms of the Product Development Agreement and its amendments in the forms filed as exhibits to this Annual Report on Form 10-K. You should read the form of the agreement and its amendments for a complete understanding of all of their respective terms.

Itochu and Oishi Commercial Supply Agreement

Effective February 16, 2017, Scilex Pharma entered into the Commercial Supply Agreement with Itochu and Oishi (the "Commercial Supply Agreement"). Pursuant to the Commercial Supply Agreement, Oishi agreed to manufacture, store, handle and perform quality control testing of the Products (as defined in the Product Development Agreement) at its facility in Japan. Itochu agreed to purchase Products from Oishi and handle the shipping of the Products. Both Oishi and Itochu agreed to provide us with certain technical support regarding the Products as reasonably requested by us, including but not limited to analytical test methods, method development, physical and chemical properties, and use of the Products.

Under the Itochu and Oishi Commercial Supply Agreement, we pay per item transfer prices for ZTlido, ZTlido professional samples and ZTlido placebo samples, in each case subject to certain minimum order quantities. We are required to provide a 12-month rolling purchase forecast of the estimated quantities of the Products in writing on a monthly basis. Oishi is required to promptly notify us and Itochu if it lacks the capacity to meet the forecast. All Products ordered by us will be in the form of a firm written purchase order. During the years ended December 31, 2024 and 2023, we purchased inventory in the amount of $5.0 million and $8.2 million, respectively, under the Itochu and Oishi Commercial Supply Agreement.

The Itochu and Oishi Commercial Supply Agreement will remain in effect until the termination of the Product Development Agreement. Additionally, either we or the Developers may terminate the Itochu and Oishi Commercial Supply Agreement (1) if the other party is in material breach of the agreement and the breach is not substantially cured within 60 days after receiving written notice specifying the nature of the breach, or (2) in the event of any of the parties' insolvency, bankruptcy or assignment for the benefit of creditors. Any third-party claim arising out of a breach by a party of any representation, warranty or obligation under the Itochu and Oishi Commercial Supply Agreement, or a failure by a party to comply with applicable laws, or the negligence or willful misconduct of a party, will be subject to and governed by the Product Development Agreement.

The foregoing is a summary of the material terms of the Itochu and Oishi Commercial Supply Agreement and its amendments in the forms filed as exhibits to this Annual Report on Form 10-K. You should read the form of the agreement and its amendments for a complete understanding of all of their respective terms.

ELYXYB® License and Commercialization Agreement

On February 12, 2023, we acquired from BioDelivery Sciences International, Inc. ("BDSI") and Collegium Pharmaceutical, Inc. ("Collegium", and together with BDSI, the "ELYXYB Sellers") the rights to certain patents, trademarks, regulatory approvals, data, contracts and other rights related to ELYXYB® (celecoxib oral solution) and its commercialization in the United States and Canada (the "ELYXYB Territory").

As consideration for the acquisition, we assumed various rights and obligations under that certain asset purchase agreement, dated August 3, 2021 (the "DRL APA"), between BDSI and Dr. Reddy's Laboratories Limited ("DRL"), a company incorporated under the laws of India, including a license from DRL including an irrevocable, royalty-free, exclusive license to know-how and patents of DRL related to ELYXYB and necessary or used to exploit ELYXYB in the ELYXYB Territory. Additionally, under the DRL APA, the ELYXYB Sellers granted us an irrevocable, royalty-free, exclusive license to know-how related to ELYXYB and necessary or used to exploit ELYXYB in the ELYXYB Territory. No cash consideration was or will be payable to the ELYXYB Sellers for such acquisition; however, the obligations under the DRL APA that were assumed by us include obligations to pay royalties for sales of ELYXYB in the ELYXYB Territory for all indications and additional amounts if certain net sales and regulatory milestones are achieved.

Romeg License and Commercialization Agreement

On June 14, 2022 (the "Original Signing Date"), we entered into the Romeg License Agreement with Romeg, which agreement was subsequently amended on January 16, 2025.

Under the Romeg License Agreement, among other things, Romeg granted us (1) a license, with the right to sublicense, under the patents and know-how specified therein to (a) commercialize a pharmaceutical product comprising liquid formulations of colchicine for the prophylactic treatment of gout in adult humans (the "Initial Licensed Product") in the United States (including its territories) (the "Romeg U.S. Territory"), (b) develop other products comprising the Initial Licensed Product as an active pharmaceutical ingredient (together with the Initial Licensed Product, the "Licensed Products") and commercialize any such products in the Romeg U.S. Territory and (c) manufacture Licensed Products anywhere in the world, solely for commercialization in the Romeg U.S. Territory; (2) an exclusive license, with right to sublicense, to use the trademark "GLOPERBA" and logos, designs, translations, and modifications thereof (collectively, the "Licensed Trademark") in connection with the commercialization of the Initial Licensed Product solely in the Romeg U.S. Territory; and (3) pursuant to the amendment thereto, a license, with the right to (a) sublicense under the know-how and, if any, patents existing worldwide other than the Romeg U.S. Territory (the "Romeg Ex-U.S. Territory"), as specified therein, to develop, manufacture and commercialize Licensed Products in the Romeg Ex-U.S. Territory and (b) to use the Licensed Trademark in connection with the commercialization of the Licensed Products in the Romeg Ex-U.S. Territory. With respect to the foregoing clause (1), the license to know-how is exclusive for purposes of developing and commercializing Licensed Products in the Romeg U.S. Territory during the Romeg U.S. Territory Royalty Term, but is otherwise non-exclusive, and the license to patents is exclusive for purposes of developing and commercializing Licensed Products in the Romeg U.S. Territory until July 1, 2027 and, thereafter, is co-exclusive with Granules Pharmaceuticals, Inc. for the Romeg U.S. Territory Royalty Term for such purposes. The Romeg U.S. Territory Royalty Term begins on the Original Signing Date and ends on the later of (i) expiration of the last to expire of the patents that covers the manufacture or commercialization of the Licensed Products in the Romeg U.S. Territory or (ii) the tenth anniversary of the Original Signing Date. With respect to the foregoing clause (3), the license to know-how patents (if any) is exclusive during the Romeg Ex-U.S. Territory Royalty Term, but is otherwise non-exclusive. The "Romeg Ex-U.S. Territory Royalty Term" begins on the date of the amendment agreement and ends on the tenth anniversary of such date.

As consideration for the license under the Romeg License Agreement, we agreed to pay Romeg (1) an up-front payment of $2.0 million, (2) upon our achievement of certain net sales milestones, certain milestone payments in the aggregate amount of up to $13.0 million, (3) certain royalties in the mid-single digit percentage, based on annual net sales of the Licensed Products attributable to sales of the Licensed Products occurring in the Romeg U.S. Territory during the Romeg U.S. Territory Royalty Term, with a quarterly minimum royalty of $150,000, and (4) pursuant to the amendment thereto, (a) certain royalties in the low-single digit percentage, based on annual net sales of the Licensed Products attributable to sales of License Products in the Romeg Ex-U.S. Territory during the Romeg Ex-U.S. Territory Royalty Term and (b) a one-time, non-refundable, non-creditable payment of $700,000. Pursuant to the amendment agreement, we also transferred to Romeg 779,371 shares of our Common Stock.

The Romeg License Agreement will remain in effect until it is terminated in accordance with the terms thereof. We may terminate the Romeg License Agreement (1) upon written notice to Romeg, if we elect (or are required) to withdraw the Initial Licensed Product from the market as a result of serious adverse reactions from use of such product, which termination will be effective 30 days following the

date of such notice or (2) at any time, without cause, upon written notice to Romeg, which termination will be effective 120 days following the date of such notice, provided that a termination fee of up to $2.0 million shall be paid to Romeg depending on when during the 10-year period following the date of the agreement any such termination notice set forth in the immediately preceding clause (2) has been provided. Romeg may terminate the Romeg License Agreement (a) upon notice to us, if we fail to timely pay any milestone payment, percentage royalties or minimum quarterly royalties or fail to timely deliver the requisite quarterly report, which termination will be effective 30 days after the date of such notice, unless we have made such payment in full or delivered such quarterly report within such 30 day period; (b) immediately, if we challenge the licensed patents under any court action or proceeding or before any patent office or assist any third party to conduct any of these activities; or (c) by written notice to us if sales of the Licensed Products do not commence or continue within specified periods agreed to by the parties. In addition, either party may terminate the Romeg License Agreement (1) in the event the other party materially breaches the agreement, unless the breaching party has cured any such breach within 60 days after any notice thereof was provided or (2) in the event the other party (a) files in any court or agency a petition in bankruptcy or insolvency, (b) is served with an involuntary petition against it in any insolvency proceeding and such involuntary petition has not been stayed or dismissed within 90 days after its filing, or (c) makes an assignment of substantially all of its assets for the benefit of its creditors.

The Romeg License Agreement contains customary reciprocal indemnification obligations for Romeg and us. Additionally, we agreed, subject to certain exceptions, to indemnify Romeg against any loss arising out of the manufacture or commercialization of any Licensed Product by or on behalf of us or our affiliates, marketing partners, sublicensees or subcontractors on or after the date of the license.

The foregoing is a summary of the material terms of the Romeg License Agreement (including the amendment thereto) in the forms filed as exhibits to this Annual Report on Form 10-K. You should read the form of the agreements for a complete understanding of all of their terms.

Lifecore Master Services Agreement

On January 27, 2017, through our wholly owned subsidiary, Semnur, we entered into that certain 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 SEMDEXA as set forth in each separate statement of work (each a "Lifecore Statement of Work").

The parties entered into a Lifecore Statement of Work on January 27, 2017, pursuant to which Lifecore agreed to provide, among other things, (1) project management support, (2) development services, (3) clinical trial materials, and (4) stability studies. We paid Lifecore for the development and clinical trial material manufacturing services, which was invoiced at the completion of each service.

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. 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) we fail to pay past due invoices upon 30 days' written notice, or (ii) we reject or fail 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.

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 on Form 10-K. You should read the form of the agreement and its amendments for a complete understanding of all of their respective terms.

Semnur Merger Agreement

On March 18, 2019, Legacy Scilex acquired Semnur pursuant to an Agreement and Plan of Merger with Semnur (as amended, the "Semnur Merger Agreement"), Sigma Merger Sub, Inc., a wholly owned subsidiary of Legacy Scilex ("Sigma Merger Sub"), Fortis Advisors LLC, solely as representative of the holders of Semnur equity (the "Semnur Equityholders' Representative"), and for limited

purposes, Sorrento. Pursuant to the Semnur Merger Agreement, Sigma Merger Sub merged with and into Semnur (the "Semnur Merger"), with Semnur surviving as Legacy Scilex's wholly owned subsidiary.

Pursuant to the Semnur Merger Agreement, and upon the terms and subject to the conditions contained therein, Legacy Scilex also agreed to pay former holders of Semnur's capital stock (the "Semnur Equityholders") 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 NDA 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. As of the date of this Annual Report on Form 10-K, none of the foregoing payments have been triggered.

The Semnur Merger Agreement also provided that following the consummation of Legacy Scilex's first bona fide equity financing with one or more third-party financing sources on an arms' length basis with gross proceeds to Legacy Scilex of at least $40.0 million, certain of the former Semnur optionholders will be paid cash in lieu of: (i) the 352,972 shares of Legacy Scilex Common Stock otherwise issuable to such former Semnur optionholders pursuant to the Semnur Merger Agreement, and (ii) any shares that would otherwise be issued to such former Semnur optionholders upon release of shares held in escrow pursuant to the Semnur Merger Agreement, with such shares in each case valued at $1.16 per share. The Semnur optionholders subsequently agreed, under the terms of the Exchange Agreement (as defined and described below) to forego the foregoing right to any such payment in exchange for the right to participate in the Share Exchange (as defined below).

In March 2019, the Semnur Equityholders that received $55.0 million of shares of Common Stock (47,039,315 shares issued and 352,972 shares issuable, valued at $1.16 per share) (the "the Stock Consideration") were required to sign an Exchange and Registration Rights Agreement with Legacy Scilex (as amended, the "Exchange Agreement"). Pursuant to the Exchange Agreement, and upon the terms and subject to the conditions contained therein, if within 18 months following the closing of the Semnur Merger, 100% of the outstanding equity of Legacy Scilex had not been acquired by a third party or Legacy Scilex had not entered into a definitive agreement with respect to, or otherwise consummated, a firmly underwritten offering of Legacy Scilex capital stock on a major stock exchange that met certain requirements, then holders of the Stock Consideration could collectively elect to exchange, during the 60-day period commencing the date that was the 18-month anniversary of the closing of the Semnur Merger (the "Share Exchange"), the Stock Consideration for shares of Sorrento's common stock with a value of $55.0 million based on a price per share of Sorrento's common stock equal to the greater of (a) the 30-day trailing volume weighted average price of one share of Sorrento's common stock as reported on The Nasdaq Stock Market LLC ("Nasdaq") as of the consummation of the Share Exchange and (b) $5.55 (subject to adjustment for any stock dividend, stock split, stock combination, reclassification or similar transaction) (the "Exchange Price"). Pursuant to an amendment to the Exchange Agreement entered into by Sorrento and the Semnur Equityholders' Representative on September 28, 2020, on October 9, 2020, Sorrento paid $55.0 million in cash to the Semnur Equityholders in lieu of issuing $55.0 million of shares of Sorrento's common stock at the Exchange Price.

The foregoing is a summary of the material terms of the Semnur Merger Agreement (including the amendment thereto) in the forms filed as exhibits to this Annual Report on Form 10-K. You should read the Semnur Merger Agreement (including the amendment thereto) for a complete understanding of all of their respective terms.

Aardvark Asset Purchase Agreement

In April 2021, Sorrento entered into an asset purchase agreement (the "Aardvark Asset Purchase Agreement") with Aardvark Therapeutics, Inc. ("Aardvark"), pursuant to which, among other things, Sorrento acquired Aardvark's Delayed Burst Release Low Dose Naltrexone (DBR-LDN) asset and intellectual property rights, for the treatment of chronic pain, fibromyalgia and chronic post-COVID syndrome (collectively, the "SP-104 Assets"), which includes a Statement of Work dated November 18, 2020 (the "Tulex Statement of Work"), pursuant to which Tulex agreed to, among other things, develop, test and manufacture clinical supplies of SP-104 for Sorrento.

Subsequent to the acquisition, Sorrento designated Legacy Scilex to lead all development efforts related to SP-104 and on May 12, 2022, Legacy Scilex and Sorrento entered into a bill of sale and assignment and assumption agreement (the "Bill of Sale"), pursuant to which Sorrento sold, conveyed, assigned and transferred to Legacy Scilex all of its rights, title and interest in and to the SP-104 Assets (including PCT/US2021/053645 and all patents and patent applications that claim priority rights thereto) and Legacy Scilex assumed all of Sorrento's rights, liabilities and obligations under the Aardvark Asset Purchase Agreement (the "SP-104 Acquisition").

As consideration for the SP-104 Acquisition, Legacy Scilex issued a promissory note in the aggregate principal amount of $5,000,000 to Sorrento (the "Promissory Note"). The Promissory Note matures seven years from the date of issuance and bears interest at the rate

equal to the lesser of (a) 2.66% simple interest per annum and (b) the maximum interest rate permitted under law. The Promissory Note is payable in cash, shares of Common Stock (any shares so issued, the "Consideration Shares") or any combination thereof, at Legacy Scilex's sole discretion, and may be prepaid in whole or in part at any time without penalty. Legacy Scilex also agreed to file with the U.S. Securities and Exchange Commission (the "SEC") a resale registration statement, relating to the resale by Sorrento of any Consideration Shares that may be issued to Sorrento, within 60 days of the issuance of such Consideration Shares.

As the successor to the Aardvark Asset Purchase Agreement, Legacy Scilex is obligated to pay Aardvark (i) $3,000,000, upon initial approval by the FDA of a new drug application for the LDN Formulation (as defined in the Aardvark Asset Purchase Agreement) (which amount may be paid in shares of Common Stock or cash, in Legacy Scilex's sole discretion) (the "Development Milestone Payment") and (ii) $20,000,000, in cash, upon achievement of certain net sales by Legacy Scilex of a commercial product that uses the LDN Formulation (the "Commercial Product"). Legacy Scilex will also pay Aardvark certain royalties in the single digits based on percentages of annual net sales by Legacy Scilex of a commercial product that uses the LDN Formulation. The royalty percentage is subject to reduction in certain circumstances. Royalties are due for so long as Commercial Product is covered by a valid patent in the country of sale or for ten years following the first commercial sale of the Commercial Product, whichever is longer. As of the date of this Annual Report on Form 10-K, none of the foregoing payments have been triggered.

In connection with its acquisition of the SP-104 Assets, Legacy Scilex has agreed that if it issues any shares of Common Stock in respect of the Development Milestone Payment, Legacy Scilex will prepare and file one or more registration statements with the SEC for the purpose of registering for resale such shares and is required to file such registration statement with the SEC within 60 days following the date on which any such shares are issued.

Tien-Li Lee, M.D., a former member of our board of directors (the "Board"), is the founder, chief executive officer and a member of the board of directors of Aardvark.

The foregoing is a summary of the material terms of the Aardvark Asset Purchase Agreement, Bill of Sale and Promissory Note in the forms filed as exhibits to this Annual Report on Form 10-K. You should read the forms of these agreements for a complete understanding of all of their respective terms.

Tulex Master Services Agreement

As described above, in connection with the SP-104 Acquisition, Legacy Scilex acquired the Tulex Statement of Work, pursuant to which Tulex, among other things, develops, tests and manufactures clinical supplies of SP-104 for Legacy Scilex. The Tulex Statement of Work is governed by the terms of a master services agreement (the "Tulex Master Services Agreement"). The Tulex Master Services Agreement was novated to Legacy Scilex on June 15, 2022 and will remain in effect until five years after the effective date, unless terminated early by either party. Either party may terminate the Tulex Master Services Agreement or a Tulex Statement of Work by written notice (1) if the other party is in material breach of the agreement or a Tulex Statement of Work and fails to cure such breach within 15 days after receipt of notice of such breach (or such other time period expressly stated in the applicable Tulex Statement of Work) or (2) in the event of the other party's insolvency, bankruptcy, reorganization, liquidation or receivership, or a failure to remove any insolvency, bankruptcy, reorganization, liquidation or receivership proceedings within ten days from the date of institution of such proceedings. In addition, we may terminate the agreement or any Tulex Statement of Work (1) without cause upon 30 days prior written notice to Tulex or (2) immediately upon written notice in the event Tulex is dissolved or undergoes a change in control. A termination or expiration of a single Tulex Statement of Work will not cause the automatic termination of the agreement or of any other Tulex Statement of Work.

Each party under the Tulex Master Services Agreement agreed to indemnify the other party, its affiliates and each of their respective officers, directors, employees, contractors and agents against any third-party liabilities arising out of (1) such party's breach of the Tulex Master Services Agreement or a Tulex Statement of Work or (2) the negligence or willful misconduct on the part of such party, its officers, directors, employees, agents or other representatives in connection with the Tulex Master Services Agreement.

The foregoing is a summary of the material terms of the Tulex Master Services Agreement in the form filed as an exhibit to this Annual Report on Form 10-K. You should read the form of the 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 drug products, product candidates, and related 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, drug products, 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 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, 2024 contains approximately 27 issued and unexpired U.S. patents and nine pending U.S. patent applications. Our portfolio also includes certain foreign counterparts of these patents and patent applications including Australia, Brazil, Canada, China, Hong Kong, India, Israel, Japan, Korea, Mexico, New Zealand, South Africa, Taiwan, and certain countries within the European Patent Convention.

With respect to ZTlido and SP-103, our patents and patent applications cover compositions and methods of treatment. We license eight issued U.S. patents and two pending U.S. patent applications relating to lidocaine topical system compositions and methods of treating pain with lidocaine topical system compositions. The patents are U.S. Pat. Nos. 9,283,174, 9,925,264, 9,931,403, 10,765,749, 10,765,640, 11,278,623, 11,786,455, and 11,793,766, all of which expire in 2031.

With respect to GLOPERBA, our licensed patents include U.S. Pat. Nos. 9,907,751, 10,226,423, 10,383,820, 10,383,821, and 11,672,759, which relate to liquid colchicine formulations for oral administration and associated methods of use. U.S. Pat. No. 10,226,423 expires in 2037. The remaining patents related to GLOPERBA expire in 2036.

With respect to ELYXYB, our patents and patent applications relate to liquid oral celecoxib formulations and associated methods of use. The issued patents include U.S. Pat. Nos. 9,572,819, 9,795,620, 9,949,990, 10,376,527, 10,799,517, 10,722,456, and 12,168,000. U.S. Pat. No. 12,168,000 expires in 2041. The remaining patents related to ELYXYB expire in 2036.

With respect to our product candidate SEMDEXA, our 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.

With respect to SP-104, our pending U.S. patent application covers oral delayed burst formulations of low-dose naloxone or naltrexone and related methods of treatment. We continue to seek to maximize the scope of our patent protection for all our programs.

All statements regarding the expiration of our owned and licensed patents are calculated as 20 years after the earliest nonprovisional priority date and do not account for any patent term adjustment ("PTA"), regulatory extension, or terminal disclaimers not already in force as of December 31, 2024; these calculations also assume that all annuity and/or maintenance fees are paid timely. We believe that we have certain know-how and trade secrets relating to our technology and product candidates. We rely on trade secrets to protect certain aspects of our technology related to our current and future product candidates. 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 registered U.S. trademarks for the marks "SCILEX," "ZTlido," "ELYXYB," and "RESPONSIBLE BY DESIGN." We also own pending trademark applications for "SEMNUR PHARMACEUTICALS," "SCILEX BIO," and "SEMDEXA" in the United States. We also license the GLOPERBA trademark as discussed in relation to the Romeg License Agreement described above.

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.

SEMDEXA 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 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 2027. 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 SEMDEXA.

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, SP-103, SP-104 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 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 may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices ("GLPs") or other applicable regulations;
- completion of FDA's drug substance (Part 210), drug product (Part 211), combination of product and device (Part 820) and all Module 3, Chemistry, Manufacturing and Control ("CMC"), and the current Good Manufacturing Practices("cGMP") requirements for NDA filing;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin;
- approval by an institutional review board ("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 Good Clinical Practice ("GCP") requirements to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA or other marketing application (collectively, an "NDA"), for a proposed new drug, including its specific formulation and labeling;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection 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.

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 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 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. 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 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 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 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 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.

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 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, 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 has been associated with unexpected serious harm to study subjects.

During the development of a new drug, 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 that they believe will support approval of the new drug.

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 as well as validate a process for commercial manufacturing the product in accordance with cGMP requirements. The commercial manufacturing process must be capable of consistently and continuously producing quality batches of the drug 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 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. The FDA may grant deferrals for the development and submission of pediatric data or full or partial waivers after the initial submission of a pediatric study plan following an end of Phase 2 meeting. In addition, descriptions of the manufacturing process and controls, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are required to be submitted to the FDA as part of an NDA requesting approval to market the product. 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 its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of ten 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 twelve 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.

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. During the drug 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. 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 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 drugs 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 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 may require that a sponsor of a drug receiving accelerated approval perform additional adequate and well-controlled post-marketing clinical trials. 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 drugs 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 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.

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.

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 manufacturers and other entities involved in the manufacture and distribution of approved drugs 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, 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 drugs for uses, or in patient populations, that are not described in the drug'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 drugs 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, 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 some of the data are not owned by or licensed to the applicant. Section 505(j) establishes an abbreviated approval process for generic versions of approved drug products through the submission of an abbreviated new drug 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 and has been shown to be bioequivalent to the listed drug. ANDA applicants are required to conduct bioequivalence testing to confirm chemical and therapeutic equivalence to the branded reference drug. Generic versions of drugs can often, and sometimes must, be substituted by pharmacists under prescriptions written for the branded reference drug.

A 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness 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, or published literature, in support of its application. Additional preclinical and clinical data may also be submitted. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, or for any new indication sought by the 505(b)(2) applicant.

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) 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 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 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. For example, the holder of an NDA may obtain five years of exclusivity upon approval of a new drug 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 drugs 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, 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 drugs. 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 drugs, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2020 (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 drugs 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 and taxes on manufacturers of certain branded prescription drugs, 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 drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, (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 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 Tax Cuts and JOBS Act of 2017 (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. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, former President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In addition, on August 16, 2022, former President Biden signed the Inflation Reduction Act of 2022 into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The Inflation Reduction Act also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how additional healthcare reform measures of the Trump administration or other efforts, if any, to modify or invalidate the ACA or its implementing regulations, or portions thereof, will impact our business. 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 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. 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 May 16, 2019, CMS adopted a final rule that, among other things, will require Part D plans to adopt Real Time Benefit Tools that are capable of integrating with electronic prescribing or electronic health record systems and have the capability to inform prescribers when lower-cost alternative therapies are available under a beneficiary's prescription drug benefit. Similarly, since 2021, Part D Explanation of Benefits transmittals to members are required to inform Part D beneficiaries about drug prices and lower cost therapeutic alternatives. 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 drugs and biologics. The first provision allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug 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 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 drugs covered by Medicare under Part B or Part D. The rebate obligation applies if the average sales price (for Part B) or average manufacturers price (for Part D) of a single source drug or biologic increases more than the rate of inflation (as measured by the index for urban consumers). The rebate amount is the total number of units sold in Medicare coverage multiplied by the amount by which the price exceeds the inflation adjusted price. The base year against which the inflation adjustment is measured is 2021. If the price exceeds the inflation adjusted price, the difference is multiplied by the units sold in Medicare and that amount is to be rebated. A failure to pay the rebate is subject to a penalty of 125% of the original rebate amount. The provision for Part D takes effect in 2022, with rebates to be paid beginning in 2023. The provision for Part B takes effect in 2023. 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 importation from other countries and bulk purchasing. 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. Many 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, improper promotion of off-label uses (i.e., uses not expressly approved by the FDA in a drug'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 Federal Trade Commission (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 California Consumer Privacy Act and its implementing regulations (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 California Privacy Rights Act ("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 drugs, 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 are 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 and compliance 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 Foreign Corrupt Practices Act ("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. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. 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 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 healthcare professionals.

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 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 is a new chemical entity if the FDA has not previously approved any other new drug 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 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. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs 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 much like the IND prior to the commencement of human clinical trials.

In the EEA, for example, a clinical trial application ("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. An application to transition ongoing trials from the

current Clinical Trials Directive to the new Clinical Trials Regulation will need to be submitted and authorized in time before the end of the transitional period. 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 European Medicines Agency (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 General Data Protection Regulation ("EEA GDPR") and UK General Data Protection Regulation ("UK GDPR," and together, the "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, United Kingdom 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 ("ICO") 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, 2024, we had approximately 115 full-time employees, including five employees who have M.D.s or Ph.D.s. Within our workforce, 11 employees were primarily engaged in research and development, 85 were primarily engaged in sales and marketing and 19 were primarily engaged in general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We believe that we maintain good relationships with our employees. We focus on identifying, attracting, incentivizing, developing and retaining an exceptional team of highly talented and motivated employees to support our current product pipeline and future business goals. In order to drive innovation, we continuously improve our human capital management strategies and find ways to foster engagement and growth within our company.

We regularly benchmark total rewards we provide against our industry peers to ensure we offer competitive compensation and benefits packages to our employees and potential new hires. The principal purposes of our equity and cash incentive plans are to attract, retain and reward selected personnel through the granting of stock-based and cash-based compensation awards, as well as provide our employees with the opportunity to participate in our employee stock purchase plan, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. We strive to build a diverse environment where our employees can thrive and one that inspires exceptional contributions and professional and personal development in order to achieve our vision to become the leading pain management company that can have a transformative impact on patients' lives. The success of our business is fundamentally connected to the well-being, health and safety of our employees.

We plan to continue to develop our efforts related to attracting, retaining and motivating our workforce as we grow and develop.

Legal Proceedings

From time to time we may become involved in various legal proceedings, including those that may arise in the ordinary course of business.

Former Employee Action

On March 12, 2021, Scilex Pharma and Sorrento (the "Plaintiffs") filed an action (the "Former Employee Action") in the Delaware Court of Chancery against the former President of Scilex Pharma, Anthony Mack, and Virpax Pharmaceuticals, Inc. ("Virpax", and together with Mr. Mack, the "Defendants"), a company founded and then headed by Mr. Mack, alleging, among other things, breach by Mr. Mack of a restrictive covenant agreement with Sorrento related to his sale of his Scilex Pharma stock to Sorrento, tortious interference with that agreement by Virpax, breach of Mr. Mack's fiduciary duties to Scilex Pharma, aiding and abetting of that breach by Virpax, and misappropriation of Scilex Pharma's trade secrets by Mr. Mack and Virpax. Such lawsuit sought, among other relief, damages and various forms of injunctive relief. The case was tried from September 12, 2022 to September 14, 2022. On September 1, 2023, the court found in favor of the Plaintiffs on all but three counts deemed to have been waived. In its 95-page opinion, the court instructed the parties to submit supplemental briefing on the appropriate remedy to implement its rulings. On October 18, 2023, the Plaintiffs submitted a supplemental brief on remedies. On November 29, 2023, Defendants submitted a supplemental brief on remedies. On December 21, 2023, the Plaintiffs submitted a supplemental reply brief on remedies. On February 26, 2024, we and Virpax entered into a term sheet regarding a mutual release and settlement agreement, pursuant to which the parties have agreed to resolve the ongoing disputes. On February 29, 2024, we and Virpax entered into a definitive settlement agreement, which provides for, among other things, that Virpax would be obligated to make the following payments to us to settle the Former Employee Action: (i) $3.5 million (the "Initial Payment") by two business days after the Effective Date (as defined therein), which payment has been made; (ii) $2.5 million by July 1, 2024, which payment has been made on July 8, 2024 and (iii) to the extent any of the following drug candidates are ever sold, royalty payments of (a) 6% of annual Net Sales (as defined therein) of Epoladerm; (b) 6% of annual Net Sales of Probudur and (c) 6% of annual Net Sales of Envelta during the Royalty Term (as defined therein). We and Virpax provided mutual releases of all claims that existed as of the Effective Date, whether known or unknown, arising from any allegations set forth in the Former Employee Action. Plaintiffs' release relates to claims against Virpax only, which does not affect our claims against Mr. Mack. Plaintiffs have not released Mr. Mack, and litigation against him remains ongoing. The court has requested additional oral argument on the topic of remedies against Mr. Mack, which argument occurred on November 15, 2024. The parties are awaiting a final judgment from the court.

ZTlido Patent Litigation

On June 22, 2022, we filed a complaint against Aveva Drug Delivery Systems, Inc. ("Aveva"), Apotex Corp., and Apotex, Inc. (together, "Apotex") in the U.S. District Court for the Southern District of Florida (the "ZTlido Patent Litigation") alleging infringement of certain Orange Book listed patents covering ZTlido (the "ZTlido Patents"). The ZTlido Patent Litigation was initiated following the submission by Apotex, in accordance with the procedures set out in the Hatch-Waxman Act, of an abbreviated new drug application ("ANDA"). Apotex's ANDA seeks approval to market a generic version of ZTlido prior to the expiration of the ZTlido Patents and alleges that the ZTlido Patents are invalid, unenforceable, and/or not infringed. We are seeking, among other relief, an order that the effective date of any FDA approval of Apotex's ANDA be no earlier than the expiration of the asserted patents listed in the Orange Book, the latest of which expires on May 10, 2031, and such further and other relief as the court may deem appropriate. Apotex and Aveva were subject to an automatic 30-month stay preventing them from selling a generic version of ZTlido during that time which was extinguished by the U.S. District Court for the Southern District of Florida decision described below. However, to our knowledge, Aveva has not received FDA approval for any generic version of ZTlido. The two Apotex entities were dismissed from the litigation without prejudice, as they no longer had an interest in the generic product that Aveva seeks to market. Before trial, Aveva dropped its challenge to the validity and enforceability of the Company's patents. Trial in the ZTlido Patent Litigation was held from July 8, 2024 to July 11, 2024. Final post-trial briefing was submitted by the parties on July 25, 2024, and the case was submitted to the U.S. District Court for the Southern District of Florida. On August 26, 2024, that court issued a decision finding that Aveva's product does not infringe our ZTlido Patents. We are appealing that decision to the U.S. Court of Appeals for the Federal Circuit, and we filed a Notice of Appeal with the U.S. District Court for the Southern District of Florida on September 25, 2024.

Our Corporate History

Legacy Scilex was incorporated in Delaware in February 2019 for the purpose of effecting a corporate reorganization. On March 18, 2019, Legacy Scilex entered into a Contribution and Loan Agreement with Sorrento and the holders of the outstanding shares of capital stock of Scilex Pharma pursuant to which Legacy Scilex acquired 100% of the outstanding shares of capital stock of Scilex Pharma in exchange for shares of Legacy Scilex Common Stock (such transaction, the "Contribution"). Pursuant to the Contribution and Loan Agreement, Sorrento provided Legacy Scilex with a loan with an initial principal amount of $16.5 million in the form of a note payable, which loan was used to fund the acquisition of Semnur. Concurrently therewith, Legacy Scilex entered into the Semnur Merger Agreement with Semnur, Sigma Merger Sub, Inc., Legacy Scilex's prior wholly owned subsidiary, Fortis Advisors LLC, solely as representative of the holders of Semnur equity, and Sorrento, for limited purposes. Pursuant to the Semnur Merger Agreement, Sigma Merger Sub, Inc. merged with and into Semnur, with Semnur surviving the Semnur Merger as Legacy Scilex's wholly owned subsidiary. As a result of the Contribution and the Semnur Merger, Scilex Pharma and Semnur became Legacy Scilex's wholly owned subsidiaries. Prior to the Contribution and the Semnur Merger, operations of Legacy Scilex were conducted through Scilex Pharma, which was formed in September 2012. Semnur was formed in June 2013.

On November 10, 2022, we consummated the Business Combination with Vickers and Legacy Scilex. In connection with the Business Combination, Vickers changed its name from Vickers Vantage Corp. I to Scilex Holding Company.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (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.

Website Access to SEC Filings

We file annual, quarterly and special reports, proxy statements and other information with the 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 Scilex. We maintain an Internet website at www.scilexholding.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 Common Stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below before deciding whether to invest in our Common Stock. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under "Cautionary Note Regarding Forward-Looking Statements", you should carefully consider the specific risks set forth herein. 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 below are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our Common Stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the Securities and Exchange Commission (the "SEC") before making an investment decision regarding our Common Stock.

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

- We currently have three commercial products, ZTlido, ELYXYB and GLOPERBA; but we are currently heavily dependent on the commercial success of ZTlido, as ELYXYB and GLOPERBA are in the initial stages of commercialization, and we may be unable to generate sufficient revenue to support our operations.
- We have a limited operating history and have incurred significant losses since our inception. We anticipate that we will incur continued losses for the foreseeable future.
- The terms of the Oramed Note and the Tranche B Notes (each as defined below) place restrictions on our operating and financial flexibility.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.
- We may not be able to generate sufficient cash to service our indebtedness and other liquidity needs.
- 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 Commercial Operations and Product Development

- We obtain, or historically have obtained, our commercial supply of certain of our products, the clinical supply of our product candidates and certain of the raw materials used in our product candidates from sole or single source suppliers and manufacturers. In the event of a loss of one of these suppliers or manufacturers, or a failure by any such supplier or manufacturer to comply with FDA regulations, we may not be able to find an alternative source on commercially reasonable terms, or at all.
- 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 product candidates.
- 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.
- ZTlido, GLOPERBA and ELYXYB may have undesirable properties that could result in significant negative consequences, and our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval.

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.
- 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

- We are substantially dependent on the intellectual property we in-license from Oishi and Itochu, and if we lose the right to license such intellectual property or if the Product Development Agreement is terminated for any reason, our ability to commercialize ZTlido and develop and commercialize SP-103 would be harmed.
- We are party to the Romeg License Agreement for the in-licensing of certain intellectual property rights from Romeg with respect to the commercialization of GLOPERBA, and if we lose the right to license such intellectual property or if the Romeg License Agreement is terminated for any reason, our ability to commercialize GLOPERBA would be harmed.
- If we are unable to maintain patent protection for ZTlido, GLOPERBA, ELYXYB and 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.

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.
- 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 Sorrento

- Sorrento previously supported many of our important corporate functions. Accordingly, our historical 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 Sorrento, and we have and will continue to incur incremental costs as a stand-alone public company.

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 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.

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

We currently have three commercial products, ZTlido, ELYXYB and GLOPERBA; but we are currently heavily dependent on the commercial success of ZTlido, as ELYXYB and GLOPERBA are in the initial stages of commercialization, and we may be unable to generate sufficient revenue to support our operations.

We currently have three commercial products, ZTlido, ELYXYB and GLOPERBA; but we are currently heavily dependent upon ZTlido sales to generate revenue, as ELYXYB and GLOPERBA are in the initial stages of commercialization. In February 2018, we obtained FDA regulatory approval for ZTlido for the relief of neuropathic pain associated with post-herpetic neuralgia ("PHN") in adults, which is a form of post-shingles nerve pain, and we began commercializing ZTlido in the United States in October 2018. In late February 2023, we acquired ELYXYB, a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults, in the U.S. We launched ELYXYB in April of 2023. In June 2022, we acquired certain rights to GLOPERBA, the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults. We launched GLOPERBA in June 2024. As a result, it is difficult to evaluate our current business and predict our future prospects. We cannot assure that ZTlido, ELYXYB or GLOPERBA will gain market acceptance among physicians, health care payors, patients and the medical community, which is critical to our commercial success. We have limited experience engaging in commercial activities and limited relationships with physicians, hospitals and payors. Market acceptance of ZTlido, ELYXYB and GLOPERBA depends on a number of factors, including:

- acceptance by physicians, major operators of clinics and patients of ZTlido, ELYXYB and GLOPERBA as a safe and effective treatment for the relief of neuropathic pain associated with PHN (ZTlido), acute migraine pain (ELYXYB), and prevention of gout flares (GLOPERBA);
- the availability, cost and potential advantages of alternative treatments, including less expensive generic products;

- the effectiveness of our sales and marketing efforts;
- the availability of coverage, adequacy of reimbursement and favorability of pricing policies by third-party payors and government authorities;
- the timing of market introduction of other competitive products;
- the product labeling or any product inserts required by the FDA; and
- the prevalence and severity of adverse side effects.

To successfully commercialize ZTlido, ELYXYB and GLOPERBA, we will need to expand our marketing efforts to develop new relationships and expand existing relationships. Physicians may decide not to prescribe ZTlido, ELYXYB or GLOPERBA for a variety of reasons, including changes in available offerings, adverse publicity, perceived safety issues, inadequate coverage or reimbursement for ZTlido, ELYXYB or GLOPERBA or the utilization of products developed by other parties, all of which are circumstances outside of our control. Demand for ZTlido may not increase, or may not develop for ELYXYB or GLOPERBA, as quickly as we predict, and we may be unable to increase our revenue to the level that we currently expect. Even if we succeed in increasing market acceptance of ZTlido or developing market acceptance of ELYXYB and GLOPERBA, and maintaining and creating relationships with physicians, we may be unable to reach or sustain a level of profitability.

Our ability to effectively promote ZTlido, ELYXYB and GLOPERBA will also depend on pricing and cost-effectiveness, including our ability to produce and market our products at a competitive price. In addition, our efforts to educate the medical community and third-party payors on the benefits of ZTlido, ELYXYB and GLOPERBA may require significant resources, may be constrained by FDA rules and policies on product promotion and may never be successful.

We have a limited operating history and have incurred significant losses since our inception. We anticipate that we will incur continued losses for the foreseeable future.

We have a limited operating history. Prior to March 2019, our operations were conducted through Scilex Pharma, which was formed in September 2012 and is now our wholly owned subsidiary. In March 2019, we effected a corporate reorganization and acquired Semnur, which was formed in June 2013. Since our inception, 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 candidates and establishing research and development and manufacturing collaborations. Most of our revenue to date is attributable to sales of ZTlido, and we expect that sales of ZTlido will account for most of our revenue for at least the near term. 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 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, manufacturing and planned future commercialization efforts and operations;
- launch commercial sales of our product candidates, whether alone or in collaboration with others;
- initiate and continue relationships with third-party suppliers and manufacturers and have commercial quantities of product candidates manufactured at acceptable cost and quality levels and in compliance with the FDA, and other regulatory requirements;
- set acceptable prices for product candidates and obtain coverage and adequate reimbursement from third-party payors;
- achieve market acceptance of 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, with net losses of $72.8 million and $114.3 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, we had an accumulated deficit of approximately $563.1 million and $490.2 million, respectively. For the foreseeable future, we expect to continue to incur significant expenses related to the commercialization of ZTlido, GLOPERBA and ELYXYB and the research and development of our product candidates, SP-102 (10 mg dexamethasone sodium phosphate viscous gel) ("SEMDEXA"), SP-103 (lidocaine topical system) 5.4% ("SP-103"), and SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) ("SP-104"). We anticipate that our expenses will increase substantially due to any future trials related to SEMDEXA and SP-103 and initiation of the Phase 2 clinical trial for SP-104. Consequently, 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.

If we are unable to raise capital through a registered offering, we would be required to conduct our equity financing transactions on a private placement basis, which may be subject to pricing, size and other limitations imposed under the Nasdaq Listing Rules, or seek other sources of capital.

The terms of the Oramed Note and the Tranche B Notes place restrictions on our operating and financial flexibility.

On September 21, 2023, we issued and sold to Oramed a senior secured promissory note due 18 months from the date of issuance, in the principal amount of $101,875,000 (the "Oramed Note") pursuant to that certain securities purchase agreement we entered into with Oramed, dated as of September 21, 2023 (the "Scilex-Oramed SPA"). Interest under the Oramed Note accrues at a fluctuating per annum interest rate equal to the sum of (1) greater of (x) four percent (4%) and (y) Term SOFR (as defined in the Oramed Note) and (2) eight and one-half percent (8.5%), payable in-kind on a monthly basis.

Pursuant to the Oramed Note, since the outstanding principal of the Oramed Note was not repaid in full on or prior to March 21, 2024, an exit fee of $3,056,250 has been earned with respect to the Oramed Note, which shall be due and payable on the date the outstanding principal amount of the Oramed Note is paid in full. Upon the occurrence and during the continuance of an event of default under the Oramed Note, holders of more than 50% of the aggregate unpaid principal amount of the Oramed Notes may elect to cause all outstanding amounts under the Oramed Note to accrue interest at a default rate equal to the lesser of (i) Term SOFR plus fifteen percent (15%) or (ii) the maximum rate permitted under applicable law.

Any voluntary prepayments of the Oramed Note occurring prior to the one-year anniversary of the Oramed Closing Date are required to be paid together with a make-whole amount equal to 50% of the amount of additional interest that would accrue on the principal amount so prepaid under the Oramed Note from the date of such prepayment through and including the maturity date. The make-whole amount was waived by Oramed for our voluntary prepayments in March 2024. If the Oramed Note is accelerated upon an event of default, we are required to repay the principal amount of the Oramed Note at a mandatory default rate of 125% of such principal amount (together with 100% of accrued and unpaid interest thereon and all other amounts due in respect of the Oramed Note). The Oramed Note contains mandatory prepayment provisions requiring us and our subsidiaries to, following the earlier of (x) April 1, 2024, and (y) the date on which the Acceptable Indebtedness (as defined in the Oramed Note) is repaid in full, use 70% of the net cash proceeds of any Cash Sweep Financing (as defined in the Oramed Note) or advance under the ELOCs (as defined in the Oramed Note) to prepay the outstanding principal amount of the Oramed Note (the "Mandatory Prepayment Sweep"). Following each of the April 2024 RDO, the receipt of the FSF Deposit and ATM Sales Agreement (each as defined below), we made a mandatory prepayment of $9,578,835, $7,000,000 and $1,760,796, respectively, to Oramed, which equals 70% of the net cash proceeds we received from each of the April 2024 RDO, the FSF Deposit and the sale of shares pursuant to the ATM Sales Agreement. Given such payment was not a voluntary prepayment, such prepayment did not trigger the make-whole amount under the Oramed Note.

On October 8, 2024 (the "Issuance Date"), we issued and sold in a registered offering to certain institutional investors (collectively, the "Tranche B Investors") and Oramed (together with the Investors, the "Tranche B Noteholders") senior secured convertible notes in the aggregate principal amount of $50,000,000 (the "Tranche B Notes"), which notes will be convertible into shares of Common Stock, pursuant to that certain securities purchase agreement we entered into with the Tranche B Noteholders, dated as of October 7, 2024 (the "Tranche B Securities Purchase Agreement"). In consideration for Tranche B Notes issued to Oramed, the outstanding principal balance of the Oramed Note was reduced by $22,500,000, and an additional principal payment of an aggregate amount of $15,000,000 was made in November and December 2024. As of December 31, 2024, the outstanding principal amount, as well as the accrued interest and fees, of the Oramed Note was $24,955,634, with the remaining amount due on March 21, 2025, which maturity date was extended to December 31, 2025 pursuant to an amendment letter we entered into with Oramed, dated as of January 21, 2025.

Unless earlier converted or redeemed, the Tranche B Notes mature on the two-year anniversary of the Issuance Date (the "Maturity Date"), subject to extension at the option of the holder in certain circumstances as provided therein. The Tranche B Notes bear interest at a rate of 5.5% per annum, payable in arrears on the first trading day of each calendar quarter, beginning January 2, 2025, payable, at our option, either in cash or in shares of Common Stock, subject to certain conditions.

The Oramed Note and the Tranche B Notes contain affirmative and negative covenants binding on us and our subsidiaries which restrict, among other things, us and our subsidiaries from incurring indebtedness or liens, repaying certain indebtedness, or declaring or paying any cash dividends or distribution, selling or otherwise disposing of any assets, entering into transactions with affiliates, in each case as more fully set forth in, and subject to certain qualifications, exceptions, and "baskets" set forth in the Oramed Note and the Tranche B Notes. The Oramed Note also contains covenants requiring us to maintain a segregated bank account under specific terms and conditions, for purposes of receiving the Mandatory Prepayment Sweep, requiring SCLX Stock Acquisition JV LLC, our indirect wholly owned subsidiary ("SCLX JV"), to comply with the separateness representations and covenants in its organizational documents, and requiring our subsidiary, SCLX DRE Holdings LLC, to maintain its status as a passive holding company. The Tranche B Notes also require us to, at the request of the holder, not more frequently than once per fiscal year, hire an independent, reputable investment bank to investigate whether any breach of the Tranche B Notes has occurred if an event constituting an event of default has occurred and is continuing or any holder reasonably believes that an event constituting an event of default has occurred or is continuing.

The Oramed Note and the Tranche B Notes contain certain customary events of default, including, without limitation, a cross-default to other specified indebtedness or any other indebtedness involving an obligation of certain amount, a failure in payment of principal, as well as any bankruptcy, insolvency, reorganization event. The Oramed Note also contains additional events of default with respect to certain events relating to our obligations under that certain registration rights agreement, dated as of September 21, 2023, between us and Oramed and relating to (i) the warrants to purchase up to an aggregate of 13,000,000 shares of Common Stock, with an exercise price of $0.01 per share (the "Penny Warrants"), that we issued to Oramed pursuant to the Scilex-Oramed SPA, (ii) the warrants to purchase up to 4,000,000 shares of Common Stock, with an exercise price of $11.50 per share (the "Transferred Warrants"), that we transferred to Oramed pursuant to the Scilex-Oramed SPA and/or (iii) the shares of Common Stock underlying the Penny Warrants or Transferred Warrants, in each case as more fully set forth in the Oramed Note.

In addition, failure to comply with the covenants under the Oramed Note could result in an event of default. The events of default include, among others, a change of control of our company. Upon an event of default, subject to notice requirements in the case of certain events of default, all amounts outstanding under the Oramed Note may become immediately due and payable. We may not have sufficient funds or may be unable to arrange for additional financing to repay such indebtedness or to make any accelerated payments, and Oramed could seek to enforce its security interests in the collateral securing such indebtedness or other remedies available to it under the Oramed Note or as provided by applicable law. Oramed could also seek to enforce the guaranty under the Subsidiary Guarantee entered into by us and each of our subsidiaries, dated as of September 21, 2023, to carry out our payment obligations under the Oramed Note. Any failure by us to comply with the obligations under the Oramed Note could have a negative effect on our business, financial condition and results of operations.

In addition, the Tranche B Notes prohibit us from entering into specified fundamental transactions unless the successor entity assumes all of our obligations under the Tranche B Notes under a written agreement approved by the required holders of the Tranche B Notes before the transaction is completed. Upon consummation of specified fundamental transactions, the successor entity must confirm that upon conversion or redemption of the Tranche B Notes thereafter, shares of the successor entity will be issuable upon such conversion or redemption. The holders of the Tranche B Notes also have certain redemption rights upon a fundamental transaction constituting a change of control.

Our outstanding indebtedness and any future indebtedness we may incur, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

The Oramed Note and Tranche B Notes impose certain operating and financial covenants and any failure to comply with such covenants could result in an event of default that could adversely affect our business, financial condition and results of operations.

If an event of default occurs under the Oramed Note or the Tranche B Notes (collectively, the "Existing Notes"), the holder of the Oramed Note could elect to immediately accelerate the due date of such note and, in the case of the Tranche B Notes, all of the holders thereof could require that we redeem such notes in accordance with the terms thereof, including any default interest rates, liquidated damages or similar penalties that would arise pursuant to the terms of such Existing Notes upon an event of default that is not cured within the applicable periods set forth in the Existing Notes.

We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness under the Existing Notes or to make any accelerated or redemption payments, and the lenders could seek to enforce their respective security interests in the collateral securing such indebtedness or other remedies available to such lenders under the Existing Notes or as provided by applicable law. The lenders could also seek to enforce the guaranty under the Subsidiary Guarantee entered into by us and each of our subsidiaries, dated as of September 21, 2023 and amended as of October 8, 2024, to carry out our payment obligations under the Existing Notes. Any failure by us to comply with the obligations under the Existing Notes could cause our stock price to decrease significantly, result in substantial dilution or cause us to be unable to raise additional capital, which could have a material negative effect on our business, financial condition and results of operations. See the risk factor titled "*We may not have the ability to raise the funds necessary to settle the Oramed Note or the Tranche B Notes in cash upon a change of control or other event of default, and any future debt may contain limitations on our ability to pay cash upon conversion of the Tranche B Notes*" for additional information.

We may not have the ability to raise the funds necessary to settle the Oramed Note or the Tranche B Notes in cash upon a change of control or other event of default, and any future debt may contain limitations on our ability to pay cash upon conversion of the Tranche B Notes.

A change of control transaction triggers an event of default under the Oramed Note, which will result in the full unpaid principal amount of the Oramed Note, together with interest and other amounts owing in respect thereof, to the date of acceleration becoming, at the election of the holder of the Oramed Note, immediately due and payable in cash at the Mandatory Default Amount (as defined in the Oramed Note). Similarly, a change of control transaction (including any fundamental transaction in which our successor is not a public company) triggers the redemption rights of the holders under the Tranche B Notes. If the Tranche B Notes are not retired in connection with such change of control transaction, each holder may require us to redeem in cash all, or any portion, of the Tranche B Notes at a 30% redemption premium to the greater of (i) the amounts then outstanding under the Tranche B Notes to be redeemed; (ii) the equity value of our Common Stock underlying such Tranche B Notes; and (iii) the equity value of the change of control consideration payable to the holders of our Common Stock underlying such Tranche B Notes.

In such events or in the event of any other redemption event or event of default under the Oramed Note or the Tranche B Notes, we may not have enough available cash or be able to obtain financing at the time we are required to pay cash with respect to the Oramed Note or the Tranche B Notes. In addition, our ability to pay cash upon default of the Oramed Note or the Tranche B Notes may be limited by law, regulatory authority, or any agreements governing our future indebtedness**.**

We may be required to make milestone payments to the former stockholders of Semnur in connection with our development and commercialization of SEMDEXA, which could adversely affect the overall profitability of SEMDEXA, if approved.

Under the terms of the Agreement and Plan of Merger we entered into with Semnur, Sigma Merger Sub, Inc., our prior wholly owned subsidiary, Fortis Advisors LLC, solely as representative of the holders of Semnur equity (the "Semnur Equityholders"), and Sorrento, for limited purposes, we are obligated to pay the Semnur Equityholders up to an aggregate of $280.0 million in contingent cash consideration based on the achievement of certain milestones. A $40.0 million payment will be due upon obtaining the first approval of a new drug application by the FDA ("NDA") of any Semnur product, which includes SEMDEXA. Additional payments will be due upon the achievement of certain cumulative net sales of Semnur products, as follows:

- a $20.0 million payment upon the achievement of $100.0 million in cumulative net sales of a Semnur product;
- a $20.0 million payment upon the achievement of $250.0 million in cumulative net sales of a Semnur product;
- a $50.0 million payment upon the achievement of $500.0 million in cumulative net sales of a Semnur product; and
- a $150.0 million payment upon the achievement of $750.0 million in cumulative net sales of a Semnur product.

These milestone obligations could impose substantial additional costs on us, divert resources from other aspects of our business, and adversely affect the overall profitability of SEMDEXA, if approved. We may need to obtain additional financing to satisfy these milestone payments, and cannot be sure that any additional funding, if needed, will be available on terms favorable to us, or at all.

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 continue our commercialization efforts for ZTlido, GLOPERBA and ELYXYB, advance development of our current product candidates and launch and commercialize any product candidates 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, 2024, our cash and cash equivalents were approximately $3.3 million and we had an accumulated deficit of approximately $563.1 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 costs and expenses associated with our ongoing commercialization efforts for ZTlido, GLOPERBA and ELYXYB;
- the degree of success we experience in commercializing ZTlido, GLOPERBA and ELYXYB;
- the revenue generated by sales of ZTlido, GLOPERBA, ELYXYB and other products that may be approved, if any;
- the scope, progress, results and costs of conducting studies and clinical trials for our product candidates, SEMDEXA, SP-103 and SP-104;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the costs of manufacturing ZTlido, GLOPERBA, ELYXYB and our product candidates;
- 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 ZTlido, GLOPERBA, ELYXYB or any of our product candidates, 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 we develop and commercialize;
- any product liability or other lawsuits related to our products;
- 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;
- the costs related to servicing of our debt;
- the costs of financing additional clinical, regulatory and commercial activities; and
- the extent and scope of our general and administrative expenses.

Until we are able to generate significant 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 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 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 Note 2 titled “Liquidity and Going Concern” of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, 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 Note 2 titled "*Liquidity and Going Concern*" of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, 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 consolidated financial statements as of and for the years ended December 31, 2024 and 2023, which stated that management has concluded that substantial doubt exists about our ability to continue as a going concern for one year after the date our consolidated financial statements are issued. 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 approximately $563.1 million as of December 31, 2024 and approximately $490.2 million as of December 31, 2023. 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. We will need to seek additional financing to fund our current operations, including the commercialization of ZTlido, GLOPERBA and ELYXYB, as well as the development of our other material product candidates for the next 12 months. Our plans are substantially dependent upon the success of future sales of ZTlido, ELYXYB and GLOPERBA among which ELYXYB and GLOPERBA are still in the early stages of commercialization, and are dependent upon, among other things, the success of our marketing of ZTlido, ELYXYB and GLOPERBA and our ability to secure additional payor contracts with terms that are consistent with our business plan. 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. Future financial statements may disclose substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, or at all.

We have previously identified material weaknesses in our internal control over financial reporting. If we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to timely and accurately report our financial results and such material weaknesses may result in a material misstatement of our consolidated financial statements.

In connection with the audit of our consolidated financial statements for the years ended December 31, 2022 and 2021, 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 consolidated financial statements will not be prevented or detected on a timely basis.

As more fully disclosed in Item 9A of this Annual Report on Form 10-K, for the years ended December 31, 2022 and 2021, the material weakness identified in our internal control over financial reporting related to ineffective control activities in the areas of revenue, business combination, debt and derivative liabilities caused by a lack of sufficient accounting resources with appropriate experience and technical expertise to effectively execute controls over certain judgmental and technical accounting areas. As a result of the material weakness, we hired additional accounting personnel and are implementing remediation measures including, but not limited to, performing a comprehensive assessment of accounting and finance resource requirements and hiring other personnel with sufficient accounting expertise at our company to improve the operating effectiveness of our review controls and monitoring activities, and utilizing external accounting experts as appropriate. Any potential material misstatements were identified and corrected as audit adjustments in the applicable periods and are properly reflected in our consolidated financial statements included in this Annual Report on Form 10-K. We hired a new Chief Financial Officer in May 2022 at Legacy Scilex and she served as Chief Financial Officer of the Company through September 2023. In May 2023, we appointed a Chief Accounting Officer, who became our Chief Financial Officer in September 2023. In addition, we expect to hire additional personnel with accounting expertise and utilize external accounting experts.

As of December 31, 2023, we have remediated the previously identified material weaknesses in our internal control over financial reporting, and we have not identified a material weakness in our internal control over financial reporting for the year ended December 31, 2024. If we identify additional material weaknesses or deficiencies in internal controls in the future 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 our 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, in the future, we identify 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 Commercial Operations and Product Development

We obtain, or historically have obtained, our commercial supply of certain of our products, the clinical supply of our product candidates and certain of the raw materials used in our product candidates from sole or single source suppliers and manufacturers. In the event of a loss of one of these suppliers or manufacturers, or a failure by any such supplier or manufacturer to comply with FDA regulations, we may not be able to find an alternative source on commercially reasonable terms, or at all.

We rely on a number of sole or single source suppliers and manufacturers, including:

- the manufacturer and supplier for the commercial supply of ZTlido, ELYXYB and GLOPERBA;
- the manufacturer and supplier for the clinical supply of SP-103;
- the manufacturer and supplier for the clinical supply of SP-104;
- the supplier of sodium hyaluronate, one of the excipients for SEMDEXA; and
- the manufacturer for the clinical supply of SEMDEXA.

Under the Product Development Agreement and the Commercial Supply Agreement, we license the rights to ZTlido from, and rely exclusively on, Oishi and Itochu for the manufacturing and supply of ZTlido and SP-103. Oishi and Itochu have the right to terminate the Product Development Agreement and the Commercial Supply Agreement under certain circumstances, including, among other things: (1) if we are in material breach of the agreement and the breach is not curable or if the breach is curable and we fail to cure such material breach within 180 days after notice requesting to cure; (2) if, at any time during the term of the Product Development Agreement and the Commercial Supply Agreement, the market conditions are such that (a) our total net profits for ZTlido and SP-103 are equal to or less than five percent of our net sales of ZTlido and SP-103 for a period of four or more consecutive quarters, or (b) the economic viability of ZTlido and SP-103 is affected significantly as evidenced by documentation and substantial information by any external circumstances deemed detrimental to all parties as agreed to by us, on the one hand, and Oishi and Itochu, on the other hand, and the parties are unable to resolve the concerns under the foregoing clauses (a) and (b) after 30 days of good-faith discussion; and (3) in the event of our bankruptcy or assignment for the benefit of creditors. As of December 31, 2024, our net profits for ZTlido and SP-103 have not exceeded five percent of net sales. Accordingly, Oishi and Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of December 31, 2024, neither Oishi nor Itochu has exercised its right of termination. If the Product Development Agreement and the Commercial Supply Agreement are terminated, we would lose access to the intellectual property and proprietary manufacturing process upon which ZTlido and SP-103 depend.

We expect our third-party manufacturers and suppliers of both GLOPERBA and ELYXYB are capable of providing sufficient quantities of these products to meet anticipated commercial demands; however, if third parties with whom we currently work are unable to meet our manufacturing and supply requirements, we will need to secure alternate manufacturers and suppliers or face potential delays or shortages. While we believe that there are other contract manufacturers and suppliers with the technical capabilities to manufacture and supply these products, we cannot be certain that identifying and establishing relationships with such sources would not result in significant delay or material additional costs.

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 2027. Although we are currently in discussions with Sanofi S.A. ("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, we may not be able to reach agreement with Sanofi or find an alternative supplier of sodium hyaluronate on commercially reasonable terms, or at all.

Under the Lifecore Master Services Agreement, we depend on Lifecore to manufacture clinical supplies of SEMDEXA. 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 SEMDEXA 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. On June 6, 2023, Semnur entered into the Second Amendment to Lifecore Master Services Agreement with Lifecore, which extended the term of the agreement until December 31, 2028.

Under the Tulex Master Services Agreement and the statement of work with Tulex, we depend on Tulex to develop, test and manufacture clinical supplies of SP-104. Tulex has the right to terminate the Tulex Master Services Agreement under certain circumstances, including, but not limited to: (1) if we are in material breach of the agreement or a statement of work and fail to cure such breach within 15 days after receipt of notice of such breach (or such other time period expressly stated in the applicable statement of work) or (2) in the event of our insolvency, bankruptcy, reorganization, liquidation or receivership, or a failure to remove any insolvency, bankruptcy, reorganization, liquidation or receivership proceedings within ten days from the date of institution of such proceedings. In addition, we may terminate the agreement or any statement of work (a) without cause upon 30 days prior written notice to Tulex or (b) immediately upon written notice in the event Tulex is dissolved or undergoes a change in control. In the event that the Tulex Master Services Agreement or a statement of work is terminated, we may not be able to find an alternative manufacturer and supplier on commercially reasonable terms.

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 products and product candidates 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 candidates 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 cGMP regulations and that might be capable of manufacturing for us. Also, prior to the approval of our product candidates, 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 the commercial supply of our commercial products, clinical supply of our product candidates and certain of the raw materials used in our product candidates 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 profitability of ZTlido, the commercialization of GLOPERBA and ELYXYB, and the development of SEMDEXA, SP-103 and SP-104.

We rely on a single third-party logistics distribution provider for ZTlido, ELYXYB and GLOPERBA.

We currently rely on Cardinal Health 105, LLC ("Cardinal Health 105") as our third-party logistics distribution provider for ZTlido, ELYXYB and GLOPERBA in the United States. Cardinal Health 105 also performs the following services on our behalf: customer service, credit checks, invoicing, chargebacks, distributor fee for service, government reporting, customer returns, accounts receivable, inventory control, product security (DSCSA serialization) inquiries and recall assistance. If we are unable to maintain a favorable relationship with Cardinal Health 105, we expect that our revenue would decline and our business would be harmed as a result. We may be unable to control the timing of the delivery of ZTlido, ELYXYB and GLOPERBA to distributors, and any financial uncertainty or loss of key logistic employees of Cardinal Health 105, as our only third-party logistics provider, may negatively impact our sales.

If we fail to achieve certain milestones in our Product Development Agreement with Itochu and Oishi, we could lose rights that are important to our business.

Certain of our existing license and supply agreements impose various milestone and other obligations on us. For example, under our Product Development Agreement with Itochu and Oishi, if our total net profits for ZTlido and SP-103 are equal to or less than five percent of our net sales of ZTlido and SP-103 for a period of four or more consecutive quarters, Itochu and Oishi have the right to terminate the Product Development Agreement if the parties are unable to resolve the concerns after 30 days of good-faith negotiation. As of December 31, 2024, our net profits for ZTlido and SP-103 have not exceeded five percent of net sales. Accordingly, Oishi and

Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of December 31, 2024, neither Oishi nor Itochu has exercised its right of termination.

If we fail to achieve the milestones under the Product Development Agreement, we may lose our exclusivity rights or the counterparty may have the right to terminate the agreement, any of which could adversely affect our business, financial condition and results of operations.

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 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 contract research organizations ("CROs"), to conduct GCP-compliant clinical trials of our 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 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.

Our business is substantially dependent upon the intellectual property licensed from Oishi and Itochu. In the ordinary course of our business, we may enter into collaborations, additional in-licensing arrangements (such as, for example, the Romeg License Agreement), 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 additional revenue.

Before obtaining marketing approval for the sale of our 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 institutional review boards ("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 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 trials of SP-103, SP-104 and SEMDEXA, 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.

Our business could be adversely affected by the effects of health pandemics or other health crises, which could cause significant disruptions in our operations and those of our CMOs, CROs and other third parties upon whom we rely.

Health pandemics or other health crises, including COVID-19, have in the past and could again in the future result in a disruption of our businesses, delay our research and development programs and timelines, negatively impact our productivity and increase risks associated with cybersecurity. More specifically, these types of events may negatively impact personnel at third-party manufacturing facilities or the availability or cost of materials, which could disrupt our supply chain. Moreover, our clinical trials may be negatively affected. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources. Some patients may not be able or willing to comply with trial protocols if wide-spread health crisis impede patient movement or interrupt healthcare services. Our ability to recruit and retain patients, principal investigators and site staff (who as healthcare providers may have heightened exposure) may be hindered, which would adversely affect our trial operations. In addition, we rely on independent clinical investigators, CROs and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our clinical trials, including the collection of data from our trials, and the effects of health pandemics or other health crises may affect their ability to devote sufficient time and resources to our programs. As a result, the expected timeline for data readouts, including incompleteness in data collection and analysis and other related activities, and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and adversely affect our business, financial condition, results of operations and prospects. In addition, the impact of such health pandemics or other health crises on the operations of the FDA or other regulatory authorities could negatively affect our planned trials and approval processes.

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 product candidates 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 our product candidates meet 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 our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Additionally, if the results of any clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed or fail in obtaining marketing approval for our product candidates;
- 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 products are 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 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 COVID-19 (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 SEMDEXA Phase 3 clinical trial in sciatica due to the selective eligibility criteria in place to reduce the placebo effect and the impacts of COVID-19, and may experience similar issues with enrollment of our other planned clinical trials.

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

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to 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.

ZTlido and our product candidate, SP-103, face and will likely face competition from other prescription patches, generic topical lidocaine patches, and OTC lidocaine patches, including Lidoderm®, generic lidocaine patches manufactured by Mylan N.V., Teva and Par Pharmaceutical, Inc., and various OTC patches. Additionally, SP-103, if approved, will likely compete with various opioid pain medications, NSAIDs, muscle relaxants, antidepressants and anticonvulsants particularly as we seek approval for the treatment of chronic neck pain.

SEMDEXA, 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. SEMDEXA, if approved, also 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.

While there are currently no formulations containing naltrexone in clinical development for the treatment of fibromyalgia, we are aware of certain non-opioid therapeutics currently in a late-stage phase 3 pipeline containing two 505(b)(2) development programs. Our product candidate, SP-104, will likely face direct competition from these candidates.

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.

The third-party payor coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain coverage and adequate reimbursement for ZTlido, GLOPERBA, ELYXYB or our 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 ZTlido, GLOPERBA, ELYXYB and our 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 ZTlido can differ significantly from payor to payor, and we may not be able to maintain 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 our products 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 products 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 do not follow price structures of the United States and generally prices tend to be significantly lower.

Our product candidate SEMDEXA 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 SEMDEXA receives regulatory approval, the administering physician may be reimbursed only for providing the treatment or procedure in which SEMDEXA is used. To the extent separate coverage and reimbursement should become available for SEMDEXA, 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 SEMDEXA, 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 any of our product candidates. If our product candidates are 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.

Because we have multiple programs and product candidates in our development pipeline and are pursuing a variety of target indications and treatment approaches, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on development opportunities or product candidates that may be more profitable or for which there is a greater likelihood of success.

Apart from our FDA-approved products, ZTlido, GLOPERBA and ELYXYB, we currently have several product candidates that are at various stages of development. We have limited financial and management resources. As a result, we may forego or delay pursuit of opportunities with potential target indications or product candidates that later prove to have greater commercial potential than our current and planned development programs and product candidates.

We strive to progress product candidates that can address unmet or underserved medical needs and favor those candidates with large market opportunities. However, our resource allocation decisions may cause us to fail to capitalize on viable commercial product candidates or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may be required to relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

Additionally, we may pursue additional in-licenses or acquisitions of product candidates or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a successful product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive, difficult to design and implement, and can take many years to complete, in part because it is subject to rigorous regulatory requirements. The FDA or other regulatory authorities may not agree with the proposed analysis plans or trial design for the clinical trials of our product candidates. They may also not agree with the scope of our proposed investigational plan. In addition, the outcome of our clinical trials is risky and uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the pharmaceutical industry to suffer significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

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

A Phase 3 trial was completed for SEMDEXA for the treatment of sciatica, a Phase 2 trial was completed for SP-103 in 2023, and multiple Phase 1 trials were completed in the first half of 2022 for SP-104. 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 candidates 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 SEMDEXA, which reflect positive results with respect to primary and secondary endpoints, and we intend to use the results to support a NDA submission seeking approval for the treatment of sciatica. In November 2023, we had a Type C meeting with the FDA to discuss the requirements for filing a 505(b)(2) NDA for SEMDEXA. In the Type C meeting, the FDA indicated that it disagreed with us that the clinical data we had collected was sufficient to support the safety and efficacy of SEMDEXA. The FDA provided guidance regarding expectations for the additional confirmatory trial needed prior to a 505(b)(2) NDA filing and the circumstances under which one adequate and well-controlled trial would be sufficient for product registration. In February 2024, we had a Type D meeting with the FDA to preview a newly designed trial, in order to reduce the potential need for any other additional trials prior to a 505(b)(2) NDA filing. During the Type D meeting, the FDA provided further guidance with respect to efficacy requirements and expectations on the size of safety database needed to help best position us to be able to satisfy the requirements for a 505(b)(2) pathway approval. Our failure to adequately demonstrate the safety and effectiveness of our product candidates would prevent regulatory approval and, ultimately, the commercialization of that product for the proposed indication for use.

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 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 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 any of our 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.

ZTlido, GLOPERBA and ELYXYB may have undesirable properties that could result in significant negative consequences, and 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 ZTlido, GLOPERBA, ELYXYB and our product candidates. In the event that ZTlido, GLOPERBA or ELYXYB is identified to have undesirable side effects, a number of potentially significant negative consequences could occur. Regulatory authorities may withdraw their approval of the product or seize the product. Restrictions may be imposed on the manufacturing or marketing of ZTlido, GLOPERBA or ELYXYB or any component thereof, including the imposition of a REMS plan that may require creation of a Medication Guide outlining the risks of such side effects for distribution to patients, as well as elements to assure safe use of the product, such as a patient registry and training and certification of prescribers. Any of these events could damage our reputation and prevent us from achieving or maintaining market acceptance of ZTlido, GLOPERBA or ELYXYB.

In the clinical trials we conduct with our 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 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.

ZTlido, GLOPERBA, ELYXYB and our product candidates are 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 product candidates, or otherwise harm our business.

We currently depend on contract manufacturers to conduct the manufacturing and supply activities for ZTlido, GLOPERBA, ELYXYB and our product candidates. Manufacturing these product candidates require 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 ZTlido, GLOPERBA, ELYXYB or our 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 President and Chief Executive Officer, Henry Ji, Ph.D., our Executive Chairperson, 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, completion of our planned clinical trials and the successful commercialization of ZTlido, GLOPERBA and ELYXYB. 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, 2024, we had approximately 115 full-time employees. We may need to continue 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 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 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.

There is no assurance that we will complete the Business Combination with respect to the sale of our wholly owned subsidiary, Semnur, and/or our SP-102 product candidate, under the terms of the Merger Agreement or otherwise and the failure to complete the Business Combination could adversely affect our stock price and future business and financial results.

As previously announced, our Board authorized our management to explore ways in which to maximize the value of Semnur and SP-102 (SEMDEXA™), the product candidate held by Semnur, for us and our stockholders, including by way of conducting a spin-off, merger, dividend, reclassification or other similar transaction. On August 30, 2024, Semnur entered into a Merger Agreement (the "Semnur Business Combination Agreement") with Denali Capital Acquisition Corp. ("Denali") and Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali ("Denali Merger Sub"), in connection with a business combination (the "Business Combination"). The consummation of the Business Combination is subject to the satisfaction or waiver of a number of closing conditions of the respective parties. The completion of the Business Combination is not assured and is subject to risks, including, among others, the risk that approval of the Business Combination by Denali's shareholders is not obtained or that other closing conditions are not satisfied. There is also no assurance the Business Combination will actually maximize the value of Semnur and/or the SP-102 asset for us or our stockholders. In addition, we will remain liable for significant transaction costs, including legal, accounting and financial advisory fees. Furthermore, the market price of our Common Stock may reflect various market assumptions as to whether the Business Combination will occur. Consequently, the failure to complete the Business Combination could result in a significant change in the market price of our Common Stock.

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.

Manufacturing and marketing of ZTlido, GLOPERBA and ELYXYB and 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 products 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 our 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 the product, withdrawal of the product 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 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.

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

We currently collaborate with international manufacturing partners and may potentially expand our business internationally in the future. The purchase and shipment of components from international sources subjects 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 new 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 new 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 new administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. 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 blinded 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, and have experienced, 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. For example, there was a cyberattack on Change Healthcare in March 2024. We worked diligently with our co-pay savings card adjudicators to resolve the breakdown of processing of insurance claims by Change Healthcare, and restored the co-pay savings card processing for ZTlido and ELYXYB, which has been restored to normal operations. This incident did not have a material impact on the Company as a whole. A material system failure or security breach, if such an event were to occur, 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 ZTlido, GLOPERBA, ELYXYB and 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 of the Company, those of our CROs and other contractors and consultants 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, and the ability of our CROs and other contractors and consultants, to effectively manage and maintain our internal business information, and to ship products to customers and invoice them on a timely basis, depends significantly on our enterprise resource planning system and other information systems. Portions of our information technology systems and those of our CROs' and other contractors' and consultants may experience, and have experienced, 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, and have led to disruptions in systems, misappropriation of confidential or otherwise protected information, and corruption of data. If we, our CROs and other contractors and

consultants 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 and may be material to our Company as a whole. 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 also could cause disruptions to global economic conditions and affect the stability of the Middle East region. 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.

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

There is an increasing focus from certain investors, employees, regulators, listing exchanges and other stakeholders concerning factors such as corporate responsibility, corporate governance, sustainability and/or corporate involvement in social issues. Some investors and investor groups may use these factors—either in support or opposition— to guide their investment strategies and, in some cases, investors may choose not to invest in us if they believe our policies or practices relating to these factors do not align with their expectations. Currently, a variety of third-party providers of corporate responsibility and sustainability ratings measure the performance of companies on these factors, and the results of these assessments are widely publicized. Certain investors, particularly institutional investors, use these ratings to benchmark companies against their peers, and certain major institutional investors have publicly emphasized the importance of these factors to their investment decisions. Topics taken into account in such assessments include, among others, the risks faced by companies arising out of climate change, human rights, business ethics and compliance, and the role of companies' board of directors in overseeing various sustainability-related risks. Equally, certain investors, including institutional investors, actively reject the consideration of these matters when making their investment decisions. In light of certain investors' increased focus on these factors, if we are, for example, perceived as deviating from our peers in respect of practices and initiatives related to these factors, we may be exposed to shareholder activism and litigation (both in support of, or in opposition to, such practices and initiatives).

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

We may also face reputational damage if we are unable to achieve an acceptable sustainability rating from third-party rating services. A low sustainability rating by a third-party rating service could also result in the exclusion of our Common Stock from consideration by certain investors who may elect to invest with our competitors instead. Ongoing focus on corporate responsibility and sustainability matters by investors and other stakeholders as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, financial condition or

results of operations, including the sustainability of our business over time, and could cause the market value of our Common Stock to decline.

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

Risks Related to our Intellectual Property

We are substantially dependent on the intellectual property we in-license from Oishi and Itochu, and if we lose the right to license such intellectual property or if the Product Development Agreement is terminated for any reason, our ability to commercialize ZTlido and develop and commercialize SP-103 would be harmed.

Our business is substantially dependent upon the intellectual property licensed from Oishi and Itochu. Pursuant to the Product Development Agreement, we have been granted an exclusive, worldwide license (except with respect to Japan) under current and future intellectual property rights relating to ZTlido and SP-103 lidocaine tape products and the lidocaine in such products, including, among other things: (1) any patent applications, continuation applications, any issued or issuing patents, as well as any foreign patent applications; (2) all know-how, work product, trade secrets, inventions, data, processes, techniques, procedures, compositions, devices, methods, formulas, protocols and information, whether patentable or not; (3) copyrightable works, copyrights and applications, registrations and renewals; (4) logos, trademarks, service marks, and all applications and registrations relating thereto; (5) other proprietary rights; (6) abbreviated new drug applications or other applications to market; and (7) any regulatory exclusivities or supplemental protection certificates. Our ability to commercialize ZTlido and develop SP-103 depends on the effectiveness and continuation of the Product Development Agreement. If we lose the right to license the intellectual property rights granted by the Product Development Agreement, our ability to develop ZTlido and SP-103 as well as new product candidates based on the licensed intellectual property would be harmed.

The Product Development Agreement imposes various development, regulatory and/or commercial diligence obligations, payments and other obligations. Oishi and Itochu have the right to terminate the Product Development Agreement under certain circumstances, including, among other things: (1) if we are in material breach of the agreement and the breach is not curable or if the breach is curable and we fail to cure such material breach within 180 days after notice requesting to cure; (2) if, at any time during the term of the Product Development Agreement, the market conditions are such that (a) our total net profits for ZTlido and SP-103 are equal to or less than five percent of our net sales of ZTlido and SP-103 for a period of four or more consecutive quarters, or (b) the economic viability of ZTlido and SP-103 is affected significantly as evidenced by documentation and substantial information by any external circumstances deemed detrimental to all parties as agreed to by us, on the one hand, and Oishi and Itochu, on the other hand, and the parties are unable to resolve the concerns under the foregoing clauses (a) and (b) after 30 days of good-faith discussion; and (3) in the event of our bankruptcy or assignment for the benefit of creditors. As of December 31, 2024, Scilex's net profits for ZTlido and SP-103 have not exceeded five percent of net sales. Accordingly, Oishi and Itochu have the right to terminate the Product Development Agreement and Commercial Supply Agreement. As of December 31, 2024, neither Oishi nor Itochu has exercised its right of termination. If the Product Development Agreement is terminated for certain reasons, such as our material breach of the agreement, our bankruptcy, or lack of economic viability, we will be required to transfer all licensed intellectual property rights, including those relating to ZTlido and SP-103, to Oishi and Itochu or their designee, at our own cost and expense. The loss of such licenses could materially harm our business, financial condition and results of operations.

We are party to the Romeg License Agreement for the in-licensing of certain intellectual property rights from Romeg with respect to the commercialization of GLOPERBA, and if we lose the right to license such intellectual property or if the Romeg License Agreement is terminated for any reason, our ability to commercialize GLOPERBA would be harmed.

On June 14, 2022 (the "Original Signing Date"), we entered into the Romeg License Agreement for the in-licensing of certain intellectual property rights from Romeg with respect to the commercialization of GLOPERBA, which was amended by that First Amendment to License and Commercialization Agreement, dated as of January 16, 2025. Under the Romeg License Agreement, among other things, Romeg granted us (1) a license, with the right to sublicense, under the patents and know-how specified therein to (a) commercialize a pharmaceutical product comprising liquid formulations of colchicine for the prophylactic treatment of gout in adult humans (the "Initial Licensed Product") in the United States (including its territories) (the "Romeg U.S. Territory"), (b) develop other products comprising the Initial Licensed Product as an active pharmaceutical ingredient (together with the Initial Licensed Product, the "Licensed Products") and commercialize any such products in the Romeg U.S. Territory and (c) manufacture Licensed Products anywhere in the world, solely for commercialization in the Romeg U.S. Territory; (2) an exclusive license, with right to sublicense, to use the trademark "GLOPERBA" and logos, designs, translations, and modifications thereof (collectively, the "Licensed Trademark") in connection with the commercialization of the Initial Licensed Product solely in the Romeg U.S. Territory; and (3) pursuant to the amendment thereto, a license, with the right to (a) sublicense under the know-how and, if any, patents existing worldwide other than the Romeg U.S. Territory (the "Romeg Ex-U.S. Territory"), as specified therein, to develop, manufacture and commercialize Licensed Products in the Romeg Ex-U.S. Territory and (b) to use the Licensed Trademark in connection with the commercialization of the Licensed Products in the Romeg Ex-U.S. Territory. With respect to the foregoing clause (1), the license to know-how is exclusive for purposes of developing and commercializing Licensed Products in the Romeg U.S. Territory during the Romeg U.S. Territory Royalty Term, but is otherwise non-exclusive, and the license to patents is exclusive for purposes of developing and commercializing Licensed Products in the Romeg U.S. Territory until July 1, 2027 and, thereafter, is co-exclusive with Granules Pharmaceuticals, Inc. for the royalty term for such purposes. The Romeg U.S. Territory begins on the Original Signing Date and ends on the later of (i) expiration of the last-to-expire of the patents that covers the manufacture or commercialization of the Licensed Products in the Romeg U.S. Territory or (ii) the tenth anniversary of the Original Signing Date. With respect to the foregoing clause (3), the license to know-how patents (if any) is exclusive during the Romeg Ex-U.S. Territory Royalty Term, but is otherwise non-exclusive. The Romeg Ex-U.S. Territory Royalty Term begins on the date of the amendment agreement and ends on the tenth anniversary of such date. Our ability to commercialize GLOPERBA and develop Licensed Products depends on the effectiveness and continuation of the Romeg License Agreement. If we lose the right to license the intellectual property rights granted by the Romeg License Agreement, our ability to develop GLOPERBA as well as new product candidates based on the licensed intellectual property would be harmed.

The Romeg License Agreement imposes various development, regulatory and/or commercial diligence obligations, payments and other obligations. Romeg has the right to terminate the Romeg License Agreement under certain circumstances, including, among other things: (a) in the event we are in material breach of the Romeg License Agreement, unless we have cured any such breach within 60 days after any notice thereof was provided; (b) upon notice to us, if we fail to timely pay any milestone payment, percentage royalties or minimum quarterly royalties or fail to timely deliver the requisite quarterly report, which termination will be effective 30 days after the date of such notice, unless we have made such payment in full or delivered such quarterly report within such 30 day period; (c) immediately, if we challenge the licensed patents under any court action or proceeding or before any patent office or assist any third party to conduct any of these activities; (d) by written notice to us if sales of the Licensed Products do not commence or continue within specified periods agreed to by the parties; or (e) in the event of our bankruptcy or assignment for the benefit of creditors. If the Romeg License Agreement is terminated for certain reasons, such as our material breach of the agreement, our bankruptcy, or our failure to timely pay milestone payments, we will be required upon Romeg's request to transfer all licensed intellectual property rights, including those relating to GLOPERBA and the Licensed Products, to Romeg or its designee, within thirty days after the termination of the Romeg License Agreement at a price to be agreed upon by the parties. The loss of such licenses could materially harm our business, financial condition and results of operations.

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 product candidates, 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 and 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 certain of our 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 candidates. 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 ZTlido, GLOPERBA, ELYXYB and 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 ZTlido, GLOPERBA, ELYXYB and our product candidates. Our success depends in part on our ability to obtain and maintain patent protection in the United States for GLOPERBA, in the United States and Canada for ELYXYB, and in the United States and other countries with respect to ZTlido and 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 ZTlido, GLOPERBA, ELYXYB and 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 ZTlido, GLOPERBA, ELYXYB and 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 ("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 products or 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 ZTlido, GLOPERBA, ELYXYB and our product candidates, it could dissuade other companies from collaborating with us to develop product candidates, and threaten our ability to commercialize ZTlido, GLOPERBA, ELYXYB and 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.

Presently we have intellectual property rights, through acquisitions and licenses from third parties, related to ZTlido, SP-103 and GLOPERBA. Because our programs for ZTlido, GLOPERBA, ELYXYB, SP-103 and SP-104 may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our 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 products, 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 former employees (including former employees of our licensors), 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 products, 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 ZTlido, GLOPERBA, ELYXYB and our product candidates. If ZTlido, GLOPERBA, ELYXYB or any of our 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 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 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 products 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 products. Further, we may incorrectly determine that our technologies, products, 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 products or 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. For example, on June 22, 2022, we filed a complaint against Aveva and Apotex in the U.S. District Court for the Southern District of Florida alleging infringement of certain Orange Book patents covering ZTlido. See the section of this Annual Report on Form 10-K titled "*Business — Legal Proceedings*" for additional information regarding such proceedings. 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, such as ZTlido, GLOPERBA and ELYXYB, 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 mark "ZTlido," "SCILEX," "ELYXYB," and "RESPONSIBLE BY DESIGN," and we have filed trademark applications for the marks "SEMNUR PHARMACEUTICALS," "SCILEX BIO," and "SEMDEXA" in the United States. We also have trademark registrations for ZTlido in the UK and Greece and we have a pending trademark application for ZTlido in China. In China, we were involved in an ongoing dispute regarding third-party trademarks for ZTlido filed in the name of 秦皇島恆駿商貿有限公司 (Qinhuangdao Hengjun Trading Co., Ltd.). The China National Intellectual Property Administration issued a decision in our favor in February 2025, which has now become final. 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

ZTlido, GLOPERBA, ELYXYB and 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 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 ("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 ZTlido, GLOPERBA, ELYXYB and 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 require all our 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, current or former 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. For example, on March 12, 2021, we filed the Former Employee Action, as described under the section titled "*Legal Proceedings*" of this Annual Report on Form 10-K. 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.

Certain of our employees, consultants or advisors 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 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 ZTlido, GLOPERBA, ELYXYB and 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 ZTlido, GLOPERBA, ELYXYB and 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 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 ZTlido, GLOPERBA, ELYXYB or any of our 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 product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that the development and/or commercialization of ZTlido, GLOPERBA, ELYXYB or our 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 ZTlido, GLOPERBA, ELYXYB or our 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 ZTlido, GLOPERBA, ELYXYB or our 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 ZTlido, GLOPERBA, ELYXYB or any of our 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 further commercialize ZTlido, GLOPERBA and ELYXYB, or develop and commercialize one or more of our product candidates. For example, Takeda filed the GLOPERBA Patent Litigation against us and Scilex Pharma on November 6, 2023, alleging that our filing with the FDA of an application for approval of a proposed revision to the product label for our GLOPERBA product infringed the Colcrys Patents. Takeda sought an order that the effective date of any FDA approval of our labeling revision be no earlier than the expiration date of the Colcrys Patents, and such further and other relief as the court may deem appropriate. On March 7, 2024, we entered into a Settlement Agreement (the "Settlement Agreement") with Takeda to resolve the action and entered into a license agreement with Takeda pursuant to which Takeda granted a non-exclusive license to us and our affiliates of certain patents owned by Takeda. The Settlement Agreement was subject to review by the Federal Trade Commission and the U.S. Department of Justice, neither of which objected during the review period. After the expiration of the review period, the U.S. District Court for the District of Delaware entered a final consent judgment on May 3, 2024. See the section of this Annual Report on Form 10-K titled "*Business – Legal Proceedings*" for additional information regarding such proceedings. 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, cease marketing ZTlido, GLOPERBA or ELYXYB, or developing our product candidates, limit our uses, pay royalties or redesign our infringing 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 ZTlido, GLOPERBA or ELYXYB or our 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 further commercialize ZTlido, GLOPERBA or ELYXYB, or develop and commercialize one or more of our product candidates, which could harm our business, financial condition and results of operations significantly.

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 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 European Union. 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 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.

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 employees, we 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 ZTlido, GLOPERBA, ELYXYB and all of our 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 ZTlido, GLOPERBA, ELYXYB or our 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 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 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. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, and inventions agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we 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 our products and product candidates, 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 ZTlido, GLOPERBA, ELYXYB or 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 PTA. 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 ZTlido, GLOPERBA, ELYXYB and 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 ZTlido, GLOPERBA, ELYXYB and 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 ZTlido, GLOPERBA, ELYXYB or 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 SEMDEXA, we believed that we had sufficient data to support the safety and efficacy of SEMDEXA, 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 SEMDEXA. In the Type C meeting, the FDA indicated that it disagreed with us that the clinical data we had collected was sufficient to support the safety and efficacy of SEMDEXA. The FDA provided guidance regarding expectations for the additional confirmatory trial needed prior to a 505(b)(2) NDA filing and the circumstances under which one adequate and well-controlled trial would be sufficient for product registration. In February 2024, we had a Type D meeting with the FDA to preview a newly designed trial, in order to reduce the potential need for any other additional trials prior to a 505(b)(2) NDA filing. During the Type D meeting, the FDA provided further guidance with respect to efficacy requirements and expectations on the size of safety database needed to help best position us to be able to satisfy the requirements for a 505(b)(2) pathway approval. 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 a 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 candidates 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 candidates;
- 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 authorities 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 candidates, which would significantly harm our business, financial condition and results of operations. In addition, regulatory authorities may approve any of our product candidates for fewer or more limited indications

than we request, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have limited experience submitting applications for marketing authorization to the FDA, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if our clinical trials are successful. With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. Furthermore, the U.S. Supreme Court's June 2024 decision in Loper Bright Enterprises v. Raimondo, which overturned the long-standing Chevron doctrine that required courts to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes, could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. The Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rule-making process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

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

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates 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 candidates SEMDEXA, SP-103 and SP-104, we may seek FDA approval through the Section 505(b)(2) regulatory pathway. The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act (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 candidates 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 FDA accepts our plan to pursue the Section 505(b)(2) regulatory pathway, we cannot assure that our product candidates 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. 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 candidates 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 candidates. 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.

Certain manufacturers in the market in which we compete distribute certain products without completing the FDA approval process. For example, we believe certain lidocaine topical patches, plaster or poultice products marketed OTC and without FDA approval, require approval and compete inappropriately with ZTlido. In December 2018, we filed a citizen's petition asking the FDA to clarify its requirements and take enforcement action against such products. Furthermore, we believe the labeling and marketing of certain OTC lidocaine patches products are false and deceptive, which could cause significant damages to our business and a diminution of goodwill in our intellectual property. In addition, on March 7, 2020, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") was signed into law, which included statutory provisions reforming FDA's mechanisms for regulating OTC drugs. Under the CARES Act, the FDA considers a drug to be generally recognized as safe and effective ("GRASE") if it meets certain requirements, including items such as the active ingredient, indication for use, dosage, route of administration, and labeling set forth in the OTC monograph and related rulemakings. Historically, the FDA was required to establish, revise, and amend an OTC monograph by notice-and-comment rulemaking, which was lengthy and resource-intensive. The CARES Act replaces the rulemaking process with a final administrative order process. Administrative orders may be initiated by the FDA or at the request of a drug manufacturer or any other person. After a period for public comment on the administrative order, the FDA is able to issue a final administrative order, rather than a regulation, permitting the drug to be marketed over the counter. In 2023, the FDA has posted a final administrative order for external analgesic drug products for OTC human use. As this process is much more streamlined and less burdensome, this may benefit the manufacturers of lidocaine topical patches to obtain GRASE status from the FDA and thereby legally market these products over-the-counter and compete with ZTlido.

The FDA ultimately denied our citizen's petition in light of the new administrative order process under the CARES Act for considering OTC drug products. In February 2021, we filed a complaint against Sanofi and Hisamitsu, certain manufacturers of OTC lidocaine

patches, to seek an award of damages and the entry of injunctive relief enjoining further dissemination of false and deceptive advertisement concerning claims about their lidocaine patches. On January 26 and February 2, 2024, Scilex Pharma entered into two separate settlement agreements and mutual releases with the two manufacturers that resolve the Action. The terms of those agreements are confidential.

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 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 our product candidates 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 SEMDEXA for the treatment of sciatica and SP-103 for the treatment of chronic neck pain. Even though SEMDEXA and SP-103 have 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 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, 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 new administration recently announced plans to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. 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.

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 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 CCPA, which went into effect on January 1, 2020, created new individual privacy rights for California consumers and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA has been amended by the CPRA, which largely took effect on January 1, 2023. The CPRA also created a new state agency, the CPPA, vested with authority to implement and, along with the California Attorney General, enforce the CCPA. Further, Washington's My Health My Data Act, taking effect July 1, 2024, imposes requirements specific to consumer health data. Several other states have enacted or are considering similar state consumer privacy laws. 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.

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.

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 may be impacted by actions of the new U.S. administration, including executive orders, policies, new legislation and judicial decisions.

The impact of the new U.S. administration is currently unknown. However, actions of the administration may cause us to change our business operations, with an unknown impact to our stakeholders, including patients, healthcare providers and employees. Failure to comply with new administration actions could expose us to litigation or other government actions. There can be no assurance that our compliance with new administration actions will provide sufficient mitigation.

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

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

We are exposed to the risk of fraud, illegal activity or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by employees could include intentional, reckless and/or negligent conduct that fails to comply with the laws and regulations of the FDA, EU Member States, EMA and other similar foreign regulatory bodies, provide true, complete and accurate information to the FDA, EMA and other similar foreign regulatory bodies, comply with manufacturing standards we have established, comply with federal and state health-care fraud and abuse laws and regulations, comply with laws and regulations, including, but not limited to the FCPA and internal policies restricting payments to government agencies and representatives, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission or contracting, customer incentive programs and other business arrangements. Misconduct by employees, independent contractors, consultants, commercial partners and vendors could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our employees, independent contractors, consultants, commercial partners and vendors, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations, FDA debarment, exclusion from government-funded healthcare programs or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition and results of operations, including the imposition of significant fines or other sanctions and serious harm to our reputation.

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

Our current and future arrangements with healthcare professionals, clinical sites and clinical investigators, consultants, customers, patient organizations and third-party payors may subject us to various federal and state fraud and abuse laws, including, without

limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our current activities with clinical study investigators and research subjects, as well as our current and future sales, marketing, patient assistance or advocacy and education programs. In addition, we may be subject to physician payment transparency laws and patient privacy regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual, or the furnishing, recommending, or arranging for an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs — a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or special intent to violate the statute in order to have committed a violation; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- federal civil and criminal false claims laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used a false statement material to a false or fraudulent claim, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. The False Claims Act has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, 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 Department of Veterans Affairs ("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 ("HRSA"), the VA, or by the Office of Inspector General ("OIG") or Department of Justice ("DOJ"), 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 ZTlido, GLOPERBA, ELYXYB, or our 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 ZTlido, GLOPERBA, ELYXYB, and 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 products, and 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 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 or 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 ZTlido, GLOPERBA, ELYXYB, or 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 candidates' 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 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. Healthcare reform measures like the ACA may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors.

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of, on average, 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through May 31, 2022, due to the COVID-19 pandemic. The law provides for 1% Medicare sequestration in the second quarter of 2022 and allows the full 2% sequestration thereafter until 2030. To offset the temporary suspension during the COVID-19 pandemic, in 2030, the sequestration will be 2.25% for the first half of the year, and 3% in the second half of the year. The American Taxpayer Relief Act of 2012 further reduced Medicare payments

to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs, as addressed further in the risk factor below titled "*If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs applicable to our product or product candidates, if approved, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and future prospects*." 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 ZTlido, GLOPERBA, ELYXYB and our product candidates, 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 ZTlido, GLOPERBA, ELYXYB and our product candidates, 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, ZTlido, GLOPERBA and/or ELYXYB may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs applicable to our product or product candidates, if approved, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and future prospects.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies and the courts. Such interpretation can change and evolve over time. In the case of Medicaid pricing data, if a manufacturer becomes aware that its reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, the manufacturer is obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program and could result in an overage or underage in rebate liability for past quarters. Price recalculations also may affect the ceiling price at which a manufacturer is required to offer its products under the 340B program.

A failure to comply with reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively affect financial results. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes under the ACA to the Medicaid Drug Rebate Program. The final regulation has increased and will continue to increase costs and the complexity of compliance, has been and will continue to be time-consuming to implement, and could have a material adverse effect on the results of operations, particularly if CMS challenges the approach a manufacturer has taken in the implementation of the final regulation. Other regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program may have a similar impact. In addition, potential policy changes by the new administration may introduce additional uncertainty for our business, including changes to the level of scrutiny applied by the Health Resources and Services Administration ("HRSA") to enforce non-compliance with the 340B program, new price restrictions on products we sell to Medicaid, Medicare or other government purchasers, or other regulatory changes impacting reimbursement or competitive dynamics in multisource markets. Any such policy shifts could significantly impact our business and operations.

Manufacturers have obligations to report the average sales price for certain of drugs to the Medicare program as a part of the agreement to participate in the Medicaid Drug Rebate program. For calendar quarters beginning January 1, 2022, manufacturers are required to report the average sales price for certain drugs under the Medicare program regardless of whether they participate in the Medicaid Drug Rebate program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for products and the resulting Medicare payment rate, and could negatively affect results of operations. Starting in 2023, manufacturers must pay refunds to Medicare for single source drugs or biologics, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages, for units of discarded drug reimbursed by Medicare Part B in excess of 10% of total allowed charges under Medicare Part B for that drug. Manufacturers that fail to pay refunds could be subject to civil monetary penalties of 125% of the refund amount. Congress further could enact a Medicare Part B inflation rebate, under which manufacturers would owe additional rebates if the average sales price of a drug were to increase faster than the pace of inflation.

HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. Implementation of this regulation has affected manufacturer obligations and potential liability under the 340B program. Manufacturers are also required to report the 340B ceiling prices for covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that a manufacturer has violated the requirements of the program or the regulation could negatively affect financial results. Moreover, under a final regulation effective January 13, 2021, HRSA newly established an administrative dispute resolution ("ADR") process for claims by covered entities that a manufacturer has engaged in overcharging, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that can be appealed to a federal court. An ADR proceeding could subject a manufacturer to onerous procedural requirements and could result in additional liability. Further, any additional future changes to the definition of average manufacturer price and the Medicaid rebate amount under the ACA or otherwise could affect our 340B ceiling price calculations and negatively affect results of operations. In recent years, two U.S. Courts of Appeals for the Third Circuit and District of Columbia Circuits (the "Third Circuit" and "D.C. Circuit," respectively) have ruled that, under Section 340B, manufacturers are not required to provide the discounted drugs to an unlimited number of contract pharmacies, but can impose some contractual limitations on how products may be distributed. The Third Circuit also upheld the ADR rules. One other case is pending in the U.S. Court of Appeals for the Seventh Circuit. Various states have also enacted laws prohibiting manufacturers from placing conditions on covered entities' use of contract pharmacies. There is ongoing litigation over these state laws.

Civil monetary penalties can be applied if a manufacturer (i) is found to have knowingly submitted any false price or product information to the government, (ii) is found to have made a misrepresentation in the reporting of its average sales price, (iii) fails to submit the required price data on a timely basis, or (iv) is found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also decide to terminate the Medicaid Drug Rebate Agreement, or HRSA, or to terminate the 340B program participation agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for the manufacturer's covered outpatient drugs.

In addition, manufacturers are required to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. Congress could enact legislation that sunsets this discount program and replaces it with a new manufacturer discount program. Under either program, civil monetary penalties could be applied if a manufacturer fails to provide these discounts in the amount of 125% of the discount that was due. Furthermore, the Inflation Reduction Act of 2022 (the "IRA"), PL 117-169, seeks to limit manufacturers' price increases for drugs reimbursed by Medicare, to not more than the rate of inflation, at least where those increases would otherwise affect payments under Medicare. Under the provisions, beginning in October 2022, if a manufacturer increases the price of a drug reimbursed under Medicare by more than the rate of inflation (as measured by the consumer price index), the manufacturer must pay rebates to the federal government, equal to the amount by which the increase exceeds the rate of inflation in the relevant period.

Congress could also enact additional changes that affect our overall rebate liability and the information we report to the government as part of price reporting calculations. The IRA also requires the U.S. Department of Health and Human Services ("HHS") to negotiate prices for a limited number of single-source brand-name drugs or biologics without generic or biosimilar competitors that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). The number of drugs affected is limited to ten Part D drugs for 2026, another fifteen Part D drugs for 2027, another fifteen Part D and Part B drugs for 2028, and another twenty Part D and Part B drugs for 2029 and later years. On August 29, 2023, HHS announced the list of the ten drugs for which negotiations will occur. Drugs that are less than 9 years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval or licensure date are excluded from the negotiation process. Small biotech drugs, defined as those which account for 1% or less of Part D or Part B spending and account for 80% or more of spending under each part on that manufacturer's drugs, are also excluded until 2029. CMS has issued initial guidance on the implementation of the provisions.

Pursuant to applicable law, knowing provision of false information in connection with price reporting or contract-based requirements under the VA Federal Supply Schedule and/or Tricare programs can subject a manufacturer to civil monetary penalties. These programs and contract-based obligations also contain extensive disclosure and certification requirements. If a manufacturer overcharges the government in connection with its arrangements with Federal Supply Schedule or Tricare, the manufacturer may be required to refund the difference to the government. Failure to make necessary disclosures or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and/or response to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and future prospects.

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 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., European Union 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 Sorrento

Sorrento previously supported many of our important corporate functions. Accordingly, our historical 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 Sorrento, and we have and will continue to incur incremental costs as a stand-alone public company.

We have completed the process of replicating and replacing certain functions, systems and infrastructure previously provided by Sorrento (our former controlling stockholder) prior to and subsequent to the Business Combination. We currently have no shared services or other intercompany arrangements. We have made and continue to make investments and hire additional employees to operate without access to Sorrento's operational and administrative infrastructure. These functions, systems and infrastructure are costly to implement.

Historically, Sorrento performed or supported many important corporate functions for us. Our consolidated financial statements for the fiscal years ended December 31, 2023, 2022 and 2021 reflect charges for these services on an allocation basis. As a result, such consolidated 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 Sorrento during such periods. We have incurred significant costs to replace the services and resources that are no longer provided by Sorrento. We are also incurring 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 Sorrento. As we now operate separately from Sorrento, if we are not able to maintain adequate systems and business functions, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline.

Risks Related to Ownership of our Common Stock

The market price of our Common Stock may fluctuate significantly, and investors in our Common Stock may lose all or a part of their investment.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, from November 11, 2022 (the first trading day following the closing of the Business Combination) to March 25, 2025, our closing stock price ranged from $0.23 to $14.80. The market price of our Common Stock may fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our ability to commercialize ZTlido, GLOPERBA, ELYXYB or our product candidates, if approved;
- legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for ZTlido, GLOPERBA, ELYXYB or our product candidates, government investigations and the results of any proceedings or lawsuits, including, but not limited to, patent or stockholder litigation;
- extension of the lock-up restriction by court order in the Chapter 11 Cases on the 76,000,000 shares of our Common Stock that were previously distributed by Sorrento to Sorrento equityholders as a dividend;
- announcements of the introduction of new products by our company and our competitors;
- issuances of debt or equity securities;
- market conditions and trends in the pharmaceutical and biotechnology sectors;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- trading volume of our Common Stock;
- ineffectiveness of our internal controls; and
- other events or factors, many of which are beyond our control.

See the risk factor below titled "*If our operations and performance do not meet the expectations of investors or securities analysts, the market price of our securities may decline*" for more factors affecting the trading price of our securities. 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.

The equity markets in general have recently experienced extreme price and volume fluctuations. Continued market fluctuations could result in extreme volatility in the price of our Common Stock. Further, price volatility of our Common Stock might worsen if the trading volume of our Common Stock is low. Although we have had periods of high-volume daily trading in our Common Stock, generally our stock is thinly traded. As a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of those shares in either direction. If an active trading market for our Common Stock does not continue, the price of our Common Stock may be more volatile and it may be more difficult and time consuming to complete a transaction in our Common Stock, which could have an adverse effect on the realized price of our Common Stock. In addition, an adverse development in the market price for our Common Stock could negatively affect our ability to issue new equity to fund our activities.

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 ZTlido, GLOPERBA, ELYXYB or our product candidates, if approved;
- the status and cost of our marketing commitments for ZTlido, GLOPERBA, ELYXYB and our product candidates;
- announcements regarding results of any clinical trials relating to our product candidates;
- unanticipated serious safety concerns related to the use of ZTlido, GLOPERBA, ELYXYB or any of our product candidates;
- adverse regulatory decisions;
- changes in laws or regulations applicable to ZTlido, GLOPERBA, ELYXYB or our product candidates, 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 ZTlido, GLOPERBA, ELYXYB or our product candidates, 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 our competitors, including changes in market valuations of similar companies;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- changes in financial estimates by the Company or by any securities analysts who might cover our stock;
- fluctuation of the market values of any of our potential strategic investments;
- issuances of debt or equity securities;
- compliance with our contractual obligations;
- sales of our Common Stock by us or our stockholders in the future;
- trading volume of our Common Stock;
- ineffectiveness of our internal controls;
- publication of research reports about the Company or its industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- general political and economic conditions, including the wars in Ukraine and Israel;
- 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 our Common Stock might worsen if the trading volume of our 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 the Company, could cause us to incur substantial costs and divert management's attention and resources from our business. The realization of any of the above risks or any of a broad range of other risks, including those described in these "*Risk Factors*", could have a dramatic and material adverse impact on the market price of our Common Stock.

We have not paid cash dividends in the past and we do not expect to pay cash dividends in the foreseeable future and there is no assurance that we will complete the previously declared stock dividend. Any return on investment may be limited to the capital appreciation, if any, of our Common Stock.

We have not paid cash dividends on our Common Stock and we do not anticipate paying cash dividends on our Common Stock 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 Scilex. 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 cash 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.

In October 2024, the Board declared a stock dividend (the "Dividend") consisting of an aggregate of 5,000,000 shares (the "Dividend Stock") of Series 1 Mandatory Exchangeable Preferred Stock, par value $0.0001 per share, to record holders of certain of our securities as of the close of business on November 7, 2024 (which date was subsequently changed to April 11, 2025) (the "Record Date"). Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Mandatory Exchangeable Preferred Stock (the "Certificate of Designation") previously filed with the Secretary of State of the State of Delaware, designating the Dividend Stock, if the Dividend Stock is distributed, the holders of thereof may become entitled to a pro rata portion of the number of shares that represents the lesser of (a) 10% of the shares of common stock, par value $0.00001 per share (the "Semnur Common Stock"), of Semnur (or such other securities into which or for which such stock may be exchanged or converted), held by us as of immediately prior to the Effective Date (as defined in the Semnur Business Combination Agreement) (taking into account any adjustment for any stock dividend, stock split, reverse stock split or similar transaction) and (b) that number of shares of Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) equal to $200,000,000 divided by the closing price of such Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) on any national securities exchange on which such shares are listed on the date that is 10 trading days prior to the Determination Date (as defined below), which shares shall be paid from the shares of Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) held by us as of immediately prior to the Effective Time (taking into account any adjustment for any stock dividend, stock split, reverse stock split or similar transaction). For purposes of the Certificate of Designation, (a) "Effective Time" means the effective time of the Business Combination (as defined below) as determined under the terms of the Semnur Business Combination Agreement, (b) "Determination Date" means, if the Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) is listed for, and trading on, any national securities exchange, the date that is 15 trading days following the Registration Date, (c) "Registration Date" means the earlier of (i) the Effective Time, at which time the shares of Semnur Common Stock (or such other securities into which or for which such stock has been exchanged or converted) are registered under the Exchange Act and (ii) the time at which the Registration Statement is declared effective by the SEC and (d) "Registration Statement" means a registration statement, whether under the Exchange Act or the Securities Act, that is filed by Semnur or any successor thereto or affiliate thereof with respect to the registration of the Semnur Common Stock or any securities into which or for which such stock may be exchanged or converted. The Board has the right to change the Record Date and the right to revoke the Dividend at any time prior to the payment date therefor. There can be no assurance that the Board will not revoke the Dividend or that, even if such Dividend is paid, the conditions for the mandatory exchange set forth in the Certificate of Designations will ever occur (including that the Registration Date shall have occurred on or before 11:59 p.m. Eastern time on October 28, 2025).

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

On December 30, 2022, Sorrento announced that its board of directors authorized Sorrento to dividend to Sorrento equity holders of record as of January 9, 2023 an aggregate of 76,000,000 shares of our Common Stock that were held by Sorrento (the "Dividend Shares"). As of the date on which this Annual Report on Form 10-K was filed with the SEC, such shares are subject to a lock-up restriction prohibiting the sale, pledge or other transfer until April 14, 2025.

As the restrictions on resale end, the market price of shares of our Common Stock could drop significantly if the holders of these shares of Common Stock sell them or are perceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds through future offerings of our shares of Common Stock or other securities.

Our operating results may fluctuate significantly.

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

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

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

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

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

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

The trading market for our Common Stock will be influenced by the research and reports that industry or securities analysts publish about the Company or our business. We may never obtain research coverage by securities and industry analysts. Since we became public through a merger, securities analysts of major brokerage firms may not provide coverage of the Company since there is no incentive to brokerage firms to recommend the purchase of our Common Stock. If no or few securities or industry analysts commence coverage of the Company, the trading price for our capital stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover it issues an adverse opinion regarding the Company, 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 the Company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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 our Common Stock or, alternatively, may have dividend, liquidation or other preferences to our Common Stock. The issuance of additional equity securities, whether upon conversion of the Tranche B Notes into Common Stock or otherwise, will dilute the holdings of existing stockholders and may reduce the share price of our Common Stock.

Pursuant to the Scilex Holding Company 2022 Equity Incentive Plan (the "Equity Incentive Plan"), which became effective on November 9, 2022, we are authorized to grant equity awards to our employees, directors and consultants. In addition, pursuant to the Scilex Holding Company 2022 Employee Stock Purchase Plan (the "ESPP"), which became effective on November 9, 2022, we are authorized to sell shares to our employees. Further, pursuant to the Scilex Holding Company 2023 Inducement Plan (the "Inducement Plan"), which was adopted on January 17, 2023, we are authorized to grant equity awards to individuals as a material inducement to join the Company. A total of 24,426,545 shares of Common Stock (which number of shares accounts for the automatic annual increase on January 1, 2025), 5,970,115 shares of Common Stock (which number of shares accounts for the annual increase on January 1, 2025) and 1,400,000 shares of our Common Stock have been reserved for future issuance under the Equity Incentive Plan, the ESPP and the Inducement Plan, respectively. In addition, the Equity Incentive Plan and ESPP provide for annual automatic increases in the number of shares reserved thereunder, in each case, beginning on January 1, 2023. As a result of such annual increases, our stockholders may experience additional dilution, which could cause the price of our Common Stock to fall.

Pursuant to the Amended and Restated Registration Rights Agreement, dated as of November 10, 2022, by and among us, Vickers Venture Fund VI Pte Ltd, Vickers Venture Fund VI (Plan) Pte Ltd, Sorrento Therapeutics, Inc. and certain security holders set forth on the signature pages thereto (the "Registration Rights Agreement"), which was entered into in connection with the Business Combination, certain stockholders of Vickers and Legacy Scilex 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. We have filed a registration statement on Form S-1 (File No. 333-268603) which was initially declared effective by the SEC on December 27, 2022, in order to satisfy these obligations. 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 our 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 ZTlido, GLOPERBA, ELYXYB or our product candidates, 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 candidates.

Our failure to meet the continued listing standards of Nasdaq could result in a delisting of our Common Stock.

On November 1, 2024, we received a letter from Nasdaq notifying us that, because the closing bid price for our shares of Common Stock, has been below $1.00 per share for 30 consecutive business days, we no longer comply with the minimum bid price requirement for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities to maintain a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"), and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive business days.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial compliance period of 180 calendar days, or until April 30, 2025, to regain compliance with the Minimum Bid Price Requirement. If we do not regain compliance with the Minimum Bid Price Requirement by April 30, 2025, we may be afforded a second 180 calendar day grace period. To qualify, we would be required to meet the continued listing requirements for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement. In addition, we would be required to provide written notice of our intention to cure the minimum bid price deficiency during this second 180-day compliance period by effecting a reverse stock split, if necessary.

If it appears to the Staff of Nasdaq that we will not be able to cure the deficiency in connection with the Minimum Bid Price Requirement, or if we are otherwise not eligible for the additional compliance period, and we do not regain compliance by April 30, 2025 for the Minimum Bid Price Requirement, Nasdaq will provide written notification to us that our shares of Common Stock are subject to delisting. At that time, we may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules.

If Nasdaq determines to delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- causing our shares of Common Stock to be transferred to a more limited market than Nasdaq, which could affect the market price, trading volume, liquidity and resale price of such shares;
- causing an event of default under our existing debt instruments;
- reducing the number of investors, including institutional investors, willing to hold or acquire our Common Stock, which could negatively impact our ability to raise equity;
- decreasing the amount of news and analyst coverage relating to us;
- reducing the availability of information concerning the trading prices and volume of our Common Stock
- limiting our ability to issue additional securities, obtain additional financing or pursue strategic restructuring, refinancing or other transactions; and
- impacting our reputation and, as a consequence, our business and operations.

On November 21, 2024, we received a letter (the "Nasdaq Notice") from Nasdaq advising us that we were not in compliance with Nasdaq's continued listing requirements under the Nasdaq Listing Rule 5250(c)(1) (the "Listing Rule") as a result of our failure to file the Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Q3 Form 10-Q") in a timely manner. The Listing Rule requires listed companies to timely file all required periodic reports (the "Timely Reporting Requirement") with the SEC Under Nasdaq rules, we have 60 calendar days from receipt of the Nasdaq Notice, or until January 20, 2025, to submit a plan to regain compliance with the Listing Rule. If Nasdaq accepts our plan, then Nasdaq may grant an exception of up to 180 calendar days from the due date of the Q3 Form 10-Q, or until May 19, 2025, to regain compliance. We regained compliance with the Listing Rule by filing the Q3 Form 10-Q on January 17, 2025.

We and/or our directors and officers may be subject to litigation or other actions as a result of or relating to our internal investigation and our failure to timely file the Q3 Form 10-Q with the SEC and an unfavorable outcome with respect to such matters could harm our business, financial condition and results of operations.

As previously disclosed, the audit committee of the Board (the "Audit Committee") recently commenced an investigation with the assistance of independent counsel with respect to an evaluation of the following contracts: (i) the Commitment Side Letter entered into with FSF 33433 LLC (a copy of which was filed with the SEC as an exhibit to our Current Report on Form 8-K filed on June 12, 2024), (ii) a distribution agreement entered into with Endeavor Distribution LLC ("Endeavor") in June 2024, and (iii) the Satisfaction Agreement entered into with FSF 33433 LLC and Endeavor (a copy of which was filed with the SEC as an exhibit to our Current Report on Form 8-K filed on September 18, 2024). The investigation relates to the accounting treatment of such contracts and related matters.

Failure to comply with applicable laws or regulations, as interpreted and applied, or our reporting obligations with the SEC could have a material adverse effect on our reputation, the price of its securities and its business, financial condition and results of operations. We cannot predict the outcome of the above-referenced matters. Our management may be required to devote significant time and attention to these matters. An unfavorable outcome could have a material adverse impact on our financial position, results of operations or liquidity or the market for its securities, and could subject we and/or our directors and officers to litigation or other actions from third parties or regulatory bodies related to the above-referenced matters.

As a result of our failure to timely file the Q3 Form 10-Q, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise capital on terms favorable to us, in a timely manner or at all.

Form S-3 permits eligible issuers to conduct registered offerings using a short form registration statement that allows the issuer to incorporate by reference its past and future filings and reports made under the Exchange Act. In addition, Form S-3 enables eligible issuers to conduct primary offerings "off the shelf" under Rule 415 of the Securities Act. The shelf registration process, combined with the ability to forward incorporate information, allows issuers to avoid delays and interruptions in the offering process and to access the capital markets in a more expeditious and efficient manner than raising capital in a standard registered offering pursuant to a Registration Statement on Form S-1. The ability to register securities for resale may also be limited as a result of the loss of Form S-3 eligibility.

As a result of our failure to timely file the Q3 Form 10-Q, we are currently ineligible to file new short form registration statements on Form S-3, which may impair our ability to raise necessary capital to repay our debt obligations as they become due, pursue acquisition and development opportunities, and execute our business strategy. If we seek to access the capital markets through a registered offering during the period of time that we are unable to use a registration statement on Form S-3, we may experience delays in the offering

process due to SEC review of a registration statement on Form S-1, experience downward pressure on our share price given that we will have to disclose the offering prior to formal commencement, and incur increased offering and transaction costs. If we are unable to raise capital through a registered offering, we would be required to conduct financing transactions on a private placement basis, subject to pricing, size and other limitations for equity raises under Nasdaq rules, or seek other sources of capital, which are not guaranteed. The foregoing limitations on our financing approaches could impair our ability to raise capital on terms favorable to us, in a timely manner or at all, which could have a material adverse effect on our results of operations, liquidity and financial position.

Assuming we continue to timely file our required Exchange Act reports, the earliest we would regain the ability to use Form S-3 is February 1, 2026.

We have in the past and may in the future be subject to short selling strategies that may drive down the market price of our Common Stock.

Short sellers have in the past and may attempt in the future to drive down the market price of our Common Stock. Short selling is the practice of selling securities that the seller does not own but may have borrowed with the intention of buying identical securities back at a later date. The short seller hopes to profit from a decline in the value of the securities between the time the securities are borrowed and the time they are replaced. As it is in the short seller's best interests for the price of the stock to decline, many short sellers (sometimes known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by weblog ("blogging") have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market. Further, these short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the U.S. and they are not subject to certification requirements imposed by the SEC. Accordingly, the opinions they express may be based on distortions, omissions or fabrications. Companies that are subject to unfavorable allegations, even if untrue, may have to expend a significant amount of resources to investigate such allegations and/or defend themselves, including stockholder suits against the company that may be prompted by such allegations. We may in the future be the subject of stockholder suits that we believe were prompted by allegations made by short sellers.

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

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

The TCJA, as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing net operating loss ("NOL") carryforwards. The TCJA, as modified by the CARES Act, limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income (as calculated before taking the NOLs, and certain other tax attributes, into account) for taxable years beginning after December 31, 2020. In addition, NOLs arising in tax years ending after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. NOLs arising in tax years beginning after December 31, 2017 can be carried forward indefinitely. NOLs generated in tax years beginning before January 1, 2021 will not be subject to the taxable income limitation, and NOLs generated in tax years ending before January 1, 2018 will continue to have a two-year carryback and 20-year carryforward period. Deferred tax assets for NOLs will need to be measured at the applicable tax rate in effect when the NOL is expected to be utilized. The changes in the carryforward/carryback periods, as well as the new limitation on use of NOLs may significantly impact our ability to utilize our NOLs to offset taxable income in the future.

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

The preparation of consolidated 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 consolidated 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, revenue 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 our Common Stock.

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

The Restated Certificate of Incorporation of the Company (the "Certificate of Incorporation"), the Bylaws of the Company (the "Bylaws") and the General Corporation Law of the State of Delaware, as amended (the "DGCL"), contain provisions that could make it more difficult for a third party to acquire the Company, even if doing so might be beneficial to our stockholders. Among other things, these provisions include:

- allow our Board 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 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 our capital stock entitled to vote thereon, voting together as a single class;
- prohibit stockholder action by written consent;
- provide that special meetings may only be called by or at the direction of the Chairperson of the Board, the Board or the Chief Executive Officer;
- provide that any alteration, amendment or repeal, in whole or in part, of any provision of the Bylaws by our 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 our capital stock entitled to vote thereon, voting together as a single class; and
- establish advance notice requirements for nominations for elections to the Board 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 are governed by Section 203 of the DGCL, except that the restrictions on business combinations of Section 203 of the DGCL will not apply to Sorrento or its current or future Affiliates (as defined in the Certificate of Incorporation) regardless of its percentage ownership of our Common Stock. These provisions could discourage, delay or prevent a transaction involving a change in control of the 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 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 Certificate of Incorporation, the Bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of the Board 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 the Company. The existence of these provisions could negatively affect the price of our Common Stock and limit opportunities for a stockholder to realize value in a corporate transaction. For additional information regarding these and other provisions, refer to the description of our securities in the form filed as an exhibit to this Annual Report on Form 10-K. 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 Certificate of Incorporation 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 Certificate of Incorporation, 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 Certificate of Incorporation or the Bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of the Certificate of Incorporation 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 Certificate of Incorporation 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 Certificate of Incorporation 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 Certificate of Incorporation described above. Refer to the description of our securities in the form filed as an exhibit to this Annual Report on Form 10-K for additional information.

The forum selection provisions in the Certificate of Incorporation 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 initial public offering of 13,800,000 units of Vickers consummated on January 11, 2021 (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.

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.

We incur significant legal, accounting and other expenses that Legacy Scilex did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We are 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 need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating

expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for the Company to obtain directors' and officers' liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on the Board, 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 have implemented an enterprise resource planning ("ERP") system and will continue to invest in the 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 it to manage operations and track performance more effectively. However, an ERP system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using an ERP system could adversely affect our controls and harm our business, financial condition and results of operations, including our ability to forecast or make sales and collect our receivables. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention.

As a public company, we are 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 are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate 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 our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of our 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 previously identified material weaknesses in our internal control over financial reporting. If we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to timely and accurately report our financial results and such material weaknesses may result in a material misstatement of our financial statements.*" above for additional information regarding a previously identified material weakness. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources.

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

Comprehensive U.S. federal income tax reform could adversely affect the Company.

Changes to tax laws, which changes may have retroactive application, could adversely affect the Company 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, then-President Trump signed into law the CARES Act, which included certain changes in tax law (including to the TCJA) intended to stimulate the U.S. economy in light of the COVID-19 pandemic, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. On August 16, 2022, former President Biden signed the IRA into law, which contained certain tax measures, including a corporate alternative minimum tax of 15% on some large

corporations, an excise tax of 1% on certain corporate stock buy-backs, and an excise tax with respect to certain drug sales for failing to offer a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation.

Many provisions of the TCJA expire at the end of 2025 or are modified beginning in 2026. The U.S. Congress and the current administration have indicated that they intend to pursue legislation in 2025 to make permanent the 2017 TCJA provisions but there is no guarantee that this initiative will be successful. 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.

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

As of December 31, 2024, outstanding SPAC Warrants (as defined below) to purchase an aggregate of 6,958,309 shares of our Common Stock are exercisable in accordance with the terms of the Warrant Agreement (the "Warrant Agreement"), dated as of January 6, 2021, between Continental Stock Transfer & Trust Company, as warrant agent, and Vickers, governing those securities. The exercise price of these SPAC Warrants is $11.50 per share. "SPAC Warrants" means (i) the redeemable warrants that were included in the Units (each of which consisted of one Vickers ordinary share and one-half of one redeemable warrant) that entitle the holder of each whole warrant to purchase one Vickers ordinary share at a price of $11.50 per share (the "Public Warrants"), and (ii) the 6,840,000 warrants sold in a private placement to Vickers Venture Fund VI Pte Ltd and Vickers Venture Fund VI (Plan) Pte Ltd consummated on January 11, 2021 (of which 2,736,000 were subsequently forfeited and 3,104,000 were transferred to Sorrento, in each case in connection with the Business Combination) (the "Private Warrants").

As of December 31, 2024, (i) outstanding Penny Warrants to purchase an aggregate of 6,500,000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $0.01 per share, (ii) outstanding February 2024 BDO Firm Warrants to purchase an aggregate of 3,803,447 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $1.70 per share; (iii) outstanding February 2024 BDO Representative Warrants to purchase an aggregate of 470,588 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $2.125 per share; (iv) outstanding Deposit Warrant to purchase an aggregate of 3,250,000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $1.20 per share, (v) outstanding April 2024 RDO Common Warrants to purchase an aggregate of 15,000,000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $1.10 per share and (vi) outstanding April 2024 RDO Placement Agent Warrants to purchase an aggregate of 1,200,000 shares of our Common Stock are exercisable under the terms thereof, the exercise price of which is $1.25 per share.

On October 8, 2024, we issued the October 2024 Noteholder Warrants to purchase an aggregate of 7,500,000 shares of Common Stock, which are exercisable as of the date of this Annual Report on Form 10-K. On the same date, we also issued the October Placement Agent Warrants to purchase an aggregate of 3,669,724 shares of Common Stock, which will become exercisable 180 days following the date of issuance. The exercise price of both the October 2024 Noteholder Warrants and the October 2024 Placement Agent Warrants was initially $1.09 per share (which was automatically reduced to $1.04 per share of Common Stock subsequent to the December 2024 RDO in accordance with the terms of such warrants).

On December 13, 2024, we issued the December 2024 RDO Pre-Funded Warrants to purchase an aggregate of 2,401,132 shares of Common Stock, which have been fully exercised as of the date of this Annual Report on Form 10-K. On the same date, we also issued the December 2024 RDO Common Warrants to purchase an aggregate of 57,512,958 shares of Common Stock and the StockBlock Warrants to purchase an aggregate of 4,601,036 shares of Common Stock, which will become exercisable 180 days following the date of issuance. The exercise price of both the December 2024 RDO Common Warrants and the StockBlock Warrants is $0.649 per share and $0.7375 per share, respectively.

To the extent the SPAC Warrants, the Penny Warrants, the February 2024 BDO Firm Warrants, the February 2024 BDO Representative Warrants, the Deposit Warrant, the Fee Warrant, the April 2024 RDO Common Warrants, the April 2024 RDO Placement Agent Warrants, the October 2024 Noteholder Warrants, the October 2024 Placement Agent Warrants, the December 2024 RDO Common Warrants and/or the StockBlock Warrants (collectively, the "Warrants") are exercised, additional shares of our Common Stock will be issued, which will result in dilution to the holders of our 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 our Common Stock. With respect to the SPAC Warrants, there is no guarantee that the SPAC Warrants will ever be in the money prior to their expiration, and as such, the SPAC Warrants may expire worthless. See below risk factor, "*The SPAC Warrants may never be in the money, they may expire worthless and the terms of the SPAC Warrants may be amended in a manner adverse to a holder if holders of a majority of the then-outstanding SPAC Warrants approve of such amendment*."

The SPAC Warrants may never be in the money, they may expire worthless and the terms of the SPAC Warrants may be amended in a manner adverse to a holder if holders of a majority of the then-outstanding SPAC Warrants approve of such amendment. In addition, almost all of the other warrants to purchase shares of our Common Stock are out-of-the money and may also expire worthless.

As of December 31, 2024, the exercise price for our SPAC Warrants is $11.50 per share of Common Stock. On March 25, 2025, the closing price of our Common Stock on the Nasdaq Capital Market was $0.25. If the price of our shares of Common Stock remains below $11.50 per share, which is the exercise price of our SPAC Warrants, we believe our warrant holders will be unlikely to cash exercise their SPAC Warrants, resulting in little or no cash proceeds to us. There is no guarantee that our SPAC Warrants will be in the money prior to their expiration and, as such, our SPAC Warrants may expire worthless.

The SPAC Warrants were issued in registered form under the Warrant Agreement. The Warrant Agreement provides that the terms of the SPAC 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 SPAC Warrants to make any change that adversely affects the interests of the registered holders of SPAC Warrants. Accordingly, we may amend the terms of the SPAC Warrants in a manner adverse to a holder if holders of a majority of the then-outstanding SPAC Warrants approve of such amendment. Although our ability to amend the terms of the SPAC Warrants with the consent of majority of the then-outstanding SPAC Warrants is unlimited, examples of such amendments could be amendments to, among other things, increase the exercise price of the SPAC Warrants, convert the SPAC Warrants into cash, shorten the exercise period, or decrease the number of shares of our Common Stock purchasable upon exercise of a SPAC Warrant.

In addition, other than the SPAC Warrants discussed above and the Penny Warrants, as of December 31, 2024, we had other warrants to purchase shares of our Common Stock (with exercise prices ranging from $0.6490 to $2.125) issued and outstanding. As noted above, on March 25, 2025, the closing price of our Common Stock on the Nasdaq Capital Market was $0.25. If the price of our shares of Common Stock remains below the foregoing exercise prices of such other warrants, we believe the holders of such warrants will be unlikely to cash exercise such warrants, resulting in little or no cash proceeds to us. There is no guarantee that our other warrants will be in the money prior to their expiration and, as such, those other warrants may expire worthless.

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

We have the ability to redeem outstanding SPAC Warrants (other than Private Warrants still held by the initial purchasers thereof) at any time after they become exercisable and prior to their expiration, at a price of $0.01 per SPAC Warrant, provided that the closing price of our Common Stock equals or exceeds $18.00 per share (as adjusted for share subdivisions, share dividends, rights issuances, subdivisions, reorganizations, recapitalizations and the like) on each of the 20 trading days within any 30-trading-day period commencing after the SPAC Warrants become exercisable and ending on the third trading day prior to the date on which notice of redemption is given. If and when the SPAC Warrants become redeemable by us, 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 SPAC Warrants could force the holders thereof to: (i) exercise such SPAC Warrants and pay the exercise price therefor at a time when it may be disadvantageous for a holder to do so; (ii) sell such SPAC Warrants at the then-current market price when a holder might otherwise wish to hold such SPAC Warrants; or (iii) accept the nominal redemption price that, at the time the outstanding SPAC Warrants are called for redemption, is likely to be substantially less than the market value of such Warrants.

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

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, 2024. For more information, please see the risk factor disclosures included in Item 1A of this Annual Report on Form 10-K.

Item 2. Properties.

Our principal executive office is currently located in Palo Alto, California, and consists of approximately 12,500 square feet of leased office space. The lease term expires in September 2027. We also sublease office space in San Diego, California. 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.

The information set forth under the section titled "*Business — Legal Proceedings*" in Item 1, "Business" is incorporated herein by reference.

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 Public Warrants are currently listed on Nasdaq under the symbols "SCLX" and "SCLXW," respectively.

Holders

As of March 25, 2025, there were 315 holders of record of our Common Stock and two holders 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.

Dividends

Except as set forth below, we have never declared or paid any dividends 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. It is the present intention of our Board to retain all earnings, if any, for use in our business operations and, accordingly, our Board does not anticipate declaring any dividends in the foreseeable future.

As previously disclosed on October 27, 2024, our Board declared a stock dividend (the "Dividend") consisting of an aggregate of 5,000,000 shares (the "Dividend Stock") of Series 1 Mandatory Exchangeable Preferred Stock, par value $0.0001 per share, to record holders of the following Company securities as of the close of business on November 7, 2024 (which date was subsequently changed to April 11, 2025) (the "Record Date"): (i) our Common Stock (such record holders, the "Record Common Holders"), (ii) certain warrants to purchase Common Stock that have not been exercised prior to the Record Date (and which have the right to participate in the Dividend pursuant to the terms of their respective warrants, other than, for the avoidance of doubt any warrants to purchase Common Stock with an exercise price of $11.50 per share, and any other warrants that by their terms have not vested and are therefore not entitled to participate in the Dividend) (such warrants, the "Participating Warrants" and such record holders, the "Record Warrant Holders"), (iii) the Tranche B Notes issued by us in October 2024 (such notes, the "Participating Notes" and such record holders, the "Record Note Holders"), and (iv) our Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock" and such record holder, the "Record Preferred Holder" and together with the Record Common Holders, the Record Warrant Holders, and the Record Note Holders, the "Record Holders"). Subject to the Board's right to change the Record Date, the Dividend (unless otherwise determined by the Board) shall be paid on such date to be determined by subsequent resolutions of the Board, which payment date shall be within 60 days following the Record Date (i.e., by June 10, 2025) (such date as determined by the Board, the "Payment Date") and shall be apportioned on a pro rata basis among the Record Holders in accordance with each Record Holder's ownership percentage of our common stock (assuming the full exercise of all Participating Warrants to purchase common stock held by the Record Warrant Holders, the conversion of all Participating Notes held by the Record Note Holders and deemed conversion of all outstanding Series A Preferred Stock held by the Record Preferred Holder) as of the Record Date as set forth in the records of our transfer agent (with respect to the Record Common Holders and Record Preferred Holder) and ours (with respect to the Record Warrant Holders and the Record Note Holders) as of the Record Date. As of the date of this Annual Report on Form 10-K, the Board has not yet set a Payment Date for the Dividend and retains the right to revoke the Dividend and change the Record Date.

Should we decide in the future to declare a cash dividend or any other dividend, 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. Further, our ability to pay dividends may be limited by covenants of any existing outstanding indebtedness 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

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

	Total number of warrants purchased	Average price paid per warrant
September 1 – September 30, 2024	4,000,000	$0.075(1)
Total	4,000,000	$0.075

(1) As previously disclosed on September 23, 2024, we entered into a letter agreement with Oramed (the "Oramed Letter Agreement"), dated as of September 20, 2024, pursuant to which we agreed to, among other things, pay Oramed $300,000 to repurchase 4,000,000 SPAC Warrants held by Oramed.

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 on Form 10-K. 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 on Form 10-K, including those set forth in the sections of this Annual Report on Form 10-K titled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid 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. We launched our first commercial product in October 2018, in-licensed two commercial products in 2022 and 2023, and are developing our late-stage pipeline. Our commercial product, ZTlido (lidocaine topical system) 1.8% ("ZTlido"), is a prescription lidocaine topical product approved by the U.S. Food and Drug Administration ("FDA") for the relief of neuropathic pain associated with post-herpetic neuralgia ("PHN"), which is a form of post-shingles nerve pain. ZTlido possesses novel delivery and adhesion technology designed to address many of the limitations of current prescription lidocaine patches by providing significantly improved adhesion and continuous pain relief throughout the 12-hour administration period. We market ZTlido through a dedicated sales force of over 70 people, targeting 10,000 primary care physicians, pain specialists, neurologists and palliative care physicians who we believe treat the majority of PHN patients. We in-licensed the exclusive right to commercialize GLOPERBA (colchicine USP) oral solution ("GLOPERBA"), an FDA-approved prophylactic treatment for painful gout flares in adults, in the United States of America ("U.S." or the "United States"). We launched GLOPERBA in June 2024 and believe we are well-positioned to market and distribute the product. In February 2023, we acquired the rights to patents, trademarks, regulatory approvals and other rights related to ELYXYB (celecoxib oral solution) ("ELYXYB") and its commercialization in the U.S. and Canada. In April 2023, we launched ELYXYB in the U.S. for the treatment of acute migraine, with or without aura, in adults. We filed a New Drug Submission ("NDS") to Health Canada's Pharmaceutical Drugs Directorate, Bureau of Cardiology, Allergy and Neurological Sciences for the approval of ELYXYB for acute treatment of migraine with or without aura in Canada.

Our development pipeline consists of three product candidates, (i) SP-102 ("SEMDEXA") (10 mg, dexamethasone sodium phosphate viscous gel), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain or sciatica with completed Phase 3 study, (ii) SP-103 (lidocaine topical system) 5.4% ("SP-103"), a Phase 2, next-generation, triple-strength formulation of ZTlido, for the treatment of chronic neck pain associated with muscle spasms and for which we have completed a Phase 2 trial in acute low back pain ("LBP") in the third quarter of 2023, and (iii) SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) ("SP-104"), a novel low-dose delayed-release naltrexone hydrochloride formulation for treatment of fibromyalgia, for which Phase 1 trials were completed in the second quarter of 2022.

SEMDEXA has been granted fast track designation by the FDA and, if approved, could become the first FDA-approved alternative to off-label epidural steroid injections, which are administered over 12 million times annually in the United States. We have completed a pivotal Phase 3 study with final results received in March 2022, which results reflected achievement of primary and secondary endpoints. SP-103 has also been granted fast track designation by the FDA for LBP. We received our SP-103 Phase 2 top-line results in August 2023 and the trial achieved its objectives characterizing safety, tolerability and preliminary efficacy of SP-103 in acute LBP associated with muscle spasms. SP-103 was safe and well tolerated. Increase of lidocaine load in topical system by three times, compared with approved ZTlido, 5.4% vs. 1.8%, did not result in signs of systemic toxicity or increased application site reactions with daily applications over one month treatment. We will continue to analyze the SP-103 Phase 2 trial data along with an investigator study of ZTlido in patients with neck pain completed in the second half of 2023, which also has shown promising top-line efficacy and safety results. SP-103, if approved, could become the first FDA-approved lidocaine topical product for the treatment of acute pain. SP-103 is a triple-strength lidocaine topical system designed to deliver a dose of lidocaine three times higher than any lidocaine topical product that we are aware of, either approved or in development.

We currently contract with third parties for the manufacture, assembly, testing, packaging, storage and distribution of our products. We obtain our commercial supply of certain of our products, the clinical supply of our product candidates and certain of the raw materials used in our product candidates from sole or single source suppliers and manufacturers. Prior to April 2022, we relied on a single third-party logistics distribution provider, Cardinal Health 105, for ZTlido distribution in the United States. Cardinal Health 105 purchased and shipped ZTlido to customer wholesale distribution centers. Cardinal Health 105 also performed order management services on our

behalf. On April 2, 2022, we announced the expansion of our direct distribution network to national and regional wholesalers and pharmacies. Cardinal Health 105 will continue to provide traditional third-party logistics functions for us.

Since our inception, we have invested substantial efforts and financial resources on acquiring product and technology rights while building our intellectual property portfolio and infrastructure. In June 2022, we in-licensed the exclusive right to commercialize GLOPERBA oral solution, an FDA-approved prophylactic treatment for painful gout flares in adults, in the U.S. In February 2023, we acquired rights to FDA-approved ELYXYB in the U.S. and Canada for the acute treatment of migraine. We intend to continue to explore and evaluate additional opportunities such as these to grow our business. We have incurred significant operating losses as a result of such investment efforts, including the development of SEMDEXA, conducting of Phase 3 trials for SEMDEXA, and the development of SP-103 and SP-104. Our ability to generate revenue sufficient to achieve profitability will depend on the successful commercialization of our products, ZTlido, GLOPERBA and ELYXYB, and the development of our product candidates. We had a net loss of $72.8 million and $114.3 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of approximately $563.1 million. As of December 31, 2024, we had cash and cash equivalents of approximately $3.3 million. Our management has concluded that there is substantial doubt about our ability to continue as a going concern for one year after the date that the consolidated financial statements are issued. See Note 2 titled "Liquidity and Going Concern" to our consolidated financial statements and our independent registered public accounting firm report included elsewhere in this Annual Report on Form 10-K for additional information.

We expect to continue to make investments in our sales and marketing organization and expand digital marketing efforts to broaden awareness of ZTlido, GLOPERBA and ELYXYB and in research and development, clinical trials and regulatory affairs to develop our product candidates, SEMDEXA, SP-103 and SP-104. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant 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 may be unable to raise additional funds or enter into such agreements or arrangements when needed on favorable terms, or at all. If adequate funds on acceptable terms are not available when needed, we may be required to reduce the scope of the commercialization of ZTlido, GLOPERBA and ELYXYB or delay, scale back or discontinue the development of one or more of our product candidates.

Recent Developments

Deferral and Consent under Tranche B Senior Secured Convertible Note

Pursuant to the Tranche B Notes, commencing on January 2, 2025 (the "First Amortization Payment Date"), we are required to redeem in cash (the "First Amortization Payment") such portion of the principal amount of the Tranche B Notes equal to each Tranche B Noteholder's Holder Pro Rata Amount (as defined in the Tranche B Notes) of $6,250,000 per fiscal quarter at a redemption price equal to 100% of such Amortization Amount (as defined in the Tranche B Notes).

On January 2, 2025, we entered into a deferral and consent letter with each of (i) Nomis Bay Ltd and BPY Limited (the "Nomis Bay Consent"), (ii) Oramed (the "Oramed Consent") and (iii) 3i, LP (the "3i Consent" and, together with the Nomis Bay Consent and the Oramed Consent, the "Tranche B Consents"), respectively, pursuant to which the Tranche B Noteholders agreed to defer our obligation to make the First Amortization Payment until January 31, 2025. In consideration of such deferral, and to limit the Tranche B Noteholders' right to exercise certain secured creditor remedies (including recourse against the assets of SCLX JV as a grantor under the Security Agreement (as defined in the Tranche B Consents)), SCLX JV delivered to the Tranche B Noteholders (or their designee) by deposit/withdrawal at custodian with the Depository Trust Company an aggregate of 5,000,000 Scilex Shares (as defined in, and contemplated pursuant to, the Term Sheet that is an exhibit to the Tranche B Consents (the "Term Sheet")) held by SCLX JV, of which 2,500,000 shares were delivered to Oramed, 720,000 shares were delivered to BPY Limited, 1,280,000 shares were delivered to Nomis Bay Ltd, and 500,000 shares were delivered to 3i, LP.

In addition, pursuant to the Tranche B Consents, effective as of the latest of (i) the time of execution and delivery of the Tranche B Consents, (ii) the time of the delivery of the Scilex Shares and (iii) the time of grant of the Royalty and Exclusive Rights (each as defined in, and contemplated pursuant to, the Term Sheet), the Tranche B Noteholders agreed to further defer our obligation to make the First Amortization Payment until October 8, 2026, provided that, as contemplated in the Term Sheet, we pay an aggregate of $1.1 million in respect of a portion of the First Amortization Payment and related make-whole interest (which amount has been paid).

The Term Sheet provided that we and the Tranche B Noteholders would enter into an agreement pursuant to which the Tranche B Noteholders shall collectively receive a 10 year, assignable, freely transferable, 4% royalty on the worldwide Net Sales (as defined

therein) of GLOPERBA and ELYXYB, excluding sales of ELYXYB in Canada. Please see section below titled "*Gloperba-Elyxyb Royalty Purchase Agreement*" for a description of such royalty agreement entered into by us.

Amendment to the Oramed Note

On January 21, 2025, we entered into an amendment letter with Oramed (the "Oramed Amendment"), pursuant to which, among other things, Oramed agreed to extend the Maturity Date under and as set forth in the Oramed Note from March 21, 2025 to December 31, 2025. In consideration of such extension, SCLX JV agreed to deliver to Oramed an aggregate of 3,250,000 shares of Common Stock held by SCLX JV.

ZTlido Rest of World License Agreement

On February 22, 2025 (the "***Lido Effective Date***"), Scilex Pharma entered into a License Agreement (the "***Lido License Agreement***") with RoyaltyVest Ltd. (the "***Licensee***") with respect to services, compositions, products, dosages and formulations comprising lidocaine that have been or are later developed by or on behalf of Scilex Pharma, including the product and any future product defined as a "Product" under Scilex Pharma's existing (i) Product Development Agreement, dated as of May 11, 2011, with Oishi and Itochu, as amended, and (ii) the associated Commercial Supply Agreement, dated February 16, 2017, between Scilex Pharma, Oishi and Itochu, as amended, which include (a) ZTlido (lidocaine topical system) 1.8%, including the composition of matter with the NDC 69557-111-30 and (b) SP-103 (collectively, the "***Lido Product***"). The Lido License Agreement supersedes and replaces the that certain Rest of World License Term Sheet parties entered into on October 8, 2024.

Under the Lido License Agreement, Scilex Pharma granted to the Licensee during the Lido License Term (as defined below) a worldwide (other than the United States and certain territories stated in the Lido License Agreement), exclusive, non-transferable right, license and interest in, to, and under all Product Rights Controlled (each as defined therein) by Scilex Pharma to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit all Lido Products, in all cases solely for commercialization of the Lido Products outside of the United States and certain territories stated in the Lido License Agreement (the "***Lido Licensee Territory***"). The Licensee granted to Scilex Pharma a non-exclusive, non-transferable, right and license under the Licensee Non-Blocking Patents (as defined therein) (i) in the Licensor Territory (as defined therein), to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit Lido Product for commercialization of Lido Products in the Licensor Territory in the Field (each as defined therein), and (ii) worldwide, to develop and manufacture Lido Product for commercialization in the Licensor Territory in the Field (each as defined therein). Each of the Licensee and Scilex Pharma will receive 50% of the Net Revenue (as defined therein) generated, and the Licensee shall effect the foregoing by paying to Scilex Pharma its share of the Net Revenue on a quarterly basis.

Pursuant to the Lido License Agreement, the Licensee shall (i) use commercially reasonable efforts to obtain and maintain regulatory approval for the Lido Product in at least one Major Market Country (as defined therein) within 18 months after the Lido Effective Date, and (ii) commit $200,000, or its equivalent in kind, annually towards such efforts until it obtains regulatory approval for the Lido Product in the Lido Licensee Territory. Scilex Pharma shall use commercially reasonable and diligent efforts to obtain and maintain regulatory approvals for SP-103 and all existing Lido Products in each country or jurisdiction in the Licensor Territory (as defined therein).

Promptly after the Lido Effective Date, Scilex Pharma is required to (i) facilitate an introduction between Oishi, Itochu, and the Licensee, and (ii) use reasonable efforts to cause each of Oishi and Itochu to accept a direct engagement with the Licensee for the manufacturing or supply of the Lido Product in finished dosage form. In addition, Scilex Pharma agreed to appoint the Licensee as its exclusive distributor of the Lido Product in the Licensee Territory during the Lido License Term.

The term of the Lido License Agreement commences on the Lido Effective Date and continues until expiration of the last to expire Licensed Patents (as defined therein), unless earlier terminated (the "***Lido License Term***").

Parent Guarantee for Lido License Agreement

On February 22, 2025, in connection with Lido License Agreement, we entered into that certain Parent Guarantee for Lidocaine License Agreement (the "***Parent Guarantee***") with the Licensee, pursuant to which we agreed to guarantee the due and proper performance of Scilex Pharma's obligations under the Lido License Agreement on the terms and conditions set forth in the Parent Guarantee. Pursuant to the terms of the Parent Guarantee, we shall provide the Licensee with written notice of any Change of Control (as defined therein) of

Scilex Pharma within five business days after the consummation of such Change of Control, and the Parent Guarantee and the guarantee obligations shall automatically terminate upon the consummation of such Change of Control.

Gloperba-Elyxyb Royalty Purchase Agreement

As contemplated by the Term Sheet in respect of the Royalty and Exclusive Rights described therein, on February 28, 2025 (the "Gloperba-Elyxyb Closing Date"), we entered into a Purchase and Sale Agreement (the "Gloperba-Elyxyb Royalty Purchase Agreement") with Scilex Pharma, certain institutional investors (collectively, the "Gloperba-Elyxyb Royalty Investors") and Oramed (together with the Gloperba-Elyxyb Royalty Investors, the "Gloperba-Elyxyb RPA Purchasers"). Pursuant to the Gloperba-Elyxyb Royalty Purchase Agreement, Scilex Pharma sold to the Gloperba-Elyxyb RPA Purchasers the right to receive 4% of all aggregate net sales worldwide (the "Gloperba-Elyxyb Purchased Receivables") with respect to Gloperba, Elyxyb, and any related, improved, successor, replacement and/or varying dosage forms of the foregoing (the "Gloperba-Elyxyb Covered Products").

In consideration of the Further Deferral and representing the "grant of the Royalty and Exclusive Rights" (as defined in the Term Sheet), during the period commencing on the Gloperba-Elyxyb Closing Date and expiring on the tenth anniversary of the Gloperba-Elyxyb Closing Date (the "Gloperba-Elyxyb Payment Term"), Scilex Pharma shall pay to each Gloperba-Elyxyb RPA Purchaser, by wire transfer of immediately available funds in U.S. dollars to such Gloperba-Elyxyb RPA Purchaser's account such Gloperba-Elyxyb RPA Purchaser's Specified Percentage (as defined in the Gloperba-Elyxyb Royalty Purchase Agreement) of the Covered Product Revenue Payments (each as defined in the Gloperba-Elyxyb Royalty Purchase Agreement) for each calendar quarter (commencing with the calendar quarter beginning January 1, 2025) promptly, but in any event no later than 60 calendar days after the end of each calendar quarter.

The Gloperba-Elyxyb Royalty Purchase Agreement shall terminate six months following receipt by the Gloperba-Elyxyb RPA Purchasers of all payments of the Purchased Receivables to which each Gloperba-Elyxyb RPA Purchaser is entitled during the Payment Term.

Royalty Security Agreement

Pursuant to the terms of the Gloperba-Elyxyb Royalty Purchase Agreement, we entered into a Security Agreement with Scilex Pharma and the collateral agent (as identified therein) for the benefit of the Gloperba-Elyxyb RPA Purchasers, dated as of February 28, 2025 (the "Gloperba-Elyxyb Royalty Security Agreement").

Under the Gloperba-Elyxyb Royalty Security Agreement, each of our and Scilex Pharma's due performance and payment under the Gloperba-Elyxyb Royalty Purchase Agreement is secured by certain collateral, including a collection account and certain material contracts, intellectual property rights and regulatory approvals, in each case related to the Gloperba-Elyxyb Covered Products.

Subordination Agreement

In connection with the Gloperba-Elyxyb Royalty Purchase Agreement and the Gloperba-Elyxyb Royalty Security Agreement, we entered into that certain Subordination Agreement, dated as of February 28, 2025 (the "Gloperba-Elyxyb Subordination Agreement"), by and among us, Scilex Pharma the Gloperba-Elyxyb RPA Purchasers and the Note Agent (each as defined in the Subordination Agreement). Pursuant to the Gloperba-Elyxyb Subordination Agreement, the parties agreed that all obligations, liabilities and indebtedness under the Gloperba-Elyxyb Royalty Purchase Agreement are secured by first priority liens on the collateral under the Gloperba-Elyxyb Royalty Security Agreement (the "Gloperba-Elyxyb Royalty Collateral") and the Note Agent's lien on the Gloperba-Elyxyb Royalty Collateral is subordinated and becomes a second priority lien.

Amendment No. 1 to ZTlido Royalty Purchase Agreement

On February 28, 2025, we and Scilex Pharma entered into an Amendment No. 1 to Purchase and Sale Agreement (the "ZTlido Royalty Amendment") with the purchasers (the "ZTlido Royalty Purchasers") under that certain Purchase and Sale Agreement, dated as of October 8, 2024 (the "ZTlido Royalty Purchase Agreement"). Pursuant to the Royalty Amendment, we and Scilex Pharma may assign our respective rights or delegate our respective obligations under the ZTlido Royalty Purchase Agreement without the prior written consent of the Purchasers if we receive a commitment, contingent upon an asset purchase of Covered Products (as defined in the ZTlido Royalty Purchase Agreement), that would allow us to pay in full all obligations owed under the Debt Instruments (as defined therein),

provided that such purchaser of Covered Products agrees to assume all of the obligations of our company and Scilex Pharma under the ZTlido Royalty Purchase Agreement.

Gloperba Rest of World License Agreement

On February 28, 2025 (the "Effective Date"), we entered into a License Agreement (the "Gloperba License Agreement") with Scilex Pharma and the Licensee with respect to (i) services, compositions, products, dosages and formulations comprising Gloperba that have been or are later developed by or on behalf of us, including the product and any future product defined as a "Licensed Product" under the Romeg License Agreement, as amended and as may be further amended or restated from time to time, and (ii) any related, improved, successor or replacement forms of any such product Controlled (as defined therein) by us ((i) and (ii) collectively, the "Gloperba Product").

Under the Gloperba License Agreement, we granted to the Licensee during the Gloperba License Term (as defined below) a worldwide, exclusive, non-transferable (except in connection with a permitted assignment of the Gloperba License Agreement) right, license and interest in, to, and under all Product Rights Controlled (each as defined therein) by us to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit all Gloperba Products, in all cases solely for commercialization of the Gloperba Products outside of the United States in the Field (as defined therein). The Licensee granted to us a non-exclusive, non-transferable (except in connection with a permitted assignment of the Gloperba License Agreement), right and license under the Licensee Non-Blocking Patents (as defined therein) (i) in the United States, to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit Gloperba Product for commercialization of Gloperba Products in the United States in the Field (as defined therein), and (ii) worldwide, to develop and manufacture Gloperba Product for commercialization in the United States in the Field (as defined therein). Each of the Licensee and we will receive 50% of the Net Revenue (as defined therein) generated based on Licensee's sale of the Gloperba Products, and the Licensee shall effect the foregoing by paying to us an amount required for us to receive its share of the Net Revenue on a quarterly basis.

Pursuant to the Gloperba License Agreement, the Licensee shall obtain and maintain regulatory approval for the Gloperba Product outside of the United States in accordance with its own business judgment and in its sole and absolute discretion.

Promptly after the Effective Date, we are required to (i) facilitate an introduction between the Licensee and our contract manufacturer of the Gloperba Product (the "Gloperba CMO") as of the Effective Date, and (ii) use reasonable efforts to cause such Gloperba CMO to accept a direct engagement with the Licensee for the manufacturing or supply of the Gloperba Product in finished dosage form. In addition, we agreed to appoint the Licensee as its exclusive distributor of the Gloperba Product in the entire world other than the United States during the Gloperba License Term.

The term of the Gloperba License Agreement commences on the Effective Date and continues until expiration of the last to expire Licensed Patents (as defined therein), unless earlier terminated (the "Gloperba License Term").

Sorrento Chapter 11 Filing

On February 13, 2023, Sorrento Therapeutics, Inc. ("Sorrento"), together with its wholly owned direct subsidiary, Scintilla Pharmaceuticals, Inc., commenced voluntary proceedings under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of Texas. The Chapter 11 proceedings are jointly administered under the caption In re Sorrento Therapeutics, Inc., et al, Case Number 23-90085 (DRJ) (the "Chapter 11 Cases"). While we were previously majority-owned by Sorrento, we were not a debtor in Sorrento's voluntary Chapter 11 filing. Pursuant to that certain Stock Purchase Agreement that we entered into with Sorrento on September 21, 2023 (the "the Sorrento SPA"), we repurchased shares of our Common Stock and Series A Preferred Stock from Sorrento. As a result, Sorrento no longer holds a majority of the voting power of our outstanding capital stock entitled to vote. As of December 31, 2024, we had a $3.2 million receivable from Sorrento, which was fully reserved. We evaluate the collectability of this receivable on a quarterly basis.

Components of Our Results of Operations

Net Revenue

Net revenue consists of product sales of ZTlido, ELYXYB and GLOPERBA in the United States. For product sales of ZTlido, ELYXYB and GLOPERBA, we record gross-to-net sales adjustments for government and commercial rebates, chargebacks, wholesaler and distributor fees, sales returns, special marketing programs, and prompt payment discounts. We expect that any net revenue we generate will fluctuate from year to year as a result of the unpredictability of the demand for our product.

Operating Costs and Expenses

Cost of Revenue

Cost of revenue consists of the cost of purchasing ZTlido, ELYXYB and GLOPERBA from our manufacturing partners, inventory write-downs related to expiration dates for on-hand inventory, cost of shipments, and royalty payments to our manufacturers. We expect the cost of revenue to fluctuate with related net sales revenue.

Research and Development

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

- costs related to clinical trials;
- salaries, benefits and other related costs, including stock-based compensation expense for personnel engaged in research and development functions; and
- costs related to outside consultants.

We expect our research and development expenses to increase, as we will incur incremental expenses associated with our product candidates that are 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 SEMDEXA, SP-103 and SP-104.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of costs related to our contract sales force, salaries and other related costs, including stock-based compensation, for personnel in our executive, marketing, finance, corporate and business development and administrative functions. Selling, general and administrative expenses also include professional fees for legal, patent, accounting, auditing, tax and consulting services, travel expenses and facility-related expenses, which include direct depreciation costs, and allocated expenses from Sorrento for director and officer insurance as well as employee health benefits through the consummation of the transactions pursuant to the Sorrento SPA.

We expect that our selling, general and administrative expenses will vary year over year in the future as we adapt our commercial 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 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 adjust the size of our administrative, finance and legal functions to adapt to the changes above and the anticipated growth of our business.

Intangible Amortization

Intangible amortization expense consists of the amortization expense of intangible assets recognized on a straight-line basis over the estimated useful lives of the assets. Our intangible assets, excluding goodwill, are composed of patent rights, acquired technology, acquired licenses and assembled workforce.

Legal Settlements

Legal settlements consist of gains on litigation settlements that were entered into during the first quarter of 2024. See Note 11 titled "*Commitments and Contingencies*" of the Notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Other (Income) Expense

(Gain) loss on Derivative Liability

(Gain) loss on derivative liability includes the remeasurement of the derivative warrant liability. See Note 4 titled *"Fair Value Measurements"* to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Change in Fair Value of Debt and Liability Instruments

Change in fair value of debt and liability instruments includes the remeasurement of (i) the convertible debentures (the "Convertible Debentures") issued to YA II, Ltd. ("Yorkville") pursuant to that certain securities purchase agreement dated as of March 21, 2023 and amended on October 11, 2023, between Yorkville and us, (ii) the senior secured promissory note to Oramed Pharmaceuticals Inc. ("Oramed") issued in September 2023 in the principal amount of $101.9 million (the "Oramed Note"), (iii) the non-refundable deposit in the aggregate principal amount of $10.0 million (the "FSF Deposit") pursuant to that certain Commitment Side Letter (the "Commitment Letter") dated as of June 11, 2024, entered into with FSF 33433 LLC ("FSF Lender"), (iv) senior secured convertible notes issued in October 2024 in the principal amount of $50.0 million (the "Tranche B Notes") and (v) the purchased revenue liability associated with the ZTlido Royalty Purchase Agreement with certain institutional investors (collectively, the "ZTlido Royalty Investors") and Oramed. See Note 4 titled *"Fair Value Measurements"* to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Interest Expense, Net

Interest expense, net consists of interest related to the loans in an aggregate principal amount of up to $30.0 million (the "Revolving Facility") made available by eCapital Healthcare Corp. pursuant to a Credit and Security Agreement (the "eCapital Credit Agreement") that Scilex Pharma entered into on June 27, 2023.

Loss on Foreign Currency Exchange

Loss on foreign currency exchange relates to foreign exchange losses on payments made to our foreign supplier, Itochu, a manufacturer and supplier of lidocaine tape products, including ZTlido and SP-103.

Results of Operations

The following tables summarize our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Changes
Statements of Operations Data:			
Net revenue	$ 56,590	$ 46,743	$ 9,847
Net operating costs and expenses:			
Cost of revenue	16,689	15,681	1,008
Research and development	9,641	12,746	(3,105)
Selling, general and administrative	119,016	119,641	(625)
Intangible amortization	4,031	4,106	(75)
Legal settlements	(9,391)	—	(9,391)
Total net operating costs and expenses	139,986	152,174	(12,188)
Loss from operations	(83,396)	(105,431)	22,035
Other (income) expense, net:			
(Gain) loss on derivative liability	(17,378)	512	(17,890)
Change in fair value of debt and liability instruments	4,782	7,189	(2,407)
Interest expense, net	1,963	1,068	895
Loss on foreign currency exchange	45	118	(73)
Total other (income) expense, net	(10,588)	8,887	(19,475)
Loss before income taxes	(72,808)	(114,318)	41,510
Income tax (benefit) expense	(1)	13	(14)
Net loss	$ (72,807)	$ (114,331)	$ 41,524

Comparison of the Years Ended December 31, 2024 and 2023

Net Revenue

The following table summarizes net revenue by product for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Increase (Decrease)
ZTlido			
Net Revenue	$ 52,094	$ 46,300	$ 5,794
ELYXYB			
Net Revenue	4,258	443	3,815
GLOPERBA			
Net Revenue	238	—	238
Total Net Revenue	$ 56,590	$ 46,743	$ 9,847

Net revenue for the years ended December 31, 2024 and 2023 was $56.6 million and $46.7 million, respectively. The increase of $9.9 million was comprised of $5.8 million, $3.8 million and $0.2 million increase in net product sales of ZTlido, ELYXYB and GLOPERBA, respectively, with GLOPERBA sales commencing in June 2024. The increase in net sales of ZTlido and ELYXYB was driven by an increase in gross sales by approximately 6% and 49%, respectively, as a result of an increase in the sales volume due to higher demand and a standard industry annual price increase, partially offset by an increase in rebates. The commercial launch of ELYXYB has been met with a strong response from the prescribing community since its commercial launch in April 2023 and continued to show growth during 2024, the first full year of commercialization.

Cost of Revenue

The following table summarizes cost of revenue by product for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Increase (Decrease)
ZTlido			
Cost of Revenue	$ 6,249	$ 6,631	$ (382)
Cost of Revenue - Royalties	9,854	8,544	1,310
Other Cost of Revenue	45	435	(390)
Total ZTlido	16,148	15,610	538
ELYXYB			
Cost of Revenue	181	36	145
Cost of Revenue - Royalties	341	35	306
Total ELYXYB	522	71	451
GLOPERBA			
Cost of Revenue	19	—	19
Total GLOPERBA	19	—	19
Total Cost of Revenue	$ 16,689	$ 15,681	$ 1,008

Cost of revenue for the years ended December 31, 2024 and 2023 was $16.7 million and $15.7 million, respectively. Cost of revenue for ZTlido increased by $0.5 million due to higher royalties primarily driven by an increase in gross product sales by approximately 6%, partially offset by a decrease due to favorable foreign currency exchange rate fluctuations affecting purchases from our foreign supplier, Itochu, and decrease in logistics costs due to the absence of air shipments in 2024 compared to 2023. Cost of revenue for ELYXYB increased by $0.5 million and was primarily due to the increase in gross product sales by approximately 49% with the sales commencing in April 2023. GLOPERBA sales commenced in June 2024.

Research and Development Expenses

The following table summarizes research and development expenses by project for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,		
	2024	2023	Increase (Decrease)
SP-102			
Contracted R&D	$ 1,160	$ 1,229	$ (69)
Personnel	467	254	213
Other	57	64	(7)
Total SP-102	1,684	1,547	137
SP-103			
Contracted R&D	2,472	4,270	(1,798)
Personnel	1,317	1,107	210
Other	188	474	(286)
Total SP-103	3,977	5,851	(1,874)
SP-104			
Contracted R&D	50	925	(875)
Personnel	292	605	(313)
Other	—	149	(149)
Total SP-104	342	1,679	(1,337)
GLOPERBA			
Contracted R&D	687	345	342
Personnel	813	658	155
Other	116	115	1
Total GLOPERBA	1,616	1,118	498
ELYXYB			
Contracted R&D	758	1,252	(494)
Personnel	1,068	908	160
Other	196	391	(195)
Total ELYXYB	2,022	2,551	(529)
Total Research and Development Expenses	$ 9,641	$ 12,746	$ (3,105)

Research and development expenses for the years ended December 31, 2024 and 2023 were $9.6 million and $12.7 million, respectively. The $3.1 million decrease was primarily attributed to reduced costs of SP-103 due to the completion of the Phase 2 clinical study and reduced development costs of SP-104.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the years ended December 31, 2024 and 2023 were $119.0 million and $119.6 million, respectively. The decrease of approximately $0.6 million was primarily due to a $10.1 million decrease in legal fees, a $1.6 million decrease in insurance costs, a $0.4 million decrease in advisory and financing expenses and a $0.2 million decrease as a result of a $1.4 million decrease related to allowance for credit losses that was made in March 2023 for the receivable from Sorrento offset by a $1.2 million increase related to allowances for expected credit losses on accounts receivable, partially offset by a $5.5 million increase in rebate expense related to future shipments of the Additional Product (as defined below) under the Satisfaction Agreement, a $2.9 million increase in contracted services, a $1.7 million increase in personnel expense due to increase in headcount and a merit increase starting January 2024, a $0.5 million increase in travel expenses, a $0.1 million increase in marketing expenses and a $1.0 million increase in other expenses.

Intangible Amortization Expense

Intangible amortization expense for the years ended December 31, 2024 and 2023 was $4.0 million and $4.1 million, respectively. The decrease of $0.1 million is related to the full amortization of the assembled workforce intangible asset (see Note 6 titled "*Goodwill and Intangible Assets*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Legal Settlements

Legal settlements for the years ended December 31, 2024 and 2023 were $9.4 million and nil, respectively. The increase was attributed to litigation settlements that were entered into during the first quarter of 2024. See Note 11 titled "*Commitments and Contingencies*" to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

(Gain) Loss on Derivative Liability

(Gain) loss on derivative liability for the years ended December 31, 2024 and 2023 was ($17.4) million and $0.5 million, respectively. The gain recognized during the year ended December 31, 2024 was attributed to the change in the fair value of the derivative warrant liability associated with the Private Warrants, the February 2024 BDO Firm Warrants, the April 2024 RDO Common Warrants, the Deposit Warrant, the October 2024 Noteholder Warrants and the December 2024 RDO Common Warrants (each as defined below). The loss recognized during the year ended December 31, 2023 was attributed to the change in the fair value of the derivative warrant liability associated with the Private Warrants.

Change in Fair Value of Debt and Liability Instruments

Change in fair value of debt and liability instruments for the years ended December 31, 2024 and 2023 was $4.8 million and $7.2 million, respectively. The loss recognized during the year ended December 31, 2024 was attributed to losses of $35.0 thousand for the Convertible Debentures, $3.6 million for the Oramed Note, $4.7 million for the FSF Deposit, $0.9 million for the purchased revenue liability pursuant to the ZTlido Royalty Purchase Agreement and a $2.6 million loss recognized upon issuance of the Tranche B Notes, partially offset by a gain of $6.6 million in change in fair value of the Tranche B Notes and $0.4 million gain on partial extinguishment of the Oramed Note pursuant to the Oramed Letter Agreement. The loss recognized during the year ended December 31, 2023 was attributed to losses of $4.4 million for the Convertible Debentures and $2.8 million for the Oramed Note. The Convertible Debentures were issued in March and April 2023 in an aggregate principal amount of $25.0 million, which were fully repaid during the first quarter of 2024. The Oramed Note was issued in September 2023 in the principal amount of $101.9 million, of which the principal amount of $25.0 million remained outstanding as of December 31, 2024. The FSF Deposit was received in June 2024 in the principal amount of $10.0 million and was satisfied in November 2024 by the delivery of the Additional Product (as defined below) to Endeavor. The Tranche B Notes were issued in October 2024 in the principal amount of $50.0 million, of which the principal amount of $38.0 million remained outstanding as of December 31, 2024.

Interest Expense, Net

Interest expense, net for the years ended December 31, 2024 and 2023 was $2.0 million and $1.1 million, respectively. The increase was attributed to $0.8 million of interest related to the Revolving Facility and $0.1 million of interest related to deferred consideration for GLOPERBA license acquired from Romeg in 2022.

Liquidity and Capital Resources

As of December 31, 2024, we had cash and cash equivalents of approximately $3.3 million.

We have funded our operations primarily through the Yorkville financing pursuant to the A&R Yorkville Purchase Agreement (as defined below), the B. Riley Principal Capital II, LLC ("B. Riley") financing pursuant to the B. Riley Purchase Agreement (as defined below), the Revolving Facility, the issuance of the Convertible Debentures and financing pursuant to the ATM Sales Agreement (as defined below). We also have indebtedness pursuant to the Oramed Note and Tranche B Notes as well as deferred consideration related to the GLOPERBA license acquired from Romeg in 2022. The following table summarizes the aggregate indebtedness of these issuances as of December 31, 2024 and December 31, 2023 (in thousands):

	December 31, 2024	December 31, 2023
Oramed Note (outstanding principal balance: $25.0 million and $100.9 million as of December 31, 2024 and 2023, respectively)	$ 12,161	$ 104,089
Convertible Debentures (outstanding principal balance: nil and $4.4 million as of December 31, 2024 and 2023, respectively)	—	4,340
Tranche B Notes (outstanding principal balance: $38.0 million and nil as of December 31, 2024 and 2023, respectively)	23,560	—
Purchased Revenue Liability	6,800	—
Revolving Facility	—	17,038
Deferred Consideration with Romeg	2,895	3,386
Total indebtedness	$ 45,416	$ 128,853

The Oramed Note

As of December 31, 2024, the fair value of the Oramed Note outstanding was $12.2 million pursuant to the Scilex-Oramed SPA (see Note 7 titled "*Debt*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Convertible Debentures

We fully repaid the Convertible Debentures in March 2024 (see Note 7 titled "*Debt*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Tranche B Notes

As of December 31, 2024, the fair value of the Tranche B Notes outstanding was $23.6 million pursuant to the Tranche B Securities Purchase Agreement (see Note 7 titled "*Debt*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Purchased Revenue Liability

As of December 31, 2024, the fair value of the purchased revenue liability was $6.8 million pursuant to the ZTlido Royalty Purchase Agreement (see Note 7 titled "*Debt*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Revolving Facility

We fully repaid the Revolving Facility in October 2024 (see Note 7 titled "*Debt*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Deferred Consideration

As of December 31, 2024, we have $2.9 million of deferred consideration related to minimum royalty payments that were included in the initial measurement of consideration transferred for the GLOPERBA license. Deferred consideration minimum royalty payments began in July 2023.

ZTlido, ELYXYB and GLOPERBA Royalties

In February 2013, Scilex Pharma became a party to a product development agreement (as amended, the "Product Development Agreement") with Itochu and Oishi (together, the "Developers"), pursuant to which the Developers will manufacture and supply lidocaine tape products, including ZTlido and SP-103, for Scilex Pharma. Pursuant to the Product Development Agreement, Scilex Pharma is required to make aggregate royalty payments between 25% and 35% to the Developers based on net profits. During each of the years ended December 31, 2024 and 2023, Scilex Pharma made royalty payments in the amount of $8.3 million. As of December 31, 2024 and 2023, Scilex Pharma had ending balances of accrued royalty payables of $4.0 million and $2.4 million, respectively.

In February 2023, we entered into an asset purchase agreement to acquire the rights to certain patents, trademarks, regulatory approvals, data, contracts, and other rights related to ELYXYB and its commercialization in the United States and Canada (the "ELYXYB Territory"). We are obligated to make quarterly royalty payments on net sales of ELYXYB in the ELYXYB Territory that range from high single digits to the low double digits on net sales based on the volume of sales. In April 2023, we launched ELYXYB in the U.S.

During the year ended December 31, 2024 and 2023, we made royalty payments in the amount of $0.3 million and $26.0 thousand, respectively. As of December 31, 2024 and 2023, we had ending balances of accrued royalty payables of $0.1 million and $5.0 thousand, respectively.

In June 2022, we entered into the Romeg License Agreement with Romeg, which agreement was subsequently amended in January 2025, to acquire certain rights to GLOPERBA and the exclusive license to use the trademark "GLOPERBA®". As consideration for the license under the Romeg License Agreement, we are obligated to make royalty payments on net sales of GLOPERBA that range from low-single digit to mid-single digit percentages based on annual net sales. During the years ended December 31, 2024 and 2023, we made royalty payments in the amount of $0.6 million and $0.3 million, respectively.

Contingent Consideration

We have $280.0 million, $13.0 million and $23.0 million in aggregate contingent consideration obligations in connection with the SEMDEXA, GLOPERBA and SP-104 acquisitions, respectively, that are contingent upon achieving certain specified milestones or the occurrence of certain events. Contingent consideration obligations are comprised of regulatory milestones and additional payments that will be due upon the achievement of certain amounts of net sales (see Note 3 titled "*Acquisitions and License Agreements*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

Standby Equity Purchase Agreements

On November 17, 2022, we entered into a standby equity purchase agreement (the "Original Purchase Agreement") with Yorkville. On February 8, 2023, we entered into an amended and restated standby equity purchase agreement with Yorkville (the "A&R Yorkville Purchase Agreement"), amending, restating and superseding the Original Purchase Agreement. Pursuant to the A&R Yorkville Purchase Agreement, we have the right, but not the obligation, to sell to Yorkville up to $500.0 million of shares of Common Stock at our request during the 36 months following the date on which the initial registration statement filed with respect to the shares of Common Stock issuable pursuant thereto was declared effective by the SEC, subject to the terms therein. The registration statement filed with the SEC in connection with the Original Purchase Agreement was initially declared effective by the SEC on December 9, 2022 and we are now able to offer and sell shares of our Common Stock under that agreement, subject to the limitations set forth therein. During the year ended December 31, 2024, we have sold 96,982 shares of Common Stock under the A&R Yorkville Purchase Agreement for aggregate net proceeds of approximately $0.2 million. On, and effective as of, March 25, 2024, we and Yorkville mutually agreed to terminate the A&R Yorkville Purchase Agreement.

On January 8, 2023, we entered into a standby equity purchase agreement (the "B. Riley Purchase Agreement", together with the A&R Yorkville Purchase Agreement, the "Standby Equity Purchase Agreements") with B. Riley, pursuant to which we had the right, but not the obligation, to sell to B. Riley up to $500.0 million of shares of Common Stock at our request during the 36 months following the date on which the initial registration statement filed with respect to the shares of Common Stock issuable pursuant thereto was declared effective by the SEC, subject to the terms therein. The registration statement filed with the SEC in connection with the B. Riley Purchase Agreement was initially declared effective by the SEC on January 20, 2023 and we were able to offer and sell shares of our Common Stock under that agreement, subject to the limitations set forth therein and the limitations set forth in the Convertible Debentures. During the year ended December 31, 2024, we did not sell any shares of Common Stock under the B. Riley Purchase Agreement. On, and effective as of, February 16, 2024, we and B. Riley mutually agreed to terminate the B. Riley Purchase Agreement.

At-the-Market Sales Agreement

On December 22, 2023, we entered into a Sales Agreement (the "ATM Sales Agreement") with B. Riley Securities, Inc., Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (the "Sales Agents"), which agreement was voluntarily terminated by us effective as of March 5, 2025. Pursuant to the ATM Sales Agreement, we were able to offer and sell (the "Offering") shares of Common Stock up to $170,000,000 (the "ATM Shares"), through or to the Sales Agents as part of the Offering. We had no obligation to sell any shares of Common Stock under the ATM Sales Agreement and could suspend offers at any time. The ATM Shares offered and sold in the Offering were issued pursuant to our Shelf S-3 Registration Statement. The ATM Shares were offered by means of a prospectus forming a part of the Shelf S-3 Registration Statement. The Sales Agents were entitled to a commission equal to 3.0% of the gross proceeds from each sale of shares of Common Stock. We also agreed to reimburse the Sales Agents for certain expenses and provide indemnification and contribution to the Sales Agents against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended. During the year ended December 31, 2024, we sold 2,764,187 shares of Common Stock pursuant to the ATM Sales Agreement for net proceeds of approximately $2.7 million. There were no sales made under the ATM Sales Agreement subsequent to December 31, 2024.

February 2024 Bought Deal Offering

On February 29, 2024, we entered into an underwriting agreement (the "February 2024 BDO Underwriting Agreement") with Rodman & Renshaw LLC and StockBlock, as the representatives (the "Representatives") of the underwriters named in Schedule A (the "Underwriters"). Pursuant to the February 2024 BDO Underwriting Agreement, we sold, in an underwritten offering (the "February 2024 BDO"), 5,882,353 shares (the "February 2024 BDO Firm Shares") of the Common Stock, and accompanying common warrants to purchase up to an aggregate of 5,882,353 shares of Common Stock (the "February 2024 BDO Firm Warrants"). Pursuant to the February 2024 BDO Underwriting Agreement, we also granted the Underwriters an option for a period of 30 days from the date of the February 2024 BDO Underwriting Agreement to purchase up to 882,352 additional shares of Common Stock (the "February 2024 BDO Optional Shares", and together with the February 2024 BDO Firm Shares, the "February 2024 BDO Shares") and/or common warrants to purchase up to 882,352 shares of Common Stock (the "February 2024 BDO Optional Warrants", and together with the February 2024 BDO Firm Warrants, the "February 2024 BDO Common Warrants") that may be purchased by the Underwriters, at a price per February 2024 BDO Optional Share of $1.5548 and a price per February 2024 BDO Optional Warrant of $0.0092, which amounts reflect the public offering price of $1.69 per February 2024 BDO Optional Share and $0.01 per February 2024 BDO Optional Warrant, less underwriting discounts and commissions, as applicable (the "February 2024 BDO Underwriters' Option"). The February 2024 BDO Underwriters' Option was not exercised. Each Firm Share was sold together with a February 2024 BDO Firm Warrant at a combined public offering price of $1.70. The combined price per Firm Share and accompanying February 2024 BDO Firm Warrant paid by the Underwriters was $1.564, which amount reflects the combined public offering price of $1.70, less underwriting discounts and commissions.

Subject to certain ownership limitations, the February 2024 BDO Common Warrants are exercisable immediately, will expire on the five-year anniversary of the date of issuance and have an exercise price of $1.70 per share. The exercise price of the February 2024 BDO Common Warrants is subject to certain adjustments, including (but not limited to) for stock dividends, stock splits, combinations and reclassifications of the Common Stock.

In connection with the February 2024 BDO, pursuant to the February 2024 BDO Underwriting Agreement, we issued to the Representatives warrants (the "February 2024 BDO Representative Warrants", and together with the February 2024 BDO Common Warrants, the "February 2024 BDO Warrants") to purchase up to an aggregate of 470,588 shares of Common Stock (which represents 8.0% of the aggregate number of February 2024 BDO Firm Shares sold in the February 2024 BDO). The February 2024 BDO Representative Warrants are immediately exercisable and have the same terms as the February 2024 BDO Common Warrants described above, except that the exercise price of the February 2024 BDO Representative Warrants is $2.125 per share, which represents 125% of the combined public offering price per Firm Share and accompanying February 2024 BDO Firm Warrant. We also agreed to pay certain expenses of the Representatives in connection with the February 2024 BDO, including their legal fees and out-of-pocket expenses up to $200,000 and up to $15,950 for clearing expenses.

The February 2024 BDO Shares, the February 2024 BDO Warrants and the shares of Common Stock issuable upon exercise of the February 2024 BDO Warrants were offered and sold by us pursuant to an effective shelf registration statement on Form S-3 (which was initially filed with the SEC on December 22, 2023, as amended, and was declared effective on January 11, 2024 (File No. 333-276245) (the "Shelf S-3 Registration Statement")), a base prospectus dated January 11, 2024 and a prospectus supplement dated February 29, 2024.

April 2024 Registered Direct Offering

On April 23, 2024, we entered into a securities purchase agreement (the "April 2024 RDO Purchase Agreement") with the investor named therein, pursuant to which we sold and issued, in a registered direct offering (the "April 2024 RDO"): (i) an aggregate of 15,000,000 shares (the "April 2024 RDO Shares") of Common Stock, and (ii) common warrants to purchase up to 15,000,000 shares of Common Stock (the "April 2024 RDO Common Warrants"). The offering price per share and accompanying April 2024 RDO Common Warrant to purchase one share of Common Stock was $1.00, for aggregate gross proceeds to us of $15,000,000, before deducting the placement agent fees and other offering expenses.

Subject to certain ownership limitations, the April 2024 RDO Common Warrants are exercisable on the six-month anniversary from the date of issuance, will expire on the five-year anniversary of the date of issuance and have an exercise price of $1.10 per share. The exercise price of the April 2024 RDO Common Warrants is subject to certain adjustments, including stock dividends, stock splits, combinations and reclassifications of the Common Stock.

StockBlock and its affiliate, Rodman & Renshaw LLC acted as exclusive placement agents (the "Placement Agents") in connection with the April 2024 RDO. As compensation for such placement agent services, we paid the Placement Agents an aggregate cash fee equal to 8.0% of the gross proceeds actually received by us from the April 2024 RDO. We also reimbursed the Placement Agents $100,000 for actual, reasonable and documented fees and expenses, inclusive of fees and expenses of legal counsel and out-of-pocket

expenses and $15,950 for clearing expenses. We also issued to the Placement Agents or their respective designees common warrants, substantially in the form of the April 2024 RDO Common Warrants, to purchase up to 1,200,000 shares of Common Stock (the "April 2024 RDO Placement Agent Warrants" and together with the "April 2024 RDO Common Warrants", the "April 2024 RDO Warrants"), representing up to 8.0% of the total number of the April 2024 RDO Shares issued in the April 2024 RDO. The April 2024 RDO Placement Agent Warrants have an exercise price of $1.25 per share (which represents 125% of the combined offering price per share of Common Stock and the April 2024 RDO Common Warrant sold in the April 2024 RDO), will become exercisable on the six-month anniversary of the date of issuance and expire five years from the commencement of sales in the April 2024 RDO.

The April 2024 RDO Shares, the April 2024 RDO Warrants, and the shares of Common Stock issuable upon exercise of such warrants were offered and sold by us pursuant to the Shelf S-3 Registration Statement, a base prospectus dated January 11, 2024 and a prospectus supplement dated April 23, 2024. The April 2024 RDO closed on April 25, 2024.

Commitment Letter

On June 11, 2024, we entered into that certain Commitment Letter with FSF Lender, pursuant to which the FSF Lender committed to provide us a loan in the aggregate amount of $100 million (the "Commitment Amount"). The Commitment Amount shall be payable as follows: (i) $85 million no later than the date that is 70 days following the date on which we receive the FSF Deposit (the "Outside Date" and the funding of the initial $85 million, the "Initial Closing") and (ii) the remaining $15 million within 60 days following the Initial Closing. Pursuant to the Commitment Letter, the FSF Lender provided us the non-refundable FSF Deposit in immediately available funds in the aggregate principal amount of $10 million on June 18, 2024 (the "Deposit Date"), which amount will be creditable towards the $85 million required to be funded by FSF Lender at the Initial Closing. On the Deposit Date, we issued to FSF Lender a warrant to purchase up to an aggregate of 3,250,000 shares of Common Stock (subject to adjustment for any stock dividend, stock split, reverse stock split or similar transaction) (the "Deposit Warrant"), with an exercise price of $1.20 per share. Subject to certain ownership limitations, the Deposit Warrant is immediately exercisable and will expire five years from the date of issuance.

In connection with the transactions contemplated by the Commitment Letter, we also entered into a letter agreement with FSF Lender and the FSF Lender's strategic consultant, IVI 66766 LLC ("IVI"), dated July 16, 2024, pursuant to which we agreed to reimburse the actual, reasonable and documented consulting fees incurred by the FSF Lender in connection with the preparation, negotiation and execution of the Commitment Letter and the definitive documents with respect to the transactions contemplated thereby, which fees were satisfied in full by us issuing to IVI a warrant to purchase up to an aggregate of 250,000 shares of Common Stock (the "Fee Warrant") on July 16, 2024, with an exercise price of $1.20 per share. Subject to certain ownership limitations, the Fee Warrant is immediately exercisable and will expire five years from the date of issuance.

The shares of Common Stock issuable upon exercise of the Deposit Warrant and the Fee Warrant were offered and sold by us in a private placement and were subsequently registered for resale on our registration statement on Form S-3 (the "Perigrove Form S-3 Registration Statement") (which was initially filed with the SEC on July 18, 2024, and was declared effective on July 25, 2024 (File No. 333-280882)).

On September 17, 2024, we entered into the Satisfaction Agreement with FSF Lender and Endeavor, pursuant to which the remaining obligations in respect of the FSF Deposit shall be fully satisfied by our delivery of 28,000 cartons of ZTlido to Endeavor (the "Additional Product"), which delivery shall occur no later than December 31, 2024. Upon satisfaction of such remaining obligations, the Commitment Letter shall be terminated and of no further force or effect and neither FSF Lender nor we shall have any further liability or obligations thereunder. In consideration of Endeavor assuming our payment obligation in respect of the FSF Deposit, Endeavor will not be responsible for making any payment to us for (i) the product already delivered as of the date of such agreement in an amount of approximately $13.2 million and (ii) the Additional Product. In November 2024, we delivered the Additional Product to Endeavor and fully satisfied the remaining obligations in respect of the FSF Deposit.

Tranche B Notes

On October 8, 2024, we entered into a securities purchase agreement (the "Tranche B Securities Purchase Agreement") with certain institutional investors (collectively, the "Tranche B Investors") and Oramed (together with the Tranche B Investors, the "Tranche B Noteholders"), to refinance a portion of the Oramed Note and pay off certain other indebtedness. Pursuant to the Tranche B Securities Purchase Agreement, we agreed to issue and sell, in a registered offering directly to the Tranche B Noteholders: (i) a new tranche B of senior secured convertible notes in the aggregate principal amount of $50.0 million (the "Tranche B Notes"), which notes will mature on the two-year anniversary of the issuance date and will be convertible into shares of our Common Stock at a conversion price equal to $1.09 per share (which was automatically reduced to $1.04 per share of Common Stock subsequent to the December 2024 RDO (as defined below) in accordance with the terms of such notes) and (ii) warrants (the "October 2024 Noteholder Warrants") to purchase up to 7,500,000 shares of our Common Stock directly to the Tranche B Noteholders.

We received in exchange for the issuance of the Tranche B Notes to the Tranche B Investors an aggregate amount in cash of $22,500,000, excluding fees and expenses payable by us. We received from Oramed in consideration for the Tranche B Notes issued to Oramed an exchange and reduction of the principal balance under the Oramed Note of $22,500,000.

The October 2024 Noteholder Warrants are immediately exercisable for cash at an exercise price equal to $1.09 per share of Common Stock (which was automatically reduced to $1.04 per share of Common Stock subsequent to the December 2024 RDO (as defined below) in accordance with the terms of such warrants) and will expire five years from the issuance date. The October 2024 Noteholder Warrants issued to the Tranche B Investors are initially exercisable for 3,750,000 shares of Common Stock in the aggregate. The October 2024 Noteholder Warrants issued to Oramed are initially exercisable for 3,750,000 shares of Common Stock.

Pursuant to the terms and conditions contained in the Tranche B Securities Purchase Agreement, we also agreed to reimburse the Tranche B Investors for all reasonable costs and expenses incurred by it or its affiliates in connection with the Tranche B Securities Purchase Agreement, the Tranche B Notes, the October 2024 Noteholder Warrants, the ZTlido Royalty Purchase Agreement (as defined below) and certain other transaction documents, and an aggregate amount of $950,000 non-accountable legal fees of outside counsel and special finance and collateral counsel, which shall be withheld by the Tranche B Investors from its purchase price at the closing of the transaction, less $20,000 previously paid by us. We shall also be responsible for the payment of a $2,000,000 fee to the placement agent in addition to the payment of any placement agent's reasonable fees, financial advisory fees relating to or arising out of the transactions contemplated by the Tranche B Securities Purchase Agreement. In addition, in conjunction with and pursuant to the letter agreement we entered into with Oramed, dated as of October 2, 2025 (the "Tranche B Letter Agreement"), we are also responsible for the payment of legal fees of outside counsel for Oramed relating to or arising out of the transactions contemplated hereby and the payment date extensions described under the Tranche B Letter Agreement. We shall also be responsible for the payment of any fees of the Agent and the legal fees incurred thereby relating to or arising out of the transactions contemplated by the Tranche B Securities Purchase Agreement.

In connection with the offering of the Tranche B Notes, we issued to StockBlock Securities LLC ("StockBlock") and its affiliate, Rodman & Renshaw LLC (the "Placement Agents") or their respective designees, (i) 2,197,802 shares of Common Stock (the "Placement Agent Shares") and (ii) Placement Agent Warrants to purchase up to 3,669,724 shares of Common Stock (the "October 2024 Placement Agent Warrants"). The Placement Agent Shares were subject to a 120-day lock-up, which is now expired. In addition, during such 120-day period, the Placement Agents (whether directly or indirectly through their respective affiliates) shall be prohibited from hedging, pledging or similar transactions and from short-selling our securities, subject to certain exceptions. The October 2024 Placement Agent Warrants will have the same terms as the October 2024 Noteholder Warrants, except that the Placement Agents have agreed not to exercise the October 2024 Placement Agent Warrants for a period of 180 days following the date of issuance.

December 2024 Registered Direct Offering

On December 11, 2024, we entered into a securities purchase agreement (the "December 2024 RDO Purchase Agreement") with the investors named therein, pursuant to which we agreed to sell and issue, in a registered direct offering (the "December 2024 RDO"): (i) an aggregate of 26,355,347 shares of Common Stock, (ii) pre-funded warrants to purchase up to 2,401,132 shares of Common Stock (the "December 2024 RDO Pre-Funded Warrants") and (iii) common warrants to purchase up to 57,512,958 shares of Common Stock (the "December 2024 RDO Common Warrants" and together with the December 2024 RDO Pre-Funded Warrants and the warrants issued to StockBlock pursuant to certain contractual obligations between us and StockBlock (the "StockBlock Warrants"), the "December 2024 RDO Warrants"). The combined offering price (a) per share of Common Stock and accompanying December 2024 RDO Common Warrants was $0.59 and (b) per Pre-Funded Warrant and accompanying December 2024 RDO Common Warrants was $0.5899. We received approximately $17.0 million in gross proceeds from the December 2024 RDO, before deducting offering fees and expenses. We intend to use the net proceeds from the December 2024 RDO for working capital and general corporate purposes, which may include capital expenditures, commercialization expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, business combinations and the repayment, refinancing, redemption or repurchase of indebtedness or capital stock.

Amendment to Common Stock Purchase Warrant

On December 11, 2024, we entered into a warrant amendment (the "Warrant Amendment") with one of the investors to exercise the outstanding amount of certain warrants that we issued to such investor in the February 2024 BDO on March 5, 2024. Pursuant to the Warrant Amendment, the investor agreed to exercise outstanding warrants to purchase an aggregate of 1,764,706 shares of Common Stock in cash at an amended exercise price of $0.59 per share. The gross proceeds to us from such exercise was approximately $1.0 million.

Future Liquidity Needs

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 costs and expenses associated with our ongoing commercialization efforts for ZTlido, GLOPERBA and ELYXYB;
- the degree of success we experience in commercializing ZTlido, GLOPERBA and ELYXYB;
- the revenue generated by sales of ZTlido, GLOPERBA, ELYXYB and other products that may be approved, if any;
- the scope, progress, results and costs of conducting studies and clinical trials for our product candidates, SEMDEXA, SP-103 and SP-104;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the costs of manufacturing ZTlido, GLOPERBA, ELYXYB and our product candidates;
- 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 ZTlido, GLOPERBA, ELYXYB or any of our product candidates, 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 we develop and commercialize;
- any product liability or other lawsuits related to our products;
- 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;
- the costs related to servicing of our debt; and
- the extent and scope of our general and administrative expenses.

Should our sales of ZTlido, GLOPERBA, ELYXYB and other product candidates 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 and debt financings and license agreements.

In addition to the liquidity provided by revenue generating products and the issuance of the Common Stock under the ATM Sales Agreement, the February 2024 BDO Underwriting Agreement, the April 2024 RDO Purchase Agreement, the Tranche B Securities Purchase Agreement and the December 2024 RDO Purchase Agreement, as of December 31, 2024, we will receive up to an aggregate of approximately $74.4 million from the exercise of the Private Warrants and public warrants to purchase Common Stock (the "Public Warrants", and together with the Private Warrants, the " SPAC Warrants") (at an exercise price of $11.50 per share of Common Stock), assuming the exercise in full of all of the SPAC Warrants for cash, but will not receive any proceeds from the sale of the shares of our Common Stock issuable upon such exercise. However, our ability to generate proceeds will depend on the market price of our Common Stock. If the price of our Common Stock remains below $11.50 per share, we believe warrant holders will be unlikely to cash exercise their SPAC Warrants, resulting in little or no cash proceeds to us. To the extent any of the February 2024 BDO Firm Warrants, February 2024 BDO Representative Warrants, April 2024 RDO Common Warrants, April 2024 RDO Placement Agent Warrants, Deposit Warrant, October 2024 Noteholder Warrants, October 2024 Placement Agent Warrants, December 2024 RDO Common Warrants and StockBlock Warrants is exercised, we will receive additional proceeds.

We can give no assurances 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 or as we have done pursuant to the Oramed Note and the Tranche B Notes, it could result in dilution to our existing stockholders or increased fixed payment obligations. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we incur additional 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 additional 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 ZTlido, GLOPERBA, ELYXYB, or our product candidates 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 reduce the scope of the commercialization of ZTlido, GLOPERBA or ELYXYB or delay, scale back or discontinue the development of one or more of our product candidates.

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, sales and marketing costs, suspension or winding down of clinical development programs for SP-102, SP-103 and SP-104 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 candidates, 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 2 titled "*Liquidity and Going Concern*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information. Our existing cash and cash equivalents may be insufficient to enable us to fund our operating expenses, capital expenditure requirements, and to service our debt obligations (whether under the Oramed Note, the Tranche B Notes or otherwise) 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.

Cash Flows

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

	Year Ended December 31,	
	2024	**2023**
Cash Flow Data:		
Net cash proceeds from (used for) operating activities	$ 19,349	$ (20,707)
Net cash used for investing activities	(2,675)	(330)
Net cash (used for) proceeds from financing activities	(18,131)	23,582
Net change in cash, cash equivalents and restricted cash	$ (1,457)	$ 2,545

Cash Flows from Operating Activities

For the year ended December 31, 2024, net cash proceeds from operating activities was approximately $19.3 million, attributable to non-cash reconciling items of $27.3 million related to allocated expense for financial instruments at fair value, stock-based compensation, change in fair value of debt and liability instruments, allowances for expected credit losses, depreciation and amortization, non-cash operating lease cost and gain on derivative liabilities, and changes in operating assets and liabilities that provided $64.8 million of cash, partially offset by our net loss of $72.8 million.

For the year ended December 31, 2023, net cash used for operating activities was approximately $20.7 million, attributable to our net loss of $114.3 million, partially offset by other non-cash reconciling items of $27.9 million related to loss on derivative liabilities, stock-based compensation, change in fair value of debt and liability instruments, depreciation and amortization and non-cash operating lease cost, and changes in operating assets and liabilities that provided $65.7 million of cash.

Cash Flows from Investing Activities

For the year ended December 31, 2024, net cash used for investing activities was approximately $2.7 million and was related to $0.6 million payments of deferred consideration for Romeg intangible asset acquisition under the Romeg License Agreement, $2.0 million purchase of the Class B ordinary shares of Denali and $0.1 million purchase of a convertible promissory note from Denali (see Note 5 titled "*Balance Sheet Components*" to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information).

For the year ended December 31, 2023, net cash used for investing activities was approximately $0.3 million, related to payments of deferred consideration for Romeg intangible asset acquisition and $30.0 thousand attributed to cash paid for property and equipment purchases.

Cash Flows from Financing Activities

For the year ended December 31, 2024, net cash used for financing activities was approximately $18.1 million and is primarily related to the repayment of an aggregate of $184.6 million of borrowings under the Revolving Facility, the Oramed Note, the Convertible Debentures and the Tranche B Notes, the payment of an aggregate of $4.4 million of transaction costs related to the February 2024 BDO, the April 2024 RDO and the December 2024 RDO, the payment of an aggregate of $4.2 million of transaction cost related to the Tranche B Notes and the ZTlido Royalty Purchase Agreement, a $1.4 million payment of deferred transaction costs related to the Semnur Business Combination, a $0.5 million payment of excise tax on stock repurchases, and a payment of $0.3 million cash in consideration of the repurchase of a certain portion of the SPAC Warrants, partially offset by $95.5 million in gross proceeds from the Revolving Facility, an aggregate of $42.0 million in gross proceeds from the issuance of shares under the February 2024 BDO, April 2024 RDO, December 2024 RDO and the exercise of the February 2024 BDO Firm Warrants, an aggregate of $25.0 million in gross proceeds from issuance of Tranche B Notes and ZTlido Royalty Purchase Agreement, $10.0 million in proceeds from receiving the FSF Deposit, an aggregate of $2.7 million in proceeds from the Standby Equity Purchase Agreements and the ATM Sales Agreement and an aggregate of $2.1 million in proceeds from the exercise of stock options and warrants and purchases under the ESPP.

For the year ended December 31, 2023, net cash provided by financing activities was approximately $23.6 million and is primarily related to $86.4 million in gross proceeds from the Revolving Facility between Scilex Pharma and eCapital Healthcare Corp., $35.5 million in proceeds from the Standby Equity Purchase Agreements, $24.0 million in proceeds from the Convertible Debentures and $1.1 million in proceeds from the exercise of stock options and warrants, partially offset by $89.6 million repayment of the borrowings under the Revolving Facility, Convertible Debentures, and Oramed Note, $20.0 million capital distribution to Sorrento, $10.0 million cash consideration paid for the securities purchased by the Company from Sorrento under the Sorrento SPA, $2.0 million payment of the transaction costs related to the Scilex-Oramed SPA and the Sorrento SPA and $1.8 million payment of the transaction costs related to the Business Combination and debt issuance costs.

Critical Accounting Estimates

This management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements which are prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the reported amounts of revenue and expenses during the reporting period. We continually evaluate our estimates and judgments and base them on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

We believe the following accounting policies and estimates are most critical to aid in understanding and evaluating our reported financial results.

Revenue Recognition

Our revenue to date has been generated from product sales of ZTlido, ELYXYB and GLOPERBA in the United States. We do not have significant costs associated with obtaining contracts with our customers.

We recognize revenue when control of the products is transferred to the customers in an amount that reflects the consideration we expect to receive from the customers in exchange for those products. In accordance with FASB ASC Topic 606 "*Revenue from Contracts with Customers*", this process involves identifying the contract with a customer, determining the performance obligations in the contract and the contract price, allocating the contract price to the distinct performance obligations in the contract and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once we have transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. We recognize revenue for satisfied performance obligations only when we determine there are no uncertainties regarding payment terms or transfer of control.

Our performance obligations with respect to sales of ZTlido, ELYXYB and GLOPERBA are satisfied at a certain point in time, and we consider control to have transferred upon delivery to the customer, because, upon delivery, the customer has legal title to the asset, physical possession of the asset has been transferred to the customer, the customer has significant risks and rewards in connection with

ownership of the asset, and we have a present right to payment from the customer at that time. Invoicing typically occurs upon shipment and the length of time between invoicing and the date on which payment is due is not significant.

Revenues from product sales are recorded net of reserves established for commercial and government rebates, fees, and chargebacks, wholesaler and distributor fees, sales returns and prompt payment discounts. Such variable consideration is estimated in the period of the sale and is estimated using a most likely amount approach based primarily upon provisions included in our customer contracts, customary industry practices and current government regulations.

Rebates and Chargebacks

Rebates are discounts that we pay under either government or private health care programs. Government rebate programs include state Medicaid drug rebate programs, the Medicare coverage gap discount programs and the Tricare programs. Commercial rebate and fee programs relate to contractual agreements with commercial healthcare providers, under which we pay rebates and fees for access to and position on that provider's patient drug formulary. Rebates and chargebacks paid under government programs are generally mandated under law, whereas private rebates and fees are generally contractually negotiated with commercial healthcare providers. Both types of rebates vary over time. We record a reduction to gross product sales at the time the customer takes title to the product based on estimates of expected rebate claims. We monitor the sales trends and adjust for these rebates on a regular basis to reflect the most recent rebate experience and contractual obligations. Reserves for rebates and chargebacks are recorded as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Prompt Payment Discounts

We provide our customers with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. The prompt payment discount reserve is based on actual gross sales and contractual discount rates. Reserves for prompt payment discounts are included in accounts receivable, net on the consolidated balance sheets.

Service Fees

We compensate our customers and others in the distribution chain for wholesaler and distribution services. The Company has determined such services received are not distinct from our sale of products to the customers, and therefore, these payments have been recorded as a reduction of revenue. Service fees are presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Product Returns

We are obligated to accept the return of products sold that are damaged or do not meet certain specifications. We currently estimate our product returns using historical trends and product return rates typically experienced in the industry and record this estimate as a reduction of revenue in the period the related product revenue is recognized. Product returns are presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Co-payment Assistance

Patients who have commercial insurance or pay cash and meet certain eligibility requirements may receive co- payment assistance. We accrue for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators. Co-payment assistance is presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Derivative Liability

Derivative liabilities are recorded on our consolidated balance sheets at their fair value on the date of issuance and are revalued on each balance sheet date until such instruments are exercised or expire, with changes in the fair value between reporting periods recorded as other income or expense. The warrant liability associated with the Private Warrants, the February 2024 BDO Firm Warrants, the April 2024 RDO Common Warrants, the Deposit Warrant, the October 2024 Noteholder Warrants and the December 2024 RDO Common Warrants was valued using the Black-Scholes option pricing model, which is considered to be Level 3 fair value measurement. The primary unobservable input utilized in determining the fair value of the warrants is the expected volatility of the Common Stock. The expected volatility assumption is a blend of our own stock volatility and historical volatilities of comparable companies whose share prices are publicly available as well as the implied volatility of the Public Warrants.

Stock-Based Compensation

We account for stock-based compensation in accordance with FASB ASC Topic 718 "*Compensation – Stock Compensation*", which establishes accounting for equity instruments exchanged for employee and consulting services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense, under the straight-line-method, over the employee's requisite service period (generally the vesting period of the equity grant) or non-employee's vesting period. We account for forfeitures as incurred.

For purposes of determining the inputs used in the calculation of stock-based compensation, 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. Then the Company determines an estimate of option volatility based on an assessment of historical volatilities of comparable companies whose share prices are publicly available. We use these estimates as variables in the Black-Scholes option pricing model. Depending upon the number of stock options granted, any fluctuations in these calculations could have a material effect on the results presented in our consolidated statements of operations and comprehensive loss.

Convertible Debentures, the Oramed Note, Tranche B Notes and Purchased Revenue Liability

We elected the fair value option to account for the Convertible Debentures in an aggregate principal amount of up to $25.0 million that were issued in March and April 2023, the Oramed Note in the principal amount of $101.9 million that was issued in September 2023, Tranche B Notes in the principal amount of $50.0 million that were issued in October 2024 and purchased revenue liability pursuant to the ZTlido Royalty Purchase Agreement. The Convertible Debentures, the Oramed Note, the Tranche B Notes and the purchased revenue liability are discussed in Note 7 titled "*Debt"* of the Notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. These instruments are measured at fair value on a recurring basis using Level 3 inputs. We employ the Binomial Lattice Model valuation technique to measure the fair value of the Convertible Debentures and Tranche B Notes, a Scenario-Based Method valuation technique to measure the fair value of the purchased revenue liability, and a discounted cash flow model to measure the fair value of the Oramed Note, respectively, with any changes in fair value recorded as change in fair value of debt and liability instruments in the consolidated statements of operations, except for changes due to instrument-specific credit risk, if any, which are recorded as a component of other comprehensive income. Interest expense related to these financial instruments is included in the changes in fair value.

Recent Accounting Pronouncements

See Note 1 titled "*Nature of Operations and Basis of Presentation*" of the Notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a discussion of recent accounting pronouncements.

Emerging Growth Company

An "emerging growth company" as defined in Section 2(a) of the Securities Act, as modified by 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 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 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 Scilex'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.

Scilex 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 IPO, (b) in which Scilex has total annual gross revenue of at least $1.235 billion, or (c) in which Scilex is deemed to be a large accelerated filer, which means the market value of the common equity of Scilex 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 Scilex 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. Scilex qualifies and will remain a smaller reporting company until the last day of the fiscal year in which (i) Scilex 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) Scilex 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 on Form 10-K.

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.

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 on Form 10-K.

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

On November 19, 2024, our Audit Committee approved the dismissal of Ernst & Young LLP as our independent registered public accounting firm, effective immediately. On December 5, 2024, our Audit Committee approved the appointment of BPM LLP as our new independent registered public accounting firm, effective immediately, for the quarter ended September 30, 2024 and the fiscal year ending December 31, 2024. Disclosures with respect to this Item 9 were previously included in our Current Reports on Form 8-K filed on November 22, 2024 and December 6, 2024 with the SEC. We are not aware of any transactions or events similar to those previously reported and described in our prior disclosures with respect to this Item, which were accounted for or disclosed in a manner different from that which our former accountants apparently would have concluded was required. Accordingly, we believe it is not required to make any further disclosure under Item 304(b) of Regulation S-K.

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 on Form 10-K. 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 on Form 10-K.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate ICFR as defined in Rules 13a-15(f) under the Exchange Act. Our ICFR 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 ICFR as of December 31, 2024,

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 ICFR was effective as of December 31, 2024.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on our ICFR. Management's report was not subject to attestation by the Company's 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 on Form 10-K.

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 have been no changes in our ICFR (as defined by Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our ICFR.

Item 9B. Other Information.

During the fourth quarter ended December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 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 2025 Annual Meeting of Stockholders (the "2025 Proxy Statement"), which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2025 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 10.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from the information contained in the 2025 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2025 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 11.

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 2025 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2025 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 12.

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 2025 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2025 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 13.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference from the information contained in the 2025 Proxy Statement, which we expect to file not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K. To the extent that we do not file the 2025 Proxy Statement by such date, we will file an amendment to this Annual Report on Form 10-K that includes the information required by this Item 14.

PART IV
Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

Reference is made to the Index to Consolidated Financial Statements of Scilex Holding Company appearing on page F-1 of this Annual Report on Form 10-K.

(a)(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.

(a)(3) Exhibits

Exhibit Number	Description
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. (incorporated by reference to Exhibit 2.1 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
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. (incorporated by reference to Exhibit 2.2 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on October June 27, 2022).
2.3#	Bill of Sale and Assignment and Assumption Agreement, dated May 12, 2022, by and between Scilex Holding Company and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 2.3 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
2.4^#	Asset Purchase Agreement, dated April 23, 2021, between Sorrento Therapeutics, Inc. and Aardvark Therapeutics, Inc., as assumed by Scilex Holding Company on May 12, 2022, pursuant to the Bill of Sale and Assignment and Assumption Agreement, dated as of such date, by and between Scilex Holding Company and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 2.4 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
2.5#	Agreement and Plan of Merger, dated as of March 17, 2022, by and among Vickers Vantage Corp. I, Vickers Merger Sub, Inc. and Scilex Holding Company (incorporated by reference to Exhibit 2.1 of Vickers's Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 21, 2022).
2.6#	Amendment No. 1 to Agreement and Plan of Merger, dated as of September 12, 2022, by and among Vickers Vantage Corp. I, Vickers Merger Sub, Inc. and Scilex Holding Company (incorporated by reference to Exhibit 2.1 of Vickers's Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 14, 2022).
2.7#	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. (incorporated by reference to Exhibit 2.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 3, 2024).
3.1	Restated Certificate of Incorporation of Scilex Holding Company (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
3.2	Certificate of Designations of Scilex Holding Company (incorporated by reference to Exhibit 3.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series 1 Mandatory Exchangeable Preferred Stock of Scilex Holding Company (incorporated by reference to Exhibit 3.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 28, 2024).

Exhibit Number	Description
3.4	Bylaws of Scilex Holding Company (incorporated by reference to Exhibit 3.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
4.1	Warrant Agreement, dated as of January 6, 2021, by and between Vickers Vantage Corp. I and Continental Stock Transfer & Trust Company (incorporated by reference to Exhibit 4.1 of Vickers's Current Report on Form 8-K (File No. 001-39852), filed with the SEC on January 11, 2021).
4.2	Specimen Warrant Certificate of Scilex Holding Company (f/k/a Vickers Vantage Corp. I) (incorporated by reference to Exhibit 4.3 of Vickers's Form S-1 (File No. 333-251352), filed with the SEC on December 15, 2020).
4.3	Senior Secured Promissory Note issued to Oramed Pharmaceuticals, Inc. on September 21, 2023 (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
4.4	Form of Scilex Holding Company Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
4.5	Form of Common Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 5, 2024).
4.6	Form of Representative Warrant (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 5, 2024).
4.7	Form of Common Warrant (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on April 25, 2024).
4.8	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on April 25, 2024).
4.9	Warrant to Purchase Common Stock, issued to FSF 33433 LLC on June 18, 2024 (incorporated by reference to Exhibit 4.8 of our Registration Statement on Form S-3 (File No. 333-280882), filed with the SEC on July 18, 2024).
4.10	Form of Tranche B Senior Secured Convertible Note issued by Scilex Holding Company. (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
4.11	Form of Warrant to Purchase Common Stock issued by Scilex Holding Company. (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
4.12	Form of Placement Agent Warrant issued by Scilex Holding Company (incorporated by reference to Exhibit 4.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
4.13	Form of Pre-Funded Warrant issued by Scilex Holding Company (incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 13, 2024).
4.14	Form of Common Warrant issued by Scilex Holding Company (incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 13, 2024).
4.15	Form of StockBlock Warrant issued by Scilex Holding Company (incorporated by reference to Exhibit 4.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 13, 2024).
4.16+	Description of Securities of Scilex Holding Company.
10.1*	Form of Indemnification Agreement of Scilex Holding Company (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
10.2*	Scilex Pharmaceuticals, Inc. Amended and Restated 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).

Exhibit Number	Description
10.3*	Form of Option Agreement and Stock Option Grant Notice under the Scilex Pharmaceuticals Inc. 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.4*	Scilex Holding Company 2019 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.9 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.5*	Form of Option Agreement and Stock Option Grant Notice under the Scilex Holding Company 2019 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.10 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.6*	Scilex Holding Company 2022 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on May 5, 2023).
10.7*	Form of Stock Option Grant Notice and Stock Option Agreement under the Scilex Holding Company 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
10.8*	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the Scilex Holding Company 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
10.9*	Scilex Holding Company 2022 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
10.10*	Scilex Holding Company 2023 Inducement Plan (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on January 17, 2023).
10.11*	Form of Stock Option Grant Notice and Stock Option Agreement under the Scilex Holding Company 2023 Inducement Plan (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on January 17, 2023).
10.12*	Form of Restricted Stock Unit Award Grant Notice and Award Agreement under the Scilex Holding Company 2023 Inducement Plan (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on January 17, 2023).
10.13*	Offer Letter, dated as of April 19, 2019, between Scilex Pharmaceuticals Inc. and Jaisim Shah (incorporated by reference to Exhibit 10.17 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.14^	Office Lease, dated as of August 8, 2019, by and between Scilex Pharmaceuticals Inc. and 960 San Antonio LLC (incorporated by reference to Exhibit 10.59 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.15^	First Amendment to Office Lease, dated as of September 15, 2019, by and between Scilex Pharmaceuticals Inc. and 960 San Antonio LLC (incorporated by reference to Exhibit 10.60 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.16^	Amended and Restated Industrial Lease, dated as of April 12, 2023, by and between Scilex Pharmaceuticals, Inc. and 960 San Antonio LLC (incorporated by reference to Exhibit 10.39 of Amendment No. 4 of Scilex's Form S-1 (File No. 333-271401), filed with the SEC on June 29, 2023).
10.17^	Commercial Supply Agreement, dated as of February 16, 2017, by and among Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.22 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.18^	First Addendum to Commercial Supply Agreement, dated as of August 31, 2017, by and among Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.23 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.19^	Second Addendum to Commercial Supply Agreement, dated as of May 9, 2018, by and among Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by

Exhibit Number	Description
	reference to Exhibit 10.24 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.20	Third Addendum to Commercial Supply Agreement, dated as of August 30, 2018, by and among Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.25 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.21#	Exclusive Distribution Agreement, dated as of August 6, 2015, by and among Scilex Pharmaceuticals Inc. and Cardinal Health 105, Inc. (incorporated by reference to Exhibit 10.26 of Amendment No. 4 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on September 13, 2022).
10.22	Amendment to Exclusive Distribution Agreement, dated as of May 24, 2018, by and among Scilex Pharmaceuticals Inc. and Cardinal Health 105, Inc. (incorporated by reference to Exhibit 10.27 of Amendment No. 4 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on September 13, 2022).
10.23#	Second Amendment to Exclusive Distribution Agreement, dated as of September 19, 2018, by and among Scilex Pharmaceuticals Inc. and Cardinal Health 105, Inc. (incorporated by reference to Exhibit 10.28 of Amendment No. 4 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on September 13, 2022).
10.24	Third Amendment to Exclusive Distribution Agreement, dated as of October 1, 2021, by and among Scilex Pharmaceuticals Inc. and Cardinal Health 105, LLC (f/k/a Cardinal Health 105, Inc.). (incorporated by reference to Exhibit 10.29 of Amendment No. 4 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on September 13, 2022).
10.25^	Product Development Agreement, dated as of May 11, 2011, by and between Scilex Pharmaceuticals, Inc. (as successor to Stason Pharmaceuticals, Inc.), Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation. (incorporated by reference to Exhibit 10.34 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.26	First Amendment to Product Development Agreement, dated as of April 2, 2013, by and between Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.35 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.27^	Second Amendment to Product Development Agreement, dated as of February 20, 2017, by and between Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.36 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.28^	Third Amendment to Product Development Agreement, dated as of August 29, 2018, by and between Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.37 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.29	Fourth Amendment to Product Development Agreement, dated as of December 13, 2019, by and between Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.38 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.30	Fifth Amendment to Product Development Agreement, dated as of April 30, 2021, by and between Scilex Pharmaceuticals Inc., Oishi Koseido Co., Ltd. and Itochu Chemical Frontier Corporation (incorporated by reference to Exhibit 10.39 of Amendment No. 2 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on July 21, 2022).
10.31#^	Master Services Agreement - SP-102, dated as of January 27, 2017, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC (incorporated by reference to Exhibit 10.40 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.32	Amendment No. 1 to Master Services Agreement, dated as of April 26, 2018, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC (incorporated by reference to Exhibit 10.41 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).

Exhibit Number	Description
10.33^+	Second Amendment to Master Services Agreement, dated as of June 6, 2023, by and between Semnur Pharmaceuticals, Inc. and Lifecore Biomedical, LLC.
10.34	Novation Agreement re Master Services Agreement, dated as of June 15, 2022, by and among Scilex Holding Company, Tulex Pharmaceuticals Inc. and Aardvark Therapeutics Inc. (incorporated by reference to Exhibit 10.42 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.35#	Master Services Agreement, dated as of November 23, 2020, by and between Aardvark Therapeutics Inc. and Tulex Pharmaceuticals Inc. as assumed by Scilex Holding Company on May 12, 2022, as novated to Scilex Holding Company, pursuant to the Novation Agreement re Master Services Agreement, dated as of June 15, 2022, by and among Scilex Holding Company, Tulex Pharmaceuticals Inc. and Aardvark Therapeutics Inc. (incorporated by reference to Exhibit 10.43 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.36#^	License and Commercialization Agreement, dated as of June 14, 2022, by and between Scilex Holding Company and RxOmeg Therapeutics LLC, a/k/a Romeg Therapeutics, LLC (incorporated by reference to Exhibit 10.44 of Amendment No. 1 of Vickers's Form S-4 (File No. 333-264941), filed with the SEC on June 27, 2022).
10.37+#^	First Amendment to License and Commercialization Agreement, dated as of January 16, 2025, by and between Scilex Holding Company and RxOmeg Therapeutics LLC, a/k/a Romeg Therapeutics, LLC.
10.38	Amended and Restated Registration Rights Agreement, dated as of November 10, 2022, by and among Scilex Holding Company, Vickers Venture Fund VI Pte Ltd, Vickers Venture Fund VI (Plan) Pte Ltd, Sorrento Therapeutics, Inc. and certain security holders set forth on the signature pages thereto (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on November 17, 2022).
10.39	Settlement Agreement, dated September 15, 2023, by and among Scilex Holding Company, Cove Lane Onshore Fund, LLC, HBC Investments LLC and Hudson Bay Capital Management LP (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 21, 2023).
10.40	Registration Rights Agreement, dated September 21, 2023, by and between Scilex Holding Company and Oramed Pharmaceuticals Inc. (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.41#	Securities Purchase Agreement, dated September 21, 2023, by and between Scilex Holding Company, Oramed Pharmaceuticals Inc. and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.42#	Amendment No. 1 to Securities Purchase Agreement, dated October 8, 2024, by and between Scilex Holding Company and Oramed Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.43#	Subsidiary Guarantee, dated September 21, 2023, made by certain of the Company's subsidiaries in favor of the holders of that certain Senior Secured Promissory Note dated as of the date thereof due March 21, 2025 in the original aggregate principal amount of $101,875,000 (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.44	Subsidiary Guarantee Amendment, dated October 8, 2024, made by certain of the Company's subsidiaries in favor of the holders of that certain Tranche A Note (incorporated by reference to Exhibit 10.7 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.45	Amended and Restated Security Agreement, dated October 8, 2024, by and among Scilex Holding Company, the Subsidiaries of the Company party thereto, Oramed Pharmaceuticals Inc. and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.8 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.46#	Stock Purchase Agreement, dated September 21, 2023, by and between Scilex Holding Company and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.47	Assignment, Assumption and Release Agreement, dated September 21, 2023, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc., Sorrento Therapeutics, Inc. and Scintilla Pharmaceuticals, Inc.

Exhibit Number	Description
	(incorporated by reference to Exhibit 10.7 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.48#	Letter Agreement, dated September 21, 2023, by and among Scilex Holding Company, Sorrento Therapeutics, Inc. and Scintilla Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.8 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.49#	Letter Agreement, dated September 21, 2023, by and between Scilex Holding Company and Sorrento Therapeutics, Inc. (incorporated by reference to Exhibit 10.9 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 26, 2023).
10.50#	Underwriting Agreement, dated February 29, 2024, among Scilex Holding Company, Rodman & Renshaw LLC and StockBlock Securities LLC. (incorporated by reference to Exhibit 1.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 5, 2024).
10.51*	Severance and Change of Control Agreement, dated as of November 8, 2023, by and between Jaisim Shah and Scilex Holding Company (incorporated by reference to Exhibit 10.12 of our Quarterly Report on Form 10-Q (File No. 001-39852), filed with the SEC on November 14, 2023).
10.52*	Severance and Change of Control Agreement, dated as of November 9, 2023, by and between Henry Ji and Scilex Holding Company (incorporated by reference to Exhibit 10.13 of our Quarterly Report on Form 10-Q (File No. 001-39852), filed with the SEC on November 14, 2023).
10.53*	Severance and Change of Control Agreement, dated as of November 8, 2023, by and between Stephen Ma and Scilex Holding Company (incorporated by reference to Exhibit 10.14 of our Quarterly Report on Form 10-Q (File No. 001-39852), filed with the SEC on November 14, 2023).
10.54	Settlement Agreement, dated February 29, 2024, by and between Scilex Pharmaceuticals Inc., Sorrento Therapeutics, Inc. and Virpax Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q (File No. 001-39852), filed with the SEC on May 13, 2024).
10.55	Form of Securities Purchase Agreement, dated April 23, 2024, by and between Scilex Holding Company and the purchaser party thereto. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on April 25, 2024).
10.56	Commitment Side Letter, dated June 11, 2024, by and between Scilex Holding Company and FSF 33433 LLC. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on June 12, 2024).
10.57^	Sponsor Support Agreement, dated as of August 30, 2024, by and among Denali Capital Acquisition Corp. and each of the Persons set forth on Schedule I attached thereto. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 3, 2024).
10.58#	Company Stockholder Support Agreement, dated as of August 30, 2024, by and among Scilex Holding Company, Semnur Pharmaceuticals, Inc. and Denali Capital Acquisition Corp. (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 3, 2024).
10.59#	Sponsor Interest Purchase Agreement, dated as of August 30, 2024, by and between Denali Capital Global Investments LLC and Scilex Holding Company. (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 3, 2024).
10.60#	Contribution and Satisfaction of Indebtedness Agreement, dated as of August 30, 2024 by and between Scilex Holding Company and Semnur Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 3, 2024).
10.61	Stockholder Agreement, dated as of August 30, 2024, by and between Denali Capital Acquisition Corp. and Scilex Holding Company (incorporated by reference to Exhibit 10.5 of our Current Report on Form 8-K (File No.001-39852), filed with the SEC on September 3, 2024).

Exhibit Number	Description
10.62	Satisfaction Agreement, dated as of September 17, 2024, by and among Endeavor Distribution LLC, FSF 33433 LLC and Scilex Holding Company. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 18, 2024).
10.63	Letter Agreement, dated as of September 20, 2024, by and between Oramed Pharmaceuticals Inc. and Scilex Holding Company. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on September 23, 2024).
10.64#	Securities Purchase Agreement, dated October 7, 2024, by and between Scilex Holding Company and the investors signatory thereto (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.65#	Purchase and Sale Agreement, dated October 8, 2024, by and among Scilex Holding Company, Silex Pharmaceuticals Inc. and the purchasers signatory thereto (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.66	Amendment No. 1 to Purchase and Sale Agreement, dated February 28, 2025, by and among Scilex Holding Company, Scilex Pharmaceuticals Inc., Oramed Pharmaceuticals Inc. and the other signatories thereto (incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on March 3, 2025).
10.67#	Security Agreement, dated October 8, 2024, by and among Scilex Pharmaceuticals Inc., and the purchasers signatory thereto (incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.68	Subordination Agreement, dated October 8, 2024, by and among Scilex Pharmaceuticals Inc., Acquiom Agency Services LLC and other signatories thereto (incorporated by reference to Exhibit 10.5 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on October 8, 2024).
10.69	License Agreement (ZTlido), dated February 22, 2025, by and between Scilex Pharmaceuticals Inc. and Royaltyvest Ltd. (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on February 27, 2025).
10.70	Parent Guarantee for Lidocaine License Agreement, dated February 22, 2025, by and between Scilex Holding Company and Royaltyvest Ltd. (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on February 27, 2025).
10.71	Consent under Securities Purchase Agreement and Senior Secured Promissory Note, dated December 9, 2024, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc., SCLX Stock Acquisition JV LLC and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 10. 2024).
10.72	Consent under Securities Purchase Agreement and Tranche B Senior Secured Convertible Note, dated December 9, 2024, by and among Scilex Holding Company, Nomis Bay Ltd, BPY Limited, SCLX Stock Acquisition JV LLC and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 10, 2024).
10.73	Consent under Securities Purchase Agreement and Tranche B Senior Secured Convertible Note, dated December 9, 2024, by and among Scilex Holding Company, Oramed Pharmaceuticals Inc., SCLX Stock Acquisition JV LLC and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 10, 2024).
10.74	Consent under Securities Purchase Agreement and Tranche B Senior Secured Convertible Note, dated December 9, 2024, by and among Scilex Holding Company, 3i, LP, SCLX Stock Acquisition JV LLC and Acquiom Agency Services LLC (incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 10, 2024).

Exhibit Number	Description
10.75	Form of Securities Purchase Agreement, dated December 11, 2024, by and between the Company and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K (File No. 001-39852), filed with the SEC on December 13, 2024).
19.1	Scilex Holding Company Insider Trading Policy (incorporated by reference to Exhibit 19.1 of our Annual Report on Form 10-K (File No. 001-39852), filed with the SEC on March 12, 2024).
21.1	List of Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of our Form S-1 (File No. 333-275117), filed with the SEC on October 20, 2023).
23.1+	Consent of BPM LLP, independent registered public accounting firm.
24.1	Power of Attorney (included on the signature page hereto).
31.1+	Certification of Jaisim Shah, Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Stephen Ma, Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Jaisim Shah, Principal Executive Officer, and Stephen Ma, Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Scilex Holding Company Clawback Policy (incorporated by reference to Exhibit 97.1 of our Annual Report on Form 10-K (File No. 001-39852), filed with the SEC on March 12, 2024).
101.INS+	Inline XBRL Instance Document.
101.SCH+	Inline XBRL Taxonomy Extension Schema Document.
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB+	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE+	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104+	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

***** Indicates management contract or compensatory plan or arrangement.

+ Filed herewith.

^ 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.

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.

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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

March 31, 2025

Scilex Holding Company

By: /s/ Jaisim Shah

Jaisim Shah
Chief Executive Officer and President
(Principal Executive Officer)

March 31, 2025

By: /s/ Stephen Ma

Stephen Ma
Chief Financial Officer
(Principal Financial 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 on Form 10-K, 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, this report has been signed below by the following persons on behalf of the Registrant and 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)*	March 31, 2025
/s/ Stephen Ma Stephen Ma	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 31, 2025
/s/ Henry Ji, Ph.D. Henry Ji, Ph.D.	Executive Chairperson and Director	March 31, 2025
/s/ Dorman Followwill Dorman Followwill	Director	March 31, 2025
/s/ Jay Chun Jay Chun, M.D., Ph.D.	Director	March 31, 2025
/s/ Yue Alexander Wu Yue Alexander Wu, Ph.D.	Director	March 31, 2025
/s/ Annu Navani Annu Navani, M.D.	Director	March 31, 2025

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and stockholders of
Scilex Holding Company

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Scilex Holding Company and Subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, stockholders' equity/(deficit), and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of their operations and cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. 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 audits 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 consolidated 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 audits 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 entity's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BPM LLP
We have served as the Company's auditor since 2024.

Walnut Creek, California
March 31, 2025

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

SCILEX HOLDING COMPANY
CONSOLIDATED BALANCE SHEETS
(In thousands, except for par value and share amounts)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,272	$ 3,921
Accounts receivable, net	26,442	34,597
Inventory	2,436	4,214
Prepaid expenses and other current assets	9,397	4,049
Total current assets	41,547	46,781
Property and equipment, net	708	722
Operating lease right-of-use asset	2,225	2,943
Intangibles, net	32,453	36,485
Investments	2,420	—
Goodwill	13,481	13,481
Other long-term assets	119	897
Total assets	$ 92,953	$ 101,309
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 52,620	$ 40,954
Accrued payroll	1,505	2,681
Accrued rebates and fees	162,517	89,658
Accrued expenses	2,841	7,408
Current portion of deferred consideration	447	491
Debt, current	34,876	108,429
Purchased revenue liability, current	4,115	—
Current portion of operating lease liabilities	714	759
Total current liabilities	259,635	250,380
Long-term portion of deferred consideration	2,448	2,895
Debt, net of issuance costs	845	17,038
Purchased revenue liability, net of current portion	2,685	—
Derivative liabilities	18,303	1,518
Operating lease liabilities, net of current portion	1,523	2,237
Other long-term liabilities	155	179
Total liabilities	285,594	274,247
Commitments and contingencies (See Note 11)		
Stockholders' deficit:		
Preferred stock, $0.0001 par value, 45,000,000 shares authorized		
Series A, 29,057,097 shares issued and outstanding as of each of December 31, 2024 and December 31, 2023	—	—
Series 1, 5,000,000 shares declared as a stock dividend, not yet distributed as of December 31, 2024; no shares authorized, issued and outstanding as of December 31, 2023	1	—
Common stock, $0.0001 par value, 740,000,000 shares authorized; 243,312,885 shares issued and 183,244,300 shares outstanding as of December 31, 2024; 160,084,250 shares issued and 100,015,665 shares outstanding as of December 31, 2023	24	16
Additional paid-in capital	454,591	407,813
Accumulated other comprehensive income	6,317	—
Accumulated deficit	(563,052)	(490,245)
Treasury stock, at cost; 60,068,585 shares as of each of December 31, 2024 and December 31, 2023	(90,522)	(90,522)
Total stockholders' deficit	(192,641)	(172,938)
Total liabilities and stockholders' deficit	$ 92,953	$ 101,309

See accompanying notes to audited consolidated financial statements

SCILEX HOLDING COMPANY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except for net loss per share amounts)

	Year Ended December 31,	
	2024	**2023**
Net revenue	$ 56,590	$ 46,743
Net operating costs and expenses:		
Cost of revenue	16,689	15,681
Research and development	9,641	12,746
Selling, general and administrative	119,016	119,641
Intangible amortization	4,031	4,106
Legal settlements	(9,391)	—
Total net operating costs and expenses	139,986	152,174
Loss from operations	(83,396)	(105,431)
Other (income) expense, net:		
(Gain) loss on derivative liability	(17,378)	512
Change in fair value of debt and liability instruments	4,782	7,189
Interest expense, net	1,963	1,068
Loss on foreign currency exchange	45	118
Total other (income) expense, net	(10,588)	8,887
Loss before income taxes	(72,808)	(114,318)
Income tax (benefit) expense	(1)	13
Net loss	$ (72,807)	$ (114,331)
Net loss per share attributable to common stockholders — basic	$ (0.56)	$ (1.28)
Net loss per share attributable to common stockholders — diluted	$ (0.61)	$ (1.28)
Weighted average number of shares during the period — basic	131,136	130,298
Weighted average number of shares during the period — diluted	134,075	130,298
Comprehensive loss:		
Net loss	$ (72,807)	$ (114,331)
Other comprehensive income:		
Changes in fair value attributable to instrument-specific credit risk	6,317	—
Total other comprehensive income	6,317	—
Comprehensive loss	$ (66,490)	$ (114,331)

See accompanying notes to audited consolidated financial statements

SCILEX HOLDING COMPANY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY / (DEFICIT)
(In thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Stock		Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2022	29,057	$ 3	141,349	$ 14	$ 412,136	$ —	$ (375,914)	—	$ —	$ 36,239
Shares issued under the Standby Equity Purchase Agreements	—	—	13,218	1	34,256	—	—	—	—	34,257
Disbursement of funds to Sorrento	—	—	—	—	(20,000)	—	—	—	—	(20,000)
Repurchase of Treasury Stock, Preferred Stock, and warrants	—	(3)	—	—	(53,196)	—	—	(60,069)	(90,522)	(143,721)
Issuance of Penny Warrants	—	—	—	—	10,401	—	—	—	—	10,401
Issuance of common stock in connection with Settlement Agreement	—	—	475	—	750	—	—	—	—	750
Conversion of Convertible Debentures into common stock	—	—	632	—	7,735	—	—	—	—	7,735
Retainer shares issued	—	—	4,000	1	—	—	—	—	—	1
Issuance of common stock upon warrants exercise	—	—	45	—	521	—	—	—	—	521
Stock options exercised	—	—	365	—	614	—	—	—	—	614
Stock-based compensation	—	—	—	—	14,596	—	—	—	—	14,596
Net loss	—	—	—	—	—	—	(114,331)	—	—	(114,331)
Balance, December 31, 2023	29,057	—	160,084	16	407,813	—	(490,245)	(60,069)	(90,522)	(172,938)
Shares issued under the Standby Equity Purchase Agreements and under the ATM Sales Agreement	—	—	2,861	—	2,671	—	—	—	—	2,671
Shares issued under the February 2024 BDO	—	—	5,882	1	3,768	—	—	—	—	3,769
Shares issued under the April 2024 RDO	—	—	15,000	1	5,918	—	—	—	—	5,919
April 2024 RDO Placement Agent Warrants and February 2024 BDO Representative Warrants	—	—	—	—	956	—	—	—	—	956
Retainer shares issued	—	—	10,000	1	—	—	—	—	—	1
Fee Warrant issued in connection with the Commitment Letter	—	—	—	—	310	—	—	—	—	310
Repurchase of warrants	—	—	—	—	(298)	—	—	—	—	(298)
Common stock issuable under the SIPA	—	—	—	—	345	—	—	—	—	345
Placement Agent Shares and October 2024 Placement Agent Warrants	—	—	2,197	—	3,792	—	—	—	—	3,792
Conversion of Tranche B Notes into common stock	—	—	9,215	1	9,255	—	—	—	—	9,256
Shares issued under December 2024 RDO	—	—	26,355	3	325	—	—	—	—	328
StockBlock Warrants issued in connection with the December 2024 RDO	—	—	—	—	1,265	—	—	—	—	1,265

Stock dividend declared, not yet distributed	5,000	1	—	—	(1)	—	—	—	—	—
Issuance of common stock upon warrants exercise	—	—	11,230	1	2,310	—	—	—	—	2,311
Shares issued under ESPP	—	—	334	—	246	—	—	—	—	246
Stock options exercised	—	—	154	—	227	—	—	—	—	227
Stock-based compensation	—	—	—	—	15,689	—	—	—	—	15,689
Other comprehensive income	—	—	—	—	—	6,317	—	—	—	6,317
Net loss	—	—	—	—	—	—	(72,807)	—	—	(72,807)
Balance, December 31, 2024	34,057	$ 1	243,312	$ 24	$ 454,591	$ 6,317	$ (563,052)	(60,069)	$ (90,522)	$ (192,641)

See accompanying notes to audited consolidated financial statements

SCILEX HOLDING COMPANY
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2024	2023
Operating activities		
Net loss	$ (72,807)	$ (114,331)
Adjustments to reconcile net loss to net cash proceeds from (used for) operating activities:		
Depreciation and amortization	4,046	4,146
Amortization of debt issuance costs and debt discount	316	65
Non-cash operating lease cost	718	507
Stock-based compensation	15,689	14,596
Issuance of shares under Settlement Agreement	—	750
(Gain) loss on derivative liability	(17,378)	512
Allocated expense for financial instruments at fair value	17,297	—
Change in fair value of debt and liability instruments	4,782	7,189
Allowances for expected credit losses	1,186	—
Other	661	57
Changes in operating assets and liabilities:		
Accounts receivables, net	(6,267)	(13,361)
Inventory	1,462	(2,838)
Prepaid expenses and other	(479)	(441)
Other long-term assets	(30)	855
Accounts payable	7,419	19,880
Accrued payroll	(1,176)	1,327
Accrued expenses	(8,167)	2,310
Accrued rebates and fees	72,859	58,765
Operating lease liability	(758)	(711)
Other long-term liabilities	(24)	16
Net cash proceeds from (used for) operating activities	19,349	(20,707)
Investing activities		
Acquisition consideration paid in cash for Romeg intangible asset acquisition	(600)	(300)
Purchase of equity securities	(2,000)	—
Purchase of convertible promissory note from Denali	(75)	—
Purchase of property and equipment	—	(30)
Net cash used for investing activities	(2,675)	(330)
Financing activities		
Proceeds from issuance of shares under Standby Equity Purchase Agreements and ATM Sales Agreement	2,671	35,458
Proceeds from issuance of Convertible Debentures	—	24,000
Proceeds from issuance of Revolving Facility	95,438	86,354
Proceeds from issuance of FSF Deposit	10,000	—
Proceeds from issuance of Tranche B Notes and purchased revenue liability	25,000	—
Repayment of Revolving Facility	(112,791)	(69,001)
Repayment of Oramed Note	(64,200)	(5,000)
Cash consideration paid in connection with warrant repurchase	(300)	—
Transaction costs paid related to the Business Combination	—	(1,372)
Repayment of Convertible Debentures	(4,375)	(15,625)
Repayment of Tranche B Notes	(3,283)	—
Payments of debt issuance costs	(4,172)	(380)
Disbursement of funds to Sorrento	—	(20,000)
Cash consideration paid in connection with share repurchase	—	(10,000)
Transaction costs paid in connection with share repurchase	—	(1,987)
Excise tax paid in connection with share repurchase	(450)	—
Proceeds from issuance of shares under direct offerings	41,967	—
Payments of direct offering issuance costs	(4,370)	—
Payments of deferred transaction costs related to Semnur Business Combination	(1,379)	—
Proceeds from stock options and warrants exercised and ESPP	2,113	1,135
Net cash (used for) proceeds from financing activities	(18,131)	23,582
Net change in cash, cash equivalents and restricted cash	(1,457)	2,545
Cash, cash equivalents and restricted cash at beginning of period	4,729	2,184
Cash, cash equivalents and restricted cash at end of period	$ 3,272	$ 4,729
Supplemental disclosure:		
Cash paid for interest	$ 1,561	$ 1,426

Non-cash investing and financing activities				
Issuance of shares to B. Riley pursuant to B. Riley Purchase Agreement	$	—	$	1,869
Issuance costs related to direct offerings included in accrued expenses and account payables	$	1,845	$	—
Fee Warrants issued and exercised in connection with the Commitment Letter	$	610	$	—
Settlement of FSF Deposit	$	13,000	$	—
Deferred transaction costs related to Semnur Business Combination included in accrued expenses and account payable	$	4,602	$	—
Conversion of Oramed Note into Tranche B Notes	$	25,000	$	—
Conversion of Tranche B Notes into common stock	$	9,256	$	—
Debt issuance costs included in accrued expenses	$	3,063	$	—
Placement Agent Shares and October 2024 Placement Agent Warrants	$	3,792	$	—
StockBlock Warrants issued in connection with the December 2024 RDO	$	1,265	$	—
Conversion of Convertible Debentures into common stock	$	—	$	7,735
Right-of-use assets obtained in exchange for operating lease liabilities with lease modification	$	—	$	2,523
Oramed Note issuance at fair value	$	—	$	106,252
Other non-cash consideration in connection with share repurchase	$	—	$	26,154
Excise tax in connection with share repurchase included in accrued expenses	$	860	$	1,310

See accompanying notes to audited consolidated financial statements

SCILEX HOLDING COMPANY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations and Basis of Presentation

Organization and Principal Activities

Scilex Holding Company ("Scilex" and together with its wholly owned subsidiaries, the "Company") is an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain. The Company was originally formed in 2019 and currently has five wholly owned subsidiaries, Scilex Inc. ("Legacy Scilex"), Scilex Pharmaceuticals Inc. ("Scilex Pharma"), Semnur Pharmaceuticals, Inc. ("Semnur"), SCLX DRE Holdings LLC and SCLX Stock Acquisition JV LLC. The business combination with Vickers (the "Business Combination") was closed in November 2022.

The Company launched its first commercial product in October 2018, ZTlido (lidocaine topical system) 1.8% ("ZTlido"), a prescription lidocaine topical system that is designed with novel technology to address the limitations of current prescription lidocaine therapies by providing significantly improved adhesion and continuous pain relief throughout the 12-hour administration period. In June 2022, the Company in-licensed the exclusive right to commercialize GLOPERBA (colchicine USP) oral solution ("GLOPERBA"), a U.S. Food and Drug Administration ("FDA")-approved prophylactic treatment for painful gout flares in adults, in the United States ("U.S."). In February 2023, the Company acquired the rights related to ELYXYB (celecoxib oral solution) ("ELYXYB") and the commercialization thereof in the U.S. and Canada. ELYXYB is a first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults. The Company launched ELYXYB in the U.S. in April 2023 and commercialized GLOPERBA in the U.S. in June 2024.

The Company is currently developing three product candidates, SP-102 (10 mg, dexamethasone sodium phosphate viscous gel), 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 Phase 3 study ("SP-102" or "SEMDEXA"), SP-103 (lidocaine topical system) 5.4% ("SP-103"), a next-generation, triple-strength formulation of ZTlido, for the treatment of chronic neck pain and for which the Company completed a Phase 2 trial in acute low back pain ("LBP") in the third quarter of 2023, and SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-burst release low dose naltrexone hydrochloride capsules) ("SP-104"), a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia, for which Phase 1 trials were completed in the second quarter of 2022. Since inception, the Company has devoted substantially all of its efforts to the development of SP-102, SP-103 and SP-104, and the commercialization of ZTlido.

Sorrento Chapter 11 Filing

On February 13, 2023, Sorrento Therapeutics, Inc. ("Sorrento"), the Company's then-controlling stockholder, and Sorrento's wholly owned direct subsidiary, Scintilla Pharmaceuticals, Inc. ("Scintilla" and together with Sorrento, the "Debtors"), commenced voluntary proceedings under Chapter 11 of the United States Bankruptcy Code (the "Bankruptcy Code") in the United States Bankruptcy Court for the Southern District of Texas (the "Bankruptcy Court"). The Debtors' Chapter 11 proceedings are jointly administered under the caption In re Sorrento Therapeutics, Inc., et al., Case Number 23-90085 (DRJ) (the "Chapter 11 Cases"). While the Company was majority-owned by Sorrento, the Company was not a debtor in the Chapter 11 Cases. Pursuant to that certain Stock Purchase Agreement that the Company entered into with Sorrento on September 21, 2023 (the "Sorrento SPA"), the Company repurchased shares of its Common Stock, par value $0.0001 per share (the "Common Stock"), and Series A Preferred Stock, par value $0.0001 per share (the "Series A Preferred Stock"), from Sorrento. As a result, Sorrento no longer holds a majority of the voting power of the Company's outstanding capital stock entitled to vote. As of December 31, 2024, the Company had a $3.2 million receivable from Sorrento, which was fully reserved.

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

The accompanying consolidated financial statements include the accounts of the Company as well as its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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 (the "CODM") in making decisions on how to allocate resources and assessing performance. The Company has determined that its CODM is its Chief Executive Officer. The Company is engaged primarily in the development of non-opioid products focused on pain management based on its platform technologies and all sales are based in the United States. Accordingly, the Company has determined that it operates its business as a single reportable segment. The CODM reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire Company based on consolidated results that are reported on the consolidated statements of operations and comprehensive loss. The Company has also evaluated the significant segment expenses incurred by the single segment that are regularly provided to the CODM and concluded they are consistent with those reported on the consolidated statements of operations and comprehensive loss and include cost of revenue, research and development, selling, general and administrative. The Company manages assets on a consolidated basis as reported on the consolidated balance sheets. Accordingly, the consolidated financial statements and accompanying notes contained herein include the measure of profit or loss, net revenue, categories of expenses, assets and other financial information that is evaluated by the CODM.

Use of Estimates

The preparation of these consolidated financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of these consolidated financial statements and the reported amounts of expenses during the reporting period. These estimates include, but are not limited to, revenue recognition, fair value of financial instruments and certain assumptions used in estimating stock-based compensation. Management believes that these estimates are reasonable; however, actual results may differ from these estimates.

Customer and Supplier Concentration Risk

The Company had three customers during the years ended December 31, 2024 and 2023, each of which individually generated 10% or more of the Company's total revenue. These customers accounted for 86% and 85% of the Company's revenue for the years ended December 31, 2024 and 2023, respectively, individually ranging from 23% to 34% and 22% to 32%, respectively. As of December 31, 2024 and 2023, three customers represented 95% and 91% of the Company's outstanding accounts receivable, respectively, individually ranging between 30% and 33% and 24% and 36% for respective periods. Additionally, during the years ended December 31, 2024 and 2023, the Company purchased ZTlido inventory from its sole supplier, Itochu Chemical Frontier Corporation ("Itochu"). In November 2023 and February 2024, respectively, the Company started purchasing ELYXYB and GLOPERBA inventories from its sole suppliers, Contract Pharmaceuticals Ltd Canada (CPL) and Ferndale Laboratories, Inc., respectively. This exposes the Company to concentration of customer and supplier risk. The Company monitors the financial condition of its customers and limits its credit exposure by setting credit limits. During the years ended December 31, 2024 and 2023, the Company had allowances for expected credit losses of $1.2 million and nil, respectively.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value on a recurring basis in the consolidated balance sheets. The carrying values of the Company's financial assets and liabilities, including cash and cash equivalents, restricted cash, prepaid and other current assets, accounts payable and accrued expenses approximate to their fair value due to the short-term nature of these instruments. The valuation of the derivative warrant liability for the Private Warrants, the February 2024 BDO Firm Warrants, the Deposit Warrant, the April RDO Warrants, the October 2024 Noteholder Warrants and the December 2024 RDO Common Warrants (each as defined below) is outlined in Note 4, utilizing the Black-Scholes option pricing model. The Company has chosen the fair value option for the Convertible Debentures, Oramed Note, FSF Deposit and Tranche B Notes (each as defined below), with the valuation methodologies detailed in Note 7. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. Assets and liabilities recorded at fair

value are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels are directly related to the amount of subjectivity with the inputs to the valuation of these assets or liabilities as follows:

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 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments that are readily convertible into cash without penalty and with original maturities of three months or less at the date of purchase to be cash equivalents. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents are valued at cost, which approximate their fair value.

Restricted cash as of December 31, 2023 consisted of deposits placed in a segregated bank account as required under the terms of the eCapital Credit Agreement (as defined below), which is discussed further in Note 7. Restricted cash was recorded as other long-term assets within the Company's consolidated balance sheet. There is no restricted cash as of December 31, 2024, because Scilex Pharma paid off the outstanding amount of all obligations and indebtedness under the eCapital Credit Agreement in October 2024, which agreement was terminated thereafter.

Cash equivalents were immaterial as of December 31, 2024 and 2023.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that together reflect the same amounts shown in the consolidated statements of cash flows (in thousands):

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 3,272	$ 3,921
Restricted cash	—	808
Total cash, cash equivalents, and restricted cash	$ 3,272	$ 4,729

Accounts Receivable, Net

Accounts receivable are presented net of allowances for expected credit losses and prompt payment discounts. Accounts receivable consists of trade receivables from product sales to customers, which are generally unsecured. Estimated credit losses related to trade accounts receivable are recorded as general and administrative expenses and as an allowance for expected credit losses within accounts receivable, net. The Company reviews reserves and makes adjustments based on historical experience and known collectability issues and disputes. When internal collection efforts on accounts have been exhausted, the accounts are written off by reducing the allowance for expected credit losses. As of December 31, 2024, the Company recorded $1.2 million of allowances for credit losses on its accounts receivable. As of December 31, 2023, the Company did not deem any allowances for expected credit losses on its accounts receivable necessary.

Inventory

The Company determines inventory cost on a first-in, first-out basis. The Company reduces the carrying value of inventories to a lower of cost or net realizable value for those items that are potentially excess, obsolete or slow-moving. The Company reserves for excess and obsolete inventory based upon historical experience, sales trends, and specific categories of inventory and expiration dates for on-hand inventory. Inventory costs resulting from these adjustments are recognized as cost of sales in the period in which they are incurred. When future commercialization

is considered probable and the future economic benefit is expected to be realized, based on management's judgment, the Company capitalizes pre-launch inventory costs prior to regulatory approval. As of December 31, 2024 and 2023, the Company's inventory was primarily comprised of finished goods.

Property and Equipment, Net

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. Leasehold improvements are amortized over the lesser of their estimated useful lives or the term of the respective lease on a straight-line basis. The cost of repairs and maintenance is expensed as incurred.

Acquisitions

The Company accounts for business combinations using the acquisition method of accounting, which requires that assets acquired, including in-process research and development ("IPR&D") projects and liabilities assumed be recorded at their fair values as of the acquisition date on the Company`s consolidated balance sheets. Any excess of purchase price over the fair value of net assets acquired is recorded as goodwill. The determination of estimated fair value requires the Company to make significant estimates and assumptions. As a result, the Company may record adjustments to the fair values of assets acquired and liabilities assumed within the measurement period (up to one year from the acquisition date) with the corresponding offset to goodwill. Transaction costs associated with business combinations are expensed as they are incurred.

When the Company determines net assets acquired do not meet the definition of a business combination under the acquisition method of accounting, the transaction is accounted for as an acquisition of assets and, therefore, no goodwill is recorded and contingent consideration such as payments upon achievement of various developmental, regulatory and commercial milestones generally is not recognized at the acquisition date. In an asset acquisition, up-front payments allocated to IPR&D projects at the acquisition date and subsequent milestone payments are charged to expense in the Company`s consolidated statements of operations and comprehensive loss unless there is an alternative future use.

The Company has acquired and may continue to acquire the rights to develop and commercialize new product candidates. Intangible assets acquired in a business combination that are used for IPR&D activities are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. Upon commercialization of the relevant research and development project, the Company amortizes the acquired IPR&D over its estimated useful life. Capitalized IPR&D is reviewed annually for impairment or more frequently as changes in circumstance or the occurrence of events suggest that the remaining value may not be recoverable.

Goodwill and Other Long-Lived Assets

Goodwill, which has an indefinite life, represents the excess cost over fair value of net assets acquired. Goodwill is reviewed for impairment at least annually during the fourth quarter, or more frequently if events occur indicating the potential for impairment. The Company has one reporting unit. During its goodwill impairment review, the Company may assess qualitative factors to determine whether it is more likely than not that the fair value of its reporting unit is less than its carrying amount, including goodwill. The qualitative factors include, but are not limited to, macroeconomic conditions, industry and market considerations, and the overall financial performance of the Company. If, after assessing the totality of these qualitative factors, the Company determines that it is not more likely than not that the fair value of its reporting unit is less than its carrying amount, then no additional assessment is deemed necessary. Otherwise, the Company performs a quantitative goodwill impairment test. The Company may also elect to bypass the qualitative assessment in a period and elect to proceed to perform the quantitative goodwill impairment test.

The Company evaluates its long-lived and intangible assets with definite lives, such as property and equipment, patent rights, and acquired technology, for impairment by considering competition by products prescribed for the same indication, the likelihood and estimated future entry of non-generic and generic competition with the same or similar indication and other related factors. The factors that drive the estimate of useful life are often uncertain and are reviewed on a periodic basis or when events occur that warrant review. Recoverability is measured by comparison of

the assets' book value to future net undiscounted cash flows that the assets are expected to generate to determine if a write-down to the recoverable amount is appropriate. If such assets are written down, an impairment will be recognized as the amount by which the book value of the asset group exceeds the recoverable amount.

Contingent Consideration

The fair value of contingent consideration liabilities assumed in business combinations is recorded as part of the purchase price consideration of the acquisition, and is determined using a discounted cash flow model or Monte Carlo simulation model. The significant inputs of such models are not observable in the market, such as certain financial metric growth rates, volatility rates, projections associated with applicable milestones, discount rates and the related probabilities and payment structure in the contingent consideration arrangement. Fair value adjustments to contingent consideration liabilities are recorded through operating expenses in the consolidated statements of operations and comprehensive loss. Other than contingent consideration that is accounted for in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480, *Distinguishing Liabilities from Equity, and Topic 815, Derivatives and Hedging*, contingent consideration arrangements assumed in an asset acquisition will be measured and accrued when such contingency is resolved.

Warrants

In accordance with ASC Subtopic No. 815-40, *Contracts on an Entity's Own Equity,* the Company determines how to account for warrants either assumed in connection with the Business Combination or issued under various financing arrangements. Warrants classified as equity are recorded at their issuance cost and are not subject to remeasurement at each subsequent balance sheet date. The Company records them in additional paid-in capital in the Company's consolidated balance sheets. Warrants accounted for as liabilities are recorded at their estimated fair value on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized in the consolidated statement of operations. The Company estimates the value of these warrants using a Black-Scholes option pricing formula.

Debt

The Company may enter into financing arrangements, the terms of which involve significant assumptions and estimates. This involves estimating future net product sales, determining interest expense, determining the amortization period of the debt discount, as well as determining the classification between current and long-term portions.

Convertible Debentures, the Oramed Note, FSF Deposit and Tranche B Notes

The Company has elected the fair value option to account for the Convertible Debentures, the FSF Deposit, the Tranche B Notes (each as defined in Note 2 "*Liquidity and Going Concern*" below) and the Oramed Note (as defined in Note 4 "*Fair Value Measurements*" below) that were issued in March and April 2023, June 2024, October 2024 and September 2023, respectively, as discussed further in Note 7. The Company recorded these financial instruments at fair value upon issuance with changes in fair value recorded as change in fair value of debt and liability instruments in the consolidated statements of operations, with the exception of changes in fair value due to instrument-specific credit risk, if any, which are recorded as a component of other comprehensive income. Interest expense related to these financial instruments is included in the changes in fair value. As a result of applying the fair value option, direct costs and fees related to these financial instruments were expensed as incurred. The weighted-average interest rates for the short-term loans, including these financial instruments, were 6.67% and 13.55% for the years ended December 31, 2024 and 2023, respectively.

Purchased Revenue Liability

The purchased revenue liability is associated with the Purchase and Sale Agreement (the "ZTlido Royalty Purchase Agreement") that the Company entered into in October 2024 (Note 7). The Company elected the fair value option to account for the purchased revenue liability (as described in Note 4 "Fair Value Measurements" below). The Company recorded the ZTlido Royalty Purchase Agreement at fair value upon issuance with changes in fair value recorded as change in fair value of debt and liability instruments in the consolidated statements of operations, with the exception

of changes in fair value due to instrument-specific credit risk, if any, which are recorded as a component of other comprehensive income. Interest expense related to these financial instruments is included in the changes in fair value. As a result of applying the fair value option, direct costs and fees related to the purchased revenue liability were expensed as incurred.

Derivative Liabilities

Derivative liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and are revalued on each balance sheet date until such instruments are exercised or expire, with changes in the fair value between reporting periods recorded as other income or expense.

Research and Development Costs

The Company expenses the cost of research and development as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including clinical trial costs, manufacturing costs for both clinical and preclinical materials as well as 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 FASB ASC Topic 730, *Research and Development*.

Income Taxes

The provisions of the FASB ASC Topic 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 consolidated financial statements. Under ASC Subtopic 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. As of December 31, 2024 and 2023, the Company maintained a full valuation allowance against its deferred tax assets.

Leases

The Company determines if an arrangement is a lease at inception. Operating lease right-of-use ("ROU") assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, it uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The operating lease ROU asset also includes any lease payments made and is reduced by lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term in selling, general and administrative expenses.

Revenue Recognition

The Company's revenue is generated from product sales within the United States. The Company does not incur significant direct costs to obtain contracts with its customers.

Revenue from product sales is comprised of sales of ZTlido, ELYXYB and GLOPERBA. The Company's performance obligation with respect to sales of ZTlido, ELYXYB and GLOPERBA is satisfied at a point-in-time, when control is transferred upon delivery of product to the customer. The Company considers control to have transferred upon delivery because the customer has legal title to the product, physical possession of the product has been transferred to the customer, the customer has significant risks and rewards of ownership of the product, and the

Company has a present right to payment at that time. Invoicing typically occurs upon shipment and the length of time between invoicing and when payment is due is not significant. The aggregate dollar value of unfulfilled orders as of December 31, 2024 and 2023 were not material.

Revenues from product sales are recorded net of reserves established for commercial and government rebates, fees and chargebacks, wholesaler and distributor fees, sales returns, special marketing programs and prompt payment discounts. Such variable consideration is estimated in the period of the sale and is estimated using a most likely amount approach based primarily upon provisions included in the Company's customer contract, customary industry practices and current government regulations.

Rebates and Chargebacks

Rebates are discounts which the Company pays under either government or private health care programs. Government rebate programs include state Medicaid drug rebate programs, the Medicare coverage gap discount programs and the Tricare programs. Commercial rebate and fee programs relate to contractual agreements with commercial healthcare providers, under which the Company pays rebates and fees for access to and position on that provider's patient drug formulary. Rebates and chargebacks paid under government programs are generally mandated under law, whereas private rebates and fees are generally contractually negotiated by the Company with commercial healthcare providers. Both types of rebates vary over time. The Company records a reduction to gross product sales at the time the customer takes title to the product based on estimates of expected rebate claims. The Company monitors the sales trends and adjusts for these rebates on a regular basis to reflect the most recent rebate experience and contractual obligations. Reserves for rebates and chargebacks are separately presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Prompt Payment Discounts

The Company provides its customers with prompt payment discounts which may result in adjustments to the price that is invoiced for the product transferred, in the case that payments are made within a defined period. The prompt payment discount reserve is based on actual gross sales and contractual discount rates. Reserves for prompt payment discounts are included in accounts receivable, net on the consolidated balance sheets.

Service Fees

The Company compensates its customer and others in the distribution chain for wholesaler and distribution services. The Company has determined such services received to date are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue. Service fees are presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Product Returns

The Company is obligated to accept the return of products sold that are expiring within six months, damaged or do not meet certain specifications. The Company may authorize the return of products sold in accordance with the term of its sales contracts, and estimates allowances for such amounts at the time of sale. The Company estimates the amount of its product sales that may be returned by its customer and records this estimate as a reduction of revenue in the period the related product revenue is recognized. Product returns are presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Co-Payment Assistance

Patients who have commercial insurance or pay cash and meet certain eligibility requirements may receive co-payment assistance. The Company accrues for co-payment assistance based on actual program participation and estimates of program redemption using data provided by third-party administrators. Co-payment assistance is presented as accrued rebates and fees under current liabilities within the Company's consolidated balance sheets.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with FASB ASC Topic 718, *Compensation – Stock Compensation*, which establishes accounting for equity instruments exchanged for employee and consulting services. Under such provisions, stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, 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. Then 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 as variables in the Black-Scholes option pricing model. Depending upon the number of stock options granted, any fluctuations in these calculations could have a material effect on the results presented in our consolidated statements of operations and comprehensive loss.

Treasury Stock

The Company uses the cost method to account for repurchases of its stock. In the computation of net (loss) income per share, treasury shares are not included as part of the outstanding shares.

Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share attributable to common stockholders adjusts basic earnings per share for the potentially dilutive impact of stock options and warrants, which consists of the incremental Common Stock issuable upon the exercise of stock options and warrants (using the treasury stock method or the reverse treasury stock method, as applicable).

In accordance with FASB ASC 260, *Earnings Per Share,* Penny Warrants are warrants that would be exercised for no or little consideration and therefore should be included in the calculation of weighted average shares outstanding for purposes of calculating basic and diluted net income (loss) per share to the extent all vesting conditions or exercise contingencies are removed except for the passage of time.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Improvements to Reportable Segment Disclosures* (Topic 280), which requires disclosures of significant reportable segment expenses that are regularly provided to the CODM and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. The Company adopted this ASU retrospectively on December 31, 2024.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740): Improvements to Income Tax Disclosures. The update requires a public business entity to disclose, on an annual basis, a tabular rate reconciliation using both percentages and currency amounts, broken out into specified categories with certain reconciling items further broken out by nature and jurisdiction to the extent those items exceed a specified threshold. In addition, all entities are required to disclose income taxes paid, net of refunds received disaggregated by federal, state/local, and foreign and by jurisdiction if the amount is at least 5% of total income tax payments, net of refunds received. Adoption

of the ASU allows for either the prospective or retrospective application of the amendment and is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this amendment on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures*, which will require additional expense disclosures for all public entities. The amendments require that at each interim and annual reporting period, an entity will disclose certain disaggregated expenses included in each relevant expense caption, as well as the total amount of selling expenses and, in annual periods, an entity's definition of selling expenses. ASU 2024-03 is effective for annual reporting periods beginning with the fiscal year ending December 31, 2027, and interim periods thereafter, with early adoption permitted. The Company is currently evaluating the incremental disclosures that will be required in its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-04, *Debt—Debt with Conversion and Other Options*, which clarify the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. ASU 2024-04 is effective for annual reporting periods beginning after December 15, 2025 and interim reporting periods within those annual reporting periods. Early adoption is permitted for all entities that have adopted the amendments in ASU 2020-06. The Company is currently evaluating the impact of this amendment on its consolidated financial statements.

2. 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.

On November 17, 2022, the Company entered into a standby equity purchase agreement (the "Original Purchase Agreement") with YA II PN, Ltd., a Cayman Islands exempt limited partnership ("Yorkville"). On February 8, 2023, the Company entered into an amended and restated standby equity purchase agreement with Yorkville (the "A&R Yorkville Purchase Agreement"), amending, restating and superseding the Original Purchase Agreement. On, and effective as of, March 25, 2024, the Company and Yorkville mutually agreed to terminate the A&R Yorkville Purchase Agreement.

On January 8, 2023, the Company entered into a standby equity purchase agreement (the "B. Riley Purchase Agreement" and together with A&R Yorkville Purchase Agreement, the "Standby Equity Purchase Agreements") with B. Riley Principal Capital II, LLC ("B. Riley"). Pursuant to each of the Standby Equity Purchase Agreements, the Company had the right, but not the obligation, to sell to each of Yorkville and B. Riley up to $500.0 million of shares of the Company's common stock, par value $0.0001 per share (the "Common Stock") at its request any time during the 36 months following the date on which the registration statement related to each such purchase agreement was initially declared effective by the SEC, subject to certain conditions, which are discussed further in Note 9. As consideration for Yorkville's and B. Riley's respective commitment to purchase shares of Common Stock at the Company's direction, the Company issued 250,000 commitment shares to each of Yorkville (the "Yorkville Commitment Shares") and B. Riley (the "B. Riley Commitment Shares"). On, and effective as of, February 16, 2024, the Company and B. Riley mutually agreed to terminate the B. Riley Purchase Agreement.

On March 21, 2023, the Company entered into a securities purchase agreement with Yorkville (the "Yorkville SPA"), pursuant to which the Company issued and sold to Yorkville convertible debentures in an aggregate principal amount of up to $25.0 million (the "Convertible Debentures") for net cash proceeds of $24.0 million, as discussed further in Note 7. The Company fully repaid the Convertible Debentures in March 2024.

On June 27, 2023, Scilex Pharma entered into a Credit and Security Agreement (the "eCapital Credit Agreement") with eCapital Healthcare Corp. (the "Lender"), pursuant to which the Lender made available loans (the "Revolving Facility") in an aggregate principal amount of up to $30.0 million (the "Facility Cap"). The proceeds of the Revolving Facility were used for (i) transaction fees incurred in connection with the eCapital Credit Agreement, (ii) working capital needs of Scilex Pharma and (iii) other uses not prohibited under the eCapital Credit Agreement. See Note 7 for additional discussion of the terms of the eCapital Credit Agreement. On October 8, 2024, Scilex Pharma paid off the

outstanding amount of all obligations and indebtedness of Scilex Pharma owing to the Lender under the eCapital Credit Agreement. Accordingly, the eCapital Credit Agreement, the related Loan Documents and the Subordination Agreement (each as defined in the eCapital Credit Agreement) were terminated, canceled and are of no further force and effect.

On December 22, 2023, the Company entered into a Sales Agreement (the "ATM Sales Agreement") with B. Riley Securities, Inc., Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (the "Sales Agents"), which agreement was voluntarily terminated by us effective as of March 5, 2025. Pursuant to the ATM Sales Agreement, the Company was able to offer and sell (the "Offering") shares of Common Stock up to $170.0 million (the "ATM Shares"), through or to the Sales Agents as part of the Offering. The Company had no obligation to sell any shares of Common Stock under the ATM Sales Agreement and could suspend offers thereunder at any time. As of December 31, 2024, the Company sold 2,764,187 shares of Common Stock pursuant to the ATM Sales Agreement for net proceeds of approximately $2.7 million. As of December 31, 2023, no sales of Common Stock had been made under the ATM Sales Agreement.

On June 11, 2024, the Company entered into that certain Commitment Side Letter (the "Commitment Letter") with FSF 33433 LLC ("FSF Lender"), pursuant to which FSF Lender committed to provide the Company a loan (the "FSF Loan") in the aggregate amount of $100.0 million (the "Commitment Amount"). The Commitment Amount shall be payable as follows: (i) $85.0 million no later than the date that is 70 days following the date on which the Company receives the FSF Deposit (as defined below) (the "Outside Date" and the funding of the initial $85.0 million, the "Initial Closing") and (ii) the remaining $15.0 million within 60 days following the Initial Closing (the funding of the second $15.0 million, the "Second Closing"). Pursuant to the Commitment Letter, FSF Lender was required to provide the Company a non-refundable deposit in immediately available funds in the aggregate principal amount of $10.0 million (the "FSF Deposit" and the date on which such funds are fully received, the "Deposit Date"), which amount will be creditable towards the $85.0 million required to be funded by FSF Lender at the Initial Closing. The Company received the FSF Deposit on June 18, 2024 and issued to FSF Lender a warrant to purchase up to an aggregate of 3,250,000 shares of the Common Stock (subject to adjustment for any stock dividend, stock split, reverse stock split or similar transaction) (the "Deposit Warrant"), with an exercise price of $1.20 per share. The Deposit Warrant is immediately exercisable and will expire five years from the date of issuance.

On September 17, 2024, the Company entered into a Satisfaction Agreement (the "Satisfaction Agreement") with FSF Lender and Endeavor Distribution LLC, a Delaware limited liability company and affiliate of FSF Lender ("Endeavor"), pursuant to which the remaining obligations in respect of the FSF Deposit shall be fully satisfied by the Company's delivery of 28,000 cartons of ZTlido to Endeavor (the "Additional Product"), which delivery shall occur no later than December 31, 2024. Upon satisfaction of such remaining obligations, the Commitment Letter shall be terminated and of no further force or effect and neither FSF Lender nor the Company shall have any further liability or obligations thereunder. In consideration of Endeavor assuming the payment obligation of the Company in respect of the FSF Deposit, Endeavor will not be responsible for making any payment to the Company for (i) the product already delivered as of the date of such agreement in an amount of approximately $13.2 million and (ii) the Additional Product. Pursuant to the terms of the Satisfaction Agreement, if the Company fails to fully deliver the Additional Product by December 31, 2024, the Company shall be liable to Endeavor for liquidated damages in the amount of $20,000,000. In November 2024, the Company delivered the Additional Product to Endeavor and fully satisfied the remaining obligations in respect of the FSF Deposit.

On October 8, 2024, the Company entered into a securities purchase agreement (the "Tranche B Securities Purchase Agreement") with certain institutional investors (collectively, the "Tranche B Investors") and Oramed Pharmaceuticals Inc. ("Oramed") (together with the Tranche B Investors, the "Tranche B Noteholders"), to issue and sell, in a registered offering by the Company directly to the Tranche B Noteholders, a new tranche B of senior secured convertible notes of the Company in the aggregate principal amount of $50.0 million (the "Tranche B Notes") which notes will mature on the two-year anniversary of the issuance date and will be convertible into shares of Common Stock at a conversion price equal to $1.09 per share (which was automatically reduced to $1.04 per share of Common Stock subsequent to the December 2024 RDO (as defined below) in accordance with the terms of such notes). The Company has received in exchange for the issuance of the Tranche B Notes to the Tranche B Investors an aggregate amount in cash of $22,500,000, excluding fees and expenses payable by the Company. The Company has received from Oramed in consideration for the Tranche B Notes issued to Oramed an exchange and reduction of the principal balance under the Oramed Note (as defined below) of $22,500,000.

As of December 31, 2024, the Company's negative working capital was $218.1 million, including cash and cash equivalents of approximately $3.3 million. During the year ended December 31, 2024, the Company had operating losses of $83.4 million and cash flows from operations of $19.3 million. The Company had an accumulated deficit of $563.1 million as of December 31, 2024.

The Company has plans to obtain additional resources to fund its currently planned operations and expenditures and to service its debt obligations (whether under the Oramed Note, the Tranche B Notes or otherwise) for at least twelve months from the issuance of these consolidated financial statements through a combination of equity offerings, debt financings, collaborations, government contracts or other strategic transactions. The Company's plans are also dependent upon the success of future sales of ZTlido, ELYXYB and GLOPERBA, among which GLOPERBA is still in the early stages of commercialization.

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.

3. Acquisitions and License Agreements

SP-104 Acquisition

In May 2022, the Company acquired the Delayed Burst Release Low Dose Naltrexone asset and intellectual property rights for the treatment of chronic pain, fibromyalgia and chronic post-COVID syndrome (collectively, the "SP-104 Assets"). Pursuant to the acquisition provisions, the Company is obligated to pay Aardvark Therapeutics, Inc. ("Aardvark") (i) $3.0 million upon initial approval by the FDA of a new drug application for the SP-104 Assets (which amount may be paid in shares of Common Stock or cash, in the Company's sole discretion) (the "Development Milestone Payment") and (ii) $20.0 million in cash, upon achievement of certain net sales by the Company of a commercial product that uses the SP-104 Assets (the "Sales Milestone Payment"). The Company will also pay Aardvark certain royalties in the single digits based on percentages of annual net sales by the Company of a commercial product that uses the SP-104 Assets.

The Sales Milestone Payment and sale volume-based future royalties were determined to meet a scope exception for derivative accounting and will not be recognized until the contingencies are realized. The Development Milestone Payment represents a liability, which will be measured at fair value for each reporting period. As of December 31, 2024 and December 31, 2023, the contingent consideration associated with the Development Milestone Payment was $0.2 million, recorded in the other long-term liabilities.

GLOPERBA License Agreement

On June 14, 2022 (the "Original Signing Date"), the Company entered into a License and Commercialization Agreement with RxOmeg Therapeutics LLC (a/k/a Romeg Therapeutics, LLC) ("Romeg") for the in-licensing of certain intellectual property rights from Romeg with respect to the commercialization of GLOPERBA, which was amended by that First Amendment to License and Commercialization Agreement, dated as of January 16, 2025 (such agreement, as amended, the "Romeg License Agreement"). Under the Romeg License Agreement, among other things, Romeg granted the Company (1) a license, with the right to sublicense, under the patents and know-how specified therein to (a) commercialize a pharmaceutical product comprising liquid formulations of colchicine for the prophylactic treatment of gout in adult humans (the "Initial Licensed Product") in the United States (including its territories) (the "Romeg U.S. Territory"), (b) develop other products comprising the Initial Licensed Product as an active pharmaceutical ingredient (together with the Initial Licensed Product, the "Licensed Products") and commercialize any such products in the Romeg U.S. Territory and (c) manufacture Licensed Products anywhere in the world, solely for commercialization in the Romeg U.S. Territory; (2) an exclusive license, with right to sublicense, to use the trademark "GLOPERBA" and logos, designs, translations, and modifications thereof (collectively, the "Licensed Trademark") in connection with the commercialization of the Initial Licensed Product solely in the Romeg U.S. Territory; and (3) pursuant to the amendment thereto, a license, with the right to (a) sublicense under the know-how and, if any, patents existing worldwide other than the Romeg U.S. Territory (the "Romeg Ex-U.S. Territory"), as specified therein, to develop, manufacture and commercialize Licensed Products in the Romeg Ex-U.S. Territory and

(b) to use the Licensed Trademark in connection with the commercialization of the Licensed Products in the Romeg Ex-U.S. Territory. The Initial Licensed Product, GLOPERBA, was approved and made available in the United States in 2020.

As consideration for the license under the Romeg License Agreement, the Company agreed to pay Romeg (1) an up-front license fee of $2.0 million, (2) upon the Company's achievement of certain net sales milestones, certain milestone payments in the aggregate amount of up to $13.0 million, (3) certain royalties in the mid-single digit percentage based on annual net sales of the Licensed Products attributable to sales of the Licensed Products occurring in the Romeg U.S. Territory during the Romeg U.S. Territory Royalty Term, with a quarterly minimum royalty of $150,000, and (4) pursuant to the amendment thereto, (a) certain royalties at rates in the low-single digit percentage, based on annual net sales of the Licensed Products attributable to sales of License Products in the Romeg Ex-U.S. Territory during the Romeg Ex-U.S. Territory Royalty Term and (b) a one-time, non-refundable, non-creditable payment of $700,000. Pursuant to the amendment agreement, we also transferred to Romeg 779,371 shares of our Common Stock.

In connection with the Romeg License Agreement, the Company recorded an intangible asset for acquired licenses of $5.7 million, which is comprised of the upfront license fee of $2.0 million and deferred consideration of $3.7 million that is the present value of the future minimum royalty payments and immaterial transaction costs. During the years ended December 31, 2024 and 2023, the Company made royalty payments in the amount of $0.6 million and $0.3 million, respectively. No contingent consideration was recognized as a liability or included in the fair value of the assets as of December 31, 2024 or December 31, 2023.

ELYXYB Acquisition

In February 2023, the Company entered into an asset purchase agreement (the "ELYXYB APA") with BioDelivery Sciences International, Inc. ("BDSI") and Collegium Pharmaceutical, Inc. ("Collegium", and together with BDSI, the "Sellers") to acquire the rights to certain patents, trademarks, regulatory approvals, data, contracts, and other rights related to ELYXYB and its commercialization in the United States and Canada (the "ELYXYB Territory").

As consideration for the acquisition, the Company assumed various rights and obligations under the asset purchase agreement between BDSI and Dr. Reddy's Laboratories Limited, a company incorporated under the laws of India ("DRL"), dated August 3, 2021 (the "DRL APA"), including an irrevocable, royalty-free, exclusive license to know-how and patents of DRL related to ELYXYB and necessary or used to exploit ELYXYB in the ELYXYB Territory. No cash consideration was or will be payable to the Sellers for such acquisition; however, the obligations under the DRL APA that were assumed by the Company include contingent sales and regulatory milestone payments and sales royalties. The Company is also obligated to make quarterly royalty payments to DRL on net sales of ELYXYB in the ELYXYB Territory. In April 2023, the Company launched ELYXYB in the U.S. As of December 31, 2024 and 2023, the Company had ending balances of accrued royalty payables of $0.1 million and $5.0 thousand, respectively, which was recorded as accrued expenses under current liabilities on the consolidated balance sheets. During the years ended December 31, 2024 and 2023, the Company made royalty payments in the amount of $0.3 million and $26.0 thousand, respectively. As of December 31, 2024, no sales or regulatory milestone payments had been accrued as there were no potential milestones yet considered probable of achievement.

4. Fair Value Measurements

The following table presents the Company's financial assets and liabilities that are measured at fair value on a recurring basis and the level of inputs used in such measurements (in thousands):

	December 31, 2024			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Oramed Note	$ 12,161	$ —	$ —	$ 12,161
Tranche B Notes	23,560	—	—	23,560
Purchased Revenue Liability	6,800	—	—	6,800
Derivative liabilities	18,303	—	—	18,303
Other long-term liabilities	155	—	—	155
Total liabilities measured at fair value	$ 60,979	$ —	$ —	$ 60,979

	December 31, 2023			
	Balance	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Liabilities				
Oramed Note	$ 104,089	$ —	$ —	$ 104,089
Convertible Debentures	4,340	—	—	4,340
Derivative liabilities	1,518	—	—	1,518
Other long-term liabilities	179	—	—	179
Total liabilities measured at fair value	$ 110,126	$ —	$ —	$ 110,126

The Oramed Note

In September 2023, the Company issued a senior secured promissory note to Oramed in the principal amount of $101.9 million (the "Oramed Note") (see Note 7). The Company elected the fair value option to account for the Oramed Note with any changes in the fair value of such note recorded in the consolidated statements of operations, with the exception of changes in fair value due to instrument-specific credit risk, if any, which are recorded as a component of other comprehensive income. The Company uses a discounted cash flow model to determine the fair value of the Oramed Note based on Level 3 inputs. This methodology discounts the interest and principal payments using a risk-adjusted discount rate. The fair value as of December 31, 2024 and 2023 was determined to be $12.2 million and $104.1 million, respectively, by applying a discount rate of 128.82% and 13.05%, respectively. For the years ended December 31, 2024 and 2023, the Company recorded a loss of $3.6 million and $2.8 million in change in fair value of the Oramed Note, respectively. For the years ended December 31, 2024 and 2023, the change in fair value due to instrument-specific credit risk recorded as a component of other comprehensive income was $6.3 million and nil, respectively. During the year ended December 31, 2024 the Company reclassified $5.0 million from accumulated other comprehensive income to the consolidated statement of operations. This reclassification was related to the principal payments and partial conversion of the Oramed Note balance into the Tranche B Notes (see Note 7).

FSF Deposit

In June 2024, the Company received the FSF Deposit in the aggregate principal amount of $10.0 million from FSF Lender (see Note 2 and Note 7). The Company elected the fair value option to account for the FSF Deposit with any changes in the fair value of the deposit recorded in the consolidated statements of operations and comprehensive loss. For the year ended December 31, 2024, the Company recorded a loss of $4.7 million in change in fair value of the FSF Deposit in the consolidated statement of operations. In November 2024, the Company delivered the Additional Product to Endeavor and fully satisfied the remaining obligations in respect of the FSF Deposit. Upon the satisfaction of the FSF Deposit, the Deposit Warrant became a freestanding instrument under ASC 480 and was included in derivative liabilities on the Company's consolidated balance sheet.

Tranche B Notes

In October 2024, the Company entered into the Tranche B Securities Purchase Agreement to issue and sell the Tranche B Notes in the principal amount of $50.0 million (see Note 7). The Company elected the fair value option to account for the Tranche B Notes with any changes in the fair value of such notes recorded in the consolidated statements of operations, with the exception of changes in fair value due to instrument-specific credit risk, if any, which are recorded as a component of other comprehensive income. The Tranche B Notes are measured at fair value on a recurring basis using the Level 3 inputs. The Company uses the Binomial Lattice Model valuation technique to measure the fair value of the Tranche B Notes. The fair value as of December 31, 2024, was determined to be $23.6 million. For the year ended December 31, 2024, the Company recorded a gain of $6.6 million in change in fair value of the Tranche B Notes in the consolidated statement of operations.

Purchased Revenue Liability

In October 2024, the Company entered into the ZTlido Royalty Purchase Agreement with certain institutional investors (collectively, the "ZTlido Royalty Investors") and Oramed (see Note 7). The Company elected the fair value option for the purchased revenue liability with changes in fair value recorded as change in fair value of debt and liability instruments in the consolidated statements of operations, with the exception of changes in fair value due to instrument-specific credit risk, if any, which are recorded as a component of other comprehensive income. The Company uses a Scenario-Based Method valuation technique to measure the fair value of the purchased revenue liability. The fair value as of December 31, 2024, was determined to be $6.8 million. For the year ended December 31, 2024, the Company recorded a loss of $0.9 million in change in fair value of the purchased revenue liability in the consolidated statement of operations.

Convertible Debentures

In March and April 2023, the Company issued the Convertible Debentures in the principal amount of $25.0 million (see Note 7). The Convertible Debentures were measured at fair value on a recurring basis using Level 3 inputs. The Company used the Binomial Lattice Model valuation technique to measure the fair value of the Convertible Debentures with any changes in the fair value of the Convertible Debentures recorded in the consolidated statements of operations and comprehensive loss. Interest expense related to the Convertible Debentures is included in the changes in fair value. For the years ended December 31, 2024 and 2023, the Company recorded a loss of $35.0 thousand and a loss of $4.4 million in change in fair value of the Convertible Debentures, respectively. The Company fully repaid the Convertible Debentures in March 2024.

Derivative Liabilities

The Company recorded a gain of $17.4 million for the year ended December 31, 2024, attributed to warrant liabilities consisting of the Private Warrants, the February 2024 BDO Firm Warrants, the April 2024 RDO Common Warrants, the October 2024 Noteholder Warrants, and December 2024 RDO Common Warrants (each as defined below). The Company recorded a loss of $0.5 million for the year ended December 31, 2023, on derivative liabilities which was attributed to the Private Warrants that the Company assumed from Vickers in November 2022 in connection with the Business Combination ("Private Warrants").

As of December 31, 2024, the following warrants to purchase Common Stock that are included in derivative liabilities were outstanding: 1,000,000 Private Warrants, 3,803,447 February 2024 BDO Firm Warrants, 15,000,000 April 2024 RDO Common Warrants, 3,250,000 Deposit Warrant, 7,500,000 October 2024 Noteholder Warrants and 57,512,958 December 2024 RDO Common Warrants. As of December 31, 2024, the fair value of derivative warrant liabilities related to these warrants was $18.3 million.

The following table includes a summary of the derivative liabilities measured at fair value during the years ended December 31, 2024 and 2023 (in thousands):

	Fair Value
Ending Balance as of December 31, 2022	$ 1,231
Change in fair value measurement	512
Forfeiture of Private Warrants	(225)
Ending Balance as of December 31, 2023	1,518
Issuance of February 2024 BDO Firm Warrants as part of February 2024 BDO, April 2024 RDO Common Warrants as part of April 2024 RDO, October 2024 Noteholder Warrants as part of Tranche B Notes, December 2024 RDO Common Warrants as part of December 2024 RDO, and December 2024 RDO Pre-Funded Warrants as part of December 2024 RDO	34,330
Reclass of Deposit Warrant liability upon satisfaction of FSF Deposit	1,690
Cancellation of Private Warrants as part of Oramed Letter Agreement	(445)
Warrant amendment and exercise as part of December 2024 RDO	(428)
Settlement of December 2024 RDO Pre-Funded Warrants	(984)
Change in fair value measurement	(17,378)
Ending Balance as of December 31, 2024	$ 18,303

Warrant Liability Measurement

The derivative warrant liability was valued using the Black-Scholes option pricing model, which is considered to be Level 3 fair value measurement. The primary unobservable input utilized in determining the fair value of the warrant is the expected volatility of the Common Stock. The expected volatility assumption is based on the Company's historical volatility, historical volatilities of comparable companies whose share prices are publicly available as well as the implied volatility of the Public Warrants (see Note 9). A summary of the inputs used in valuing the derivative warrant liabilities is as follows:

	Private Warrants	February 2024 BDO Firm Warrants	April 2024 RDO Common Warrants	Deposit Warrant	October 2024 Noteholder Warrants	December 2024 RDO Common Warrants (5yr)	December 2024 RDO Common Warrants (2.5yr)
	December 31, 2024						
Equity value	$ 0.43	$ 0.43	$ 0.43	$ 0.43	$ 0.43	$ 0.43	$ 0.43
Exercise price	$ 11.50	$ 1.70	$ 1.10	$ 1.20	$ 1.04	$ 0.65	$ 0.65
Term, in years	2.86	4.18	4.32	4.47	4.77	4.95	2.45
Volatility	109.0%	81.0%	80.0%	73.0%	77.0%	76.0%	95.0%
Risk-free rate	4.22%	4.29%	4.30%	4.30%	4.32%	4.33%	4.21%
Dividend yield	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Call option value	$ 0.21	$ 0.15	$ 0.19	$ 0.16	$ 0.20	$ 0.24	$ 0.20

	Private Warrants
	December 31, 2023
Equity value	$ 2.04
Exercise price	$ 11.50
Term, in years	3.86
Volatility	76.0%
Risk-free rate	3.90%
Dividend yield	0.0%
Call option value	$ 0.42

Contingent Consideration Related to SP-104 Acquisition

The Development Milestone Payment related to the SP-104 Assets represents an obligation to potentially settle a fixed value in a variable number of shares of Common Stock and requires remeasurement at fair value through settlement.

Upon the achievement of FDA approval for a new drug application for SP-104, the Company will transfer $3.0 million in cash or shares of Common Stock, at the discretion of the Company. The fair value of the contingent consideration liability associated with the Development Milestone Payment was estimated using a probability-weighted discounted cash flow method. Significant unobservable inputs assumptions included the likelihood of receiving FDA approval for SP-104, expected timing for receipt of FDA approval for SP-104, and a discount rate of 10.0%. As of December 31, 2024 and 2023, the fair value of contingent consideration related to the Development Milestone Payment was $0.2 million.

There were no transfers between fair value measurement levels during the years ended December 31, 2024 and 2023.

5. Balance Sheet Components

Investments

Convertible Promissory Note

On August 9, 2024, Denali Capital Acquisition Corp. ("Denali") issued a convertible promissory note (the "Convertible Promissory Note") in the total principal amount of up to $180,000 to the Company. The Convertible Promissory Note was issued with an initial principal balance of $15,063.74, with the remaining $164,936.26 drawable at Denali's request and upon the consent of the Company prior to the maturity of the Convertible Promissory Note. The Convertible Promissory Note matures upon the earlier of (i) the effective date of the consummation of Denali's initial business combination or (ii) the date of the liquidation of Denali. Any future drawdowns of the remaining $164,936.26 principal amount available under the Convertible Promissory Note are expected to fund future one-month extensions as necessary to provide additional time for Denali to complete a business combination. At the option of the Company, upon consummation of an initial business combination, the Convertible Promissory Note may be converted in whole or in part into additional Class A ordinary shares of Denali, at a conversion price of $10.00 per ordinary share (the "Conversion Shares"). The terms of the Conversion Shares will be identical to those of the private placement shares that were issued to Denali Capital Global Investments, LLC in connection with Denali's initial public offering (the "IPO"). In the event that Denali does not consummate an initial business combination, the Convertible Promissory Note will be repaid only from funds held outside of the trust account established in connection with the IPO or will be forfeited, eliminated or otherwise forgiven. No interest shall accrue on the unpaid principal balance of the Convertible Promissory Note. As of December 31, 2024, the balance of the Convertible Promissory Note was $75.3 thousand as a result of additional draws after the initial amount.

Semnur Business Combination Agreement and Sponsor Interest Purchase Agreement

On August 30, 2024, Semnur entered into an agreement and plan of merger (the "Semnur Business Combination Agreement") with Denali and Denali Merger Sub Inc., a Delaware corporation and wholly owned subsidiary of Denali ("Denali Merger Sub").

The Semnur Business Combination Agreement provides that, among other things, (i) on the terms and subject to the conditions set forth therein, Denali Merger Sub will merge with and into Semnur, with Semnur surviving as a wholly owned subsidiary of Denali (the "Semnur Business Combination"), and (ii) prior to the closing of the Semnur Business Combination, Denali will migrate to and domesticate as a Delaware corporation in accordance with Section 388 of the General Corporation Law of the State of Delaware, as amended (the "DGCL"), and de-register in the Cayman Islands in accordance with Section 206 of the Cayman Companies Act (the "Domestication"). Upon the closing of the Semnur Business Combination, it is anticipated that Denali will change its name to "Semnur Pharmaceuticals, Inc." ("New Semnur"). Shares of Denali common stock following the Domestication are hereinafter referred to as "New Semnur Common Shares". Shares of Denali Series A preferred stock following the Domestication are hereinafter referred to as "New Semnur Preferred Shares". Warrants to purchase New Semnur Common Shares following the Domestication are hereinafter referred to as "New Semnur Warrants".

In accordance with the terms and subject to the conditions of the Semnur Business Combination Agreement, following the Domestication and at the effective time of the Semnur Business Combination (the "Effective Time"): (i) each share of common stock, par value $0.00001 per share (the "Semnur Common Stock"), of Semnur, issued and outstanding immediately prior to the Effective Time, will be automatically converted into the right to receive, without interest, a number of New Semnur Common Shares equal to the Exchange Ratio (as defined in the Semnur Business Combination Agreement); (ii) each share of Series A preferred stock of Semnur issued and outstanding immediately prior to the Effective Time will be automatically converted into the right to receive, without interest, (a) one New Semnur Preferred Share and (b) one-tenth of one New Semnur Common Share, and (iii) subject to Denali's receipt of the Option Exchange Approval (as defined in the Semnur Business Combination Agreement), each option to purchase a share of Semnur Common Stock that is then outstanding shall be converted into the right to receive an option to purchase a number of New Semnur Common Shares as determined by the Exchange Ratio upon substantially the same terms and conditions as are in effect with respect to such option immediately prior to the Effective Time, with the exercise price thereof adjusted by the Exchange Ratio.

The Company defers specific incremental costs directly attributable to the Semnur Business Combination, such as legal, accounting and other general and administrative costs. After the consummation of the Semnur Business Combination, these costs will be classified in stockholders' deficit as a reduction of additional paid-in capital recorded as a result of the Semnur Business Combination. In the event the Semnur Business Combination Agreement is terminated, all deferred offering costs will be reclassified to general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss. As of December 31, 2024 and 2023, deferred offering costs related to the Semnur Business Combination totaled $6.0 million and nil, respectively, and were included in prepaid expenses and other current assets in the Company's consolidated balance sheet.

In connection with the execution and delivery of the Semnur Business Combination Agreement, Denali Capital Global Investments LLC, a Cayman Islands limited liability company (the "Sponsor"), and the Company entered into a Sponsor Interest Purchase Agreement (the "SIPA") dated August 30, 2024 (the "Signing Date"). Pursuant to the SIPA, the Company agreed to purchase 500,000 Class B ordinary shares, par value $0.0001 per share (the "Purchased Interests"), of Denali that are currently held by the Sponsor. The aggregate consideration for the purchase and sale of the Purchased Interests is as follows: (i) $2,000,000 (the "Cash Consideration") and (ii) 300,000 shares of Common Stock. Pursuant to the SIPA, the Company has paid the Cash Consideration on the Signing Date and has agreed to issue Common Stock to the Sponsor contingent upon and following the occurrence of the Effective Time. The Company accounted for this promise to issue shares at a future date as an equity classified instrument as it is indexed to the Company's own stock and meets the conditions to be classified in equity under FASB ASC 815, *Derivatives and Hedging*. The Purchased Interests will convert automatically, on a one-for-one basis, into one New Semnur Common Share at the effective time of the Domestication pursuant to the terms of the Semnur Business Combination Agreement. The Company determined it does not have significant influence over Denali and accounted for the Purchased Interests as equity securities at the transaction price which consists of the $2,000,000 paid by the Company to the Sponsor and the value of the 300,000 shares of the Common Stock at the closing price of $1.15 per share on the Signing Date for a total of $2.3 million. The Company elected to subsequently measure the investment at cost less any impairment. As of December 31, 2024, the Company's investment in the Purchased Interests had a balance of $2.3 million. No impairment loss was recognized during the year ended December 31, 2024.

Property and Equipment, Net

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

	December 31, 2024	December 31, 2023
Construction in progress	$ 689	$ 689
Furniture	17	5
Computers and equipment	16	36
Leasehold improvements	50	50
Property and equipment, gross	772	780
Less: Accumulated depreciation	(64)	(58)
Property and equipment, net	$ 708	$ 722

The Company recognized depreciation expense of $14.0 thousand and $40.0 thousand for the years ended December 31, 2024 and 2023, respectively.

Accrued Expenses

Accrued expenses consists of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued professional service fees	$ 667	$ 2,029
Accrued sales and marketing costs	876	1,601
Accrued research and development costs	315	1,546
Accrued tax payable	876	1,452
Accrued litigation expenses	—	500
Accrued others	107	280
Accrued expenses	$ 2,841	$ 7,408

6. Goodwill and Intangible Assets

As of December 31, 2024 and 2023, the Company had recorded goodwill of $13.5 million. No goodwill impairment was recognized for the years ended December 31, 2024 and 2023.

Amortization of the intangible assets that have finite useful lives is generally recorded on a straight-line basis over their useful lives, ranging from 6.8 to 13.0 years. A summary of the Company's identifiable intangible assets as of December 31, 2024 and 2023 is as follows (in thousands):

	December 31, 2024		
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Patent rights	$ 32,630	$ 17,770	$ 14,860
Acquired technology	21,940	9,143	12,797
Acquired licenses	5,711	915	4,796
Assembled workforce	500	500	—
Total intangible assets	$ 60,781	$ 28,328	$ 32,453

	December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Intangibles, net
Patent rights	$ 32,630	$ 15,591	$ 17,039
Acquired technology	21,940	7,679	14,261
Acquired licenses	5,711	551	5,160
Assembled workforce	500	475	25
Total intangible assets	$ 60,781	$ 24,296	$ 36,485

As of December 31, 2024, the weighted average remaining life for identifiable intangible assets was 8.5 years. Aggregate amortization expense was $4.0 million and $4.1 million for the years ended December 31, 2024 and 2023, respectively. Patent rights, acquired technology and acquired licenses are amortized over a 15-year period. Assembled workforce is amortized over a five-year period.

Estimated future amortization expense related to intangible assets as of December 31, 2024 is as follows (in thousands):

	Amount
2025	$ 4,006
2026	4,006
2027	4,006
2028	4,006
2029	4,006
Thereafter	12,423
Total	$ 32,453

7. Debt

Convertible Debentures

On March 21, 2023, the Company entered into the Yorkville SPA, pursuant to which the Company would issue and sell to Yorkville Convertible Debentures in an aggregate principal amount of up to $25.0 million. The Yorkville SPA provided that the Convertible Debentures would be issued and sold at a purchase price equal to 96% of the applicable principal amount in three tranches as follows: (i) $10.0 million upon the signing of the Yorkville SPA, which was funded on March 21, 2023; (ii) $7.5 million upon the filing of a registration statement on Form S-1 with the SEC to register the resale by Yorkville of any shares of Common Stock issuable upon conversion of the Convertible Debentures under the Securities Act of 1933, as amended (the "Securities Act"), which was funded on April 11, 2023; and (iii) $7.5 million at the time such registration statement was declared effective by the SEC, which was funded on April 20, 2023.

The Convertible Debentures bore interest at an annual rate of 7.00% and were initially set to mature on December 21, 2023. On October 11, 2023, the Company and Yorkville amended the Convertible Debentures. The Default Conversion Price (as defined therein) was originally set not to fall below $2.00 per share and such floor price has been amended to mean a price per share of Common Stock equal to 95% of the lowest daily VWAP (as defined therein) during the five consecutive trading days immediately preceding the conversion date, but not lower than $0.50 per share. The maturity date of the Convertible Debentures was also extended from December 21, 2023 to March 15, 2024. The outstanding principal amount was to be repaid in equal installments that are due every 30 days beginning on May 20, 2023, which is 60 days after the date on which the first Convertible Debenture was issued to Yorkville. The Convertible Debentures provided a conversion right, in which any portion of the outstanding and unpaid principal and any accrued but unpaid interest, may be converted into shares of Common Stock, at a conversion price of $8.00 per share at the option of the holder of the Convertible Debentures.

The Company had the option to repay either (i) in cash, with premium equal to 5% in respect of the principal amount of such payment, or (ii) by submitting a notice for an advance under the A&R Yorkville Purchase Agreement, or a series of advances thereunder, or any combination of (i) or (ii) as determined by the Company. In the case of (ii), the proceeds from the shares sold to Yorkville are applied against the outstanding amounts.

The Company had the right, but not the obligation, in its sole discretion, to redeem, upon five business days' prior written notice to Yorkville (the "Redemption Notice"), all or any portion of the amounts outstanding under the Convertible Debentures; provided that the trading price of the Common Stock is less than the Conversion Price at the time of the Redemption Notice. The redemption amount shall be equal to the outstanding principal balance being redeemed by the Company, plus the redemption premium of 10% of the principal amount being redeemed, plus all accrued and unpaid interest in respect of such redeemed principal amount.

The Company elected the fair value option for the Convertible Debentures and recorded the changes in the fair value within the consolidated statements of operations and comprehensive loss at the end of each reporting period. Pursuant to the Yorkville SPA, the Company issued additional Convertible Debentures in an aggregate principal amount of $15.0 million in April 2023 for $14.4 million in net cash proceeds. In April 2023, Yorkville elected to convert $5.0 million of the outstanding principal and accrued interest of the first Convertible Debentures issued to Yorkville, resulting in the issuance of 632,431 shares of Common Stock at a conversion price of $8.00 per share and reducing the outstanding Convertible Debentures fair value balance by $7.7 million. The Company repaid $4.4 million of the Convertible Debentures during the year ended December 31, 2024. Interest expense related to the Convertible Debentures and included in the changes in fair value was $35.0 thousand and $0.7 million for the years ended December 31, 2024 and 2023, respectively.

The following table provides a summary of the changes in the balance and the estimated fair value of the Convertible Debentures (in thousands):

		December 31, 2024
Ending Balance as of December 31, 2023	$	4,340
Repayment of Convertible Debentures		(4,375)
Change in fair value of Convertible Debentures		35
Ending Balance as of December 31, 2024	$	—

Revolving Facility

On June 27, 2023, Scilex Pharma entered into the eCapital Credit Agreement, pursuant to which the Lender shall make available the Revolving Facility in an aggregate principal amount of up to $30.0 million. The Facility Cap may, at the request of Scilex Pharma and with the consent of the Lender, be increased in increments of $250,000 at such time as the outstanding principal balance under the eCapital Credit Agreement equals or exceeds 95% of the then-existing Facility Cap. The amount available to Scilex Pharma under the Revolving Facility at any one time is the lesser of the Facility Cap and 85% of the Net Collectible Value of Eligible Receivables (each as defined therein) minus the amount of any reserves or adjustments against receivables required by the Lender, in its discretion.

Under the terms of the eCapital Credit Agreement, interest would accrue daily on the principal amount outstanding at a rate per annum equal to the Wall Street Journal Prime Rate plus 1.5%, based on a year consisting of 360 days, and which shall be payable by Scilex Pharma monthly in arrears, commencing July 1, 2023. The eCapital Credit Agreement provided for an early termination fee of 0.5% of the Facility Cap if Scilex Pharma voluntarily prepaid and terminated in full the Revolving Facility prior to the first anniversary of the closing of the Revolving Facility.

In connection with the eCapital Credit Agreement, Scilex Pharma and the Lender entered into blocked account control agreements with respect to Scilex Pharma's collections and eCapital Credit Agreement funding accounts, which permitted the Lender to sweep all funds in the collections account to an account of the Lender for application to the outstanding amounts under the Revolving Facility, and to exercise customary secured party remedies with respect to the eCapital Credit Agreement funding account. All indebtedness incurred and outstanding under the eCapital Credit Agreement would be due and payable in full on July 1, 2026, unless the eCapital Credit Agreement was earlier terminated.

The eCapital Credit Agreement contained a financial covenant requiring Scilex Pharma to maintain cash on hand of at least $1.0 million at all times. Scilex Pharma's obligations under the eCapital Credit Agreement were secured by a continuing security interest in Scilex Pharma's accounts receivable, arising from customers in the ordinary course of business. The eCapital Credit Agreement contained customary events of default and also provided that an event of default included a change of control of Scilex Pharma and the failure by the Company to issue at least $75.0 million of debt or equity by September 30, 2023, which condition was satisfied by the issuance of the Oramed Note.

On September 21, 2023, Scilex Pharma signed a subordination agreement (the "Subordination Agreement") with the Lender and Acquiom Agency Services LLC (the "Agent"). Pursuant to the Subordination Agreement, the rights and interests of the Lender under the eCapital Credit Agreement would be secured by first priority liens on the ABL Priority Collateral (as defined therein). The ABL Priority Collateral consisted of all of the Company's properties

identified in the description of collateral in the UCC-1 Financing Statement filed with the Delaware Secretary of State on June 27, 2023. The Agent's rights and interests under the Subsidiary Guarantee, dated as of September 21, 2023, entered into by the Company and each of its subsidiaries with Oramed and the Agent (the "Subsidiary Guarantee"), would be secured by first priority liens on certain other collateral and second priority liens on the ABL Priority Collateral. The Subordination Agreement also included other standard interlender terms and requires that the Facility Cap (as defined therein) shall not exceed $30.0 million.

On October 8, 2024, Scilex Pharma paid off the outstanding amount of all obligations and indebtedness of Scilex Pharma owing to the Lender under the eCapital Credit Agreement. Accordingly, the eCapital Credit Agreement, the related Loan Documents (as defined in the eCapital Credit Agreement) and the Subordination Agreement were terminated, canceled and are of no further force and effect. As of December 31, 2024 and 2023, the outstanding balance under the Revolving Facility for Scilex Pharma was nil and $17.0 million, respectively, which was classified as a long-term liability in the consolidated balance sheet.

The Oramed Note

On September 21, 2023, the Company entered into a securities purchase agreement with Oramed (the "Scilex-Oramed SPA"), pursuant to which the Company issued the Oramed Note. The Oramed Note, which has a principal amount of $101.9 million, matures on March 21, 2025. It is payable in six principal installments, with the first installment of $5.0 million payable on December 21, 2023, the second installment in the principal amount of $15.0 million payable on March 21, 2024, the next three installments each in the principal amount of $20.0 million payable on each of June 21, 2024, September 21, 2024 and December 21, 2024 and the last installment in the entire remaining principal balance of the Oramed Note payable on March 21, 2025. Interest under the Oramed Note accrues at a fluctuating per annum interest rate equal to the sum of (1) the greater of (x) 4% and (y) Term SOFR (as defined in the Oramed Note) and (2) 8.5%, payable in-kind on a monthly basis. Pursuant to the Oramed Note, since the outstanding principal of the Oramed Note was not repaid in full on or prior to March 21, 2024, an exit fee of approximately $3.1 million has been earned with respect to the Oramed Note, which shall be due and payable on the date the outstanding principal amount of the Oramed Note is paid in full. Upon the occurrence and during the continuance of an event of default under the Oramed Note, holders of more than 50% of the aggregate unpaid principal amount of the Oramed Notes may elect to accrue interest at a default rate equal to the lesser of (i) Term SOFR plus 15% or (ii) the maximum rate permitted under applicable law. Voluntary prepayments made before the one-year anniversary of the closing date of the Scilex-Oramed SPA must include a make-whole amount equal to 50% of the additional interest that would accrue on the principal amount so prepaid from the date of such prepayment through and including the maturity date. If the Oramed Note is accelerated upon an event of default, repayment is required at a mandatory default rate of 125% of the principal amount (together with 100% of accrued and unpaid interest thereon and all other amounts due in respect of the Oramed Note). The Oramed Note contains mandatory prepayment provisions requiring use of 70% of net cash proceeds from any Cash Sweep Financing (as defined in the Oramed Note) or advances under the ELOCs (as defined in the Oramed Note) to prepay the outstanding principal after the earlier of April 1, 2024 or full repayment of Acceptable Indebtedness (as defined in the Oramed Note). Following each of the April 2024 RDO (as defined below and as described under Note 9), the receipt of the FSF Deposit (as described below) and the sale of shares of Common Stock pursuant to the ATM Sales Agreement, the Company made a mandatory prepayment of $9,578,835, $7,000,000 and $1,760,796, respectively, to Oramed, which equals 70% of the net cash proceeds the Company received from the April 2024 RDO, the FSF Deposit and sale of shares of Common Stock pursuant to the ATM Sales Agreement. Given such payment was not a voluntary prepayment, such prepayment did not trigger the make-whole amount under the Oramed Note.

The Oramed Note contains affirmative and negative covenants binding on the Company and its subsidiaries, which restrict, among other things, the Company and its subsidiaries from incurring indebtedness or liens, amending charter and organizational documents, repaying or repurchasing stock, repaying, repurchasing, or acquiring indebtedness, paying or declaring cash dividends, assigning, selling, transferring or otherwise disposing of assets, making or holding investments, entering into transactions with affiliates, and entering into settlement agreements, in each case as more fully set forth in, and subject to certain qualifications and exceptions set forth in, the Oramed Note.

In connection with the Oramed Note, the Company and each of its subsidiaries (collectively, the "Guarantors") entered into a security agreement (the "Security Agreement") with Oramed (together with its successors and permitted assigns, the "Holder") and the Agent, which acts as the collateral agent for the holders of the Oramed Note. Under this

agreement, the Company and the Guarantors granted to the Agent (on behalf of and for the benefit of the holders of the Oramed Note and any Additional Notes as defined thereunder) a security interest in all or substantially all of the properties of the Company and each of the Guarantors. This was done to ensure the timely payment, performance, and full discharge of all obligations under the Oramed Note. The Security Agreement contains certain customary representations, warranties and covenants regarding the collateral thereunder, all of which are detailed in the Security Agreement.

On September 20, 2024, the Company and Oramed entered into a letter agreement (the "Oramed Letter Agreement"), pursuant to which the Company agreed to pay to Oramed $2,000,000 (the "Specified September Payment") on September 23, 2024, which payment was applied as follows: (i) $1,700,000 was applied to the amortization payment due under the Oramed Note on March 21, 2025 (the "Maturity Date") and (y) $300,000 to purchase an aggregate of 4,000,000 SPAC Warrants (as defined below) owned by Oramed.

The parties further agreed, upon receipt of the Specified September Payment by Oramed, (i) that notwithstanding the minimum Liquidity (as defined therein) requirements set forth in Section 7(b)(x) of the Oramed Note, the Company and its Subsidiaries (as defined therein) shall be required to maintain the following minimum liquidity during the specified time periods instead: from and after September 19, 2024 until the Maturity Date, $0, and (ii) to extend the due date of the $20,000,000 amortization payment from September 23, 2024 to September 30, 2024. Oramed further agreed to extend such due date to October 8, 2024, on which date a consent and amendment letter was signed with Oramed ("Oramed Consent and Amendment") under which: (i) the Company made a payment of $12,500,000 to Oramed in lieu of the payment due on September 23, 2024, using the proceeds from the issuance of the Tranche B Notes, and (ii) the remaining payments under the Oramed Note were amended as follows: installment payment of $15,000,000 payable on December 21, 2024, which payment was made on December 13, 2024, and the remaining principal balance, accrued interest and fees payable on the Maturity Date. On January 21, 2025, the Company and Oramed agreed to extend the Maturity Date under and as set forth in the Oramed Note from March 21, 2025 to December 31, 2025.

At issuance, the Company concluded that certain features of the Oramed Note would be considered derivatives that would require bifurcation. In lieu of bifurcating such features, the Company has elected the fair value option for this financial instrument and records the changes in the fair value within the consolidated statements of operations and comprehensive loss at the end of each reporting period. As of December 31, 2024, the fair value of the Oramed Note was $12.2 million, which is classified as debt, current in the consolidated balance sheet.

The following table provides a summary of the changes in the balance and the estimated fair value of the Oramed Note (in thousands):

	December 31, 2024
Ending Balance as of December 31, 2023	$ 104,089
Repayment of Oramed Note	(64,200)
Conversion into Tranche B Notes	(25,000)
Change in fair value of Oramed Note – recorded in the consolidated statements of operations	3,589
Change in fair value of Oramed Note – due to instrument-specific credit risk recorded as a component of other comprehensive income	(6,317)
Ending Balance as of December 31, 2024	$ 12,161

Commitment Letter

On June 11, 2024, the Company entered into the Commitment Letter with FSF Lender, pursuant to which FSF Lender committed to provide the Company the FSF Loan in the aggregate amount of $100.0 million. The Commitment Amount should be payable as follows: (i) $85.0 million no later than the Outside Date, which is 70 days following the date on which the Company received the FSF Deposit and (ii) the remaining $15.0 million within 60 days following the Initial Closing.

Pursuant to the Commitment Letter, FSF Lender provided the Company a non-refundable FSF Deposit in immediately available funds in the aggregate principal amount of $10.0 million on the Deposit Date, which amount would be

creditable towards the $85.0 million required to be funded by FSF Lender at the Initial Closing. The Company received the FSF Deposit on June 18, 2024 and issued to FSF Lender the Deposit Warrant to purchase up to an aggregate of 3,250,000 shares of Common Stock (subject to adjustment for any stock dividend, stock split, reverse stock split or similar transaction), with an exercise price of $1.20 per share. The Deposit Warrant was immediately exercisable and would expire five years from the date of issuance. If the Initial Closing did not occur on or prior to the Outside Date, the FSF Deposit should automatically convert into an unsecured loan on the first day after the Outside Date. Within five days after such automatic conversion occurs, the Company should issue a promissory note (the "Unsecured Promissory Note") to FSF Lender to evidence such unsecured loan, which note should be unsecured, had a maturity date of five years after the date of the Unsecured Promissory Note and was prepayable without premium or penalty. The Unsecured Promissory Note should bear interest, payable quarterly in arrears, in an amount equal to the Unsecured Applicable Interest Amount (as defined in the Commitment Letter) for such period based on the actual number of days elapsed while principal is outstanding.

It was contemplated by the Commitment Letter that the Company and FSF Lender would enter into definitive documents with respect to the FSF Loan on terms to be mutually agreed in good faith. If such definitive documents were entered into on or before the Outside Date, the Company agreed to issue to FSF Lender (i) at the Initial Closing, a warrant to purchase up to an aggregate of 24,375,000 shares (subject to adjustment for any stock dividend, stock split, reverse stock split or similar transaction) of Common Stock (the "Initial Closing Warrant"), and (ii) at the Second Closing, a warrant to purchase up to an aggregate of 4,875,000 shares (subject to adjustment for any stock dividend, stock split, reverse stock split or similar transaction) of Common Stock (the "Second Closing Warrant"), each to have an exercise price of $1.20 per share. The Initial Closing Warrant and the Second Closing Warrant would expire five years from the date of issuance. To evidence the FSF Loan, the Company agreed to issue to FSF Lender a Senior Secured Promissory Note (the "Secured Promissory Note"), which shall have a maturity date of five years after the date of issuance. The Secured Promissory Note shall bear interest, payable quarterly in arrears, in an amount equal to the Secured Applicable Interest Amount (as defined in the Commitment Letter) for such period, based on the actual number of days elapsed, while principal is outstanding, subject to certain conditions.

At issuance, the Company concluded that certain features of the FSF Deposit would be considered derivatives that would require bifurcation. In lieu of bifurcating such features, the Company has elected the fair value option for this financial instrument and records the changes in the fair value within the consolidated statements of operations and comprehensive loss at the end of each reporting period.

In connection with the transactions contemplated by the Commitment Letter, the Company also entered into an agreement with FSF Lender and the FSF Lender's strategic consultant, IVI 66766 LLC ("IVI"), dated July 16, 2024, pursuant to which the Company agreed to reimburse the actual, reasonable and documented consulting fees incurred by FSF Lender in connection with the preparation, negotiation and execution of the Commitment Letter and the definitive documents with respect to the transactions contemplated thereby, which fees were satisfied in full by the Company issuing to IVI a warrant to purchase up to an aggregate of 250,000 shares of Common Stock (the "Fee Warrant") on July 16, 2024, with an exercise price of $1.20 per share. Subject to certain ownership limitations, the Fee Warrant is immediately exercisable and will expire five years from the date of issuance. The Company accounted for the Fee Warrant as an equity classified instrument and recognized the Fee Warrant in additional paid-in capital in the Company's consolidated balance sheets. The fair value of the Fee Warrant as of the date of issuance was $0.3 million. In October 2024, the Fee Warrant was exercised by IVI.

On September 17, 2024, the Company entered into the Satisfaction Agreement with FSF Lender and Endeavor, pursuant to which the remaining obligations in respect of the FSF Deposit shall be fully satisfied by the Company's delivery of 28,000 cartons of ZTlido to Endeavor, which delivery shall occur no later than December 31, 2024. Upon satisfaction of such remaining obligations, the Commitment Letter shall be terminated and of no further force or effect and neither FSF Lender nor the Company shall have any further liability or obligations thereunder. In consideration of Endeavor assuming the payment obligation of the Company in respect of the FSF Deposit, Endeavor will not be responsible for making any payment to the Company for (i) the product already delivered as of the date of such agreement in an amount of approximately $13.2 million and (ii) the Additional Product. Pursuant to the terms of the Satisfaction Agreement, if the Company fails to fully deliver the Additional Product by December 31, 2024, the Company shall be liable to Endeavor for liquidated damages in the amount of $20,000,000. In November 2024, the Company delivered the Additional Product to Endeavor and fully satisfied the remaining obligations in respect of the FSF Deposit.

The following table provides a summary of the changes in the balance and the estimated fair value of the FSF Deposit (in thousands):

	December 31, 2024
Beginning Balance as of June 11, 2024	$ 10,000
Change in fair value of FSF Deposit	4,690
Reclass of Deposit Warrant liability upon satisfaction of FSF Deposit	(1,690)
Repayment of FSF Deposit	(13,000)
Ending Balance as of December 31, 2024	$ —

Tranche B Notes

On October 8, 2024, the Company entered into the Tranche B Securities Purchase Agreement with the Tranche B Investors and Oramed to refinance a portion of the Oramed Note and pay off certain other indebtedness of the Company. Pursuant to the Tranche B Securities Purchase Agreement, the Company agreed to issue and sell, in a registered offering by the Company directly to the Tranche B Noteholders: (i) the Tranche B Notes, which notes will mature on the two-year anniversary of the issuance date and will be convertible into shares of Common Stock at a conversion price equal to $1.09 per share (which was automatically reduced to $1.04 per share of Common Stock subsequent to the December 2024 RDO (as defined below) in accordance with the terms of such notes) and (ii) warrants (the "October 2024 Noteholder Warrants") to purchase up to 7,500,000 shares of Common Stock directly to the Tranche B Noteholders.

The Company has received in exchange for the issuance of the Tranche B Notes to the Tranche B Investors an aggregate amount in cash of $22,500,000, excluding fees and expenses payable by the Company. The Company has received from Oramed in consideration for the Tranche B Notes issued to Oramed an exchange and reduction of the principal balance under the Oramed Note of $22,500,000.

The October 2024 Noteholder Warrants are immediately exercisable for cash at an exercise price equal to $1.09 per share of Common Stock (which was automatically reduced to $1.04 per share of Common Stock subsequent to the December 2024 RDO (as defined below) in accordance with the terms of such warrants) and will expire five years from the issuance date. The October 2024 Noteholder Warrants issued to the Tranche B Investors are initially exercisable for 3,750,000 shares of Common Stock in the aggregate. The October 2024 Noteholder Warrants issued to Oramed are initially exercisable for 3,750,000 shares of Common Stock.

In connection with the offering of the Tranche B Notes, the Company issued to StockBlock Securities LLC ("StockBlock") and its affiliate, Rodman & Renshaw LLC (collectively, the "Placement Agents") or their respective designees, (i) 2,197,802 shares of Common Stock (the "Placement Agent Shares") and (ii) warrants to purchase up to 3,669,724 shares of Common Stock (the "October 2024 Placement Agent Warrants"). The October 2024 Placement Agent Warrants will have the same terms as the October 2024 Noteholder Warrants, except that the Placement Agents have agreed not to exercise the October 2024 Placement Agent Warrants for a period of 180 days following the date of issuance.

In conjunction with the Tranche B Securities Purchase Agreement, the Company entered into the ZTlido Royalty Purchase Agreement (as defined below) for $5.0 million of the aggregate purchase price for the ZTlido Purchased Receivables in full consideration for the sale, transfer, conveyance and granting of the ZTlido Purchased Receivables, subject to the terms and conditions set forth in the ZTlido Royalty Purchase Agreement. The $50.0 million of total proceeds received were allocated based on their relative fair value to the Tranche B Notes, the October 2024 Noteholder Warrants, and the ZTlido Royalty Purchase Agreement, with the excess of fair value over the proceeds received in amount of $2.6 million recognized as a loss upon issuance in change in fair value of debt and liability instruments in the consolidated statement of operations during the year ended December 31, 2024.

The following table provides a summary of the changes in the balance and the estimated fair value of the Tranche B Notes (in thousands):

	December 31, 2024
Beginning Balance as of October 8, 2024	$ 42,740
Conversion of Tranche B notes	(9,255)
Repayment of Tranche B Notes	(3,283)
Change in fair value of Tranche B Notes	(6,641)
Ending Balance as of December 31, 2024	$ 23,560

Aggregate principal repayments for the Company's outstanding debt will be $47.7 million and $19.5 million in 2025 and 2026, respectively.

ZTlido Royalty Purchase Agreement

On October 8, 2024, in connection with the closing of the transactions contemplated by the Tranche B Securities Purchase Agreement, the Company and Scilex Pharma entered into the ZTlido Royalty Purchase Agreement with the ZTlido Royalty Purchasers. Pursuant to the ZTlido Royalty Purchase Agreement, Scilex Pharma sold to the ZTlido Royalty Purchasers the right to receive 8% of all aggregate net sales worldwide (the "ZTlido Purchased Receivables") with respect to ZTlido, SP-103 and any related, improved, successor, replacement or varying dosage forms of the foregoing, which shall be paid within 60 calendar days after the end of each calendar quarter.

In full consideration for the sale, transfer, conveyance and granting of the ZTlido Purchased Receivables, and subject to the terms and conditions set forth in the ZTlido Royalty Purchase Agreement, the aggregate purchase price for the ZTlido Purchased Receivables was $5.0 million (net of expenses of the ZTlido Royalty Purchasers). The ZTlido Royalty Investors paid to Scilex Pharma an aggregate amount equal to $2.5 million minus the expenses of the ZTlido Royalty Investors and Oramed paid to Scilex Pharma an amount equal to $2.5 million minus Oramed's expenses (collectively, the amount so paid by the ZTlido Royalty Purchasers, the "ZTlido RPA Closing Payment"). Oramed's portion of the purchase price was paid by exchanging a portion of the outstanding principal balance under the Oramed Note equivalent to its portion of the ZTlido RPA Closing Payment, which amount extinguished and reduced $2.5 million of the outstanding balance under the Oramed Note.

The Royalty Purchase Agreement terminates six months following receipt by the ZTlido RPA Purchasers of all payments of the ZTlido Purchased Receivables to which each ZTlido RPA Purchaser is entitled during the period commencing on the closing date of the ZTlido Royalty Purchase Agreement and expiring on the tenth anniversary of such closing date.

The Company elected the fair value option for the ZTlido Royalty Purchase Agreement and records the changes in the fair value within the consolidated statements of operations and comprehensive loss at the end of each reporting period. As of December 31, 2024, the fair value of the ZTlido Royalty Purchase Agreement was $6.8 million, recorded as a purchased revenue liability on the consolidated balance sheet. The Company incurred $0.2 million of issuance costs in connection with the ZTlido Royalty Purchase Agreement, which were included in the consolidated statement of operations for the year ended December 31, 2024.

The following table summarizes the purchased revenue liability activity during the year ended December 31, 2024 (in thousands):

	December 31, 2024
Beginning Balance as of October 8, 2024	$ 5,900
Change in fair value of purchased revenue liability	900
Ending Balance as of December 31, 2024	$ 6,800

8. Junior DIP Facility and Sorrento Stock Purchase Agreement

Junior DIP Facility

In July 2023, the Company entered into an agreement to provide Sorrento with a non-amortizing super-priority junior secured term loan facility ("Junior DIP Facility") in an aggregate principal amount of $20.0 million (the "Junior DIP Loan Agreement"), which was funded in the same month. The Junior DIP Facility bears interest at a per annum rate of 12.0% payable in kind on the first day of each month in arrears and on the DIP Termination Date (as defined in the Junior DIP Loan Agreement). Upon repayment or satisfaction of the DIP Loans (as defined in the Junior DIP Loan Agreement) in whole or in part, Sorrento is required to pay to the Company in cash an exit fee equal to 2.00% of the aggregate principal amount of the Junior DIP Facility. The Junior DIP Facility was to mature on the earliest of: (i) September 30, 2023; (ii) the effective date of any Chapter 11 plan of reorganization with respect to Sorrento; (iii) the consummation of any sale or other disposition of all or substantially all of the assets of Sorrento; (iv) the date of the acceleration of the DIP Loans and the termination of the DIP Commitments (as defined in the Junior DIP Loan Agreement) in accordance with the DIP Documents (as defined in the Junior DIP Loan Agreement); and (v) dismissal of the Chapter 11 Cases or conversion of the Chapter 11 Cases into cases under Chapter 7 of the Bankruptcy Code.

On September 21, 2023, Sorrento's obligations under the Junior DIP Facility were waived and deemed to be fully settled in conjunction with the Sorrento SPA as described below. Consequently, the transfer of funds associated with the Junior DIP Facility was deemed and accounted for as a capital distribution to Sorrento.

Sorrento Stock Purchase Agreement

On September 21, 2023, the Company entered into the Sorrento SPA, pursuant to which the Company purchased from Sorrento (i) 60,068,585 shares of Common Stock, (ii) 29,057,097 shares of Series A Preferred Stock and (iii) 1,386,617 Public Warrants and 3,104,000 Private Warrants (collectively, the "Purchased Securities"). On the same day, the Company and Oramed entered into the Scilex-Oramed SPA. The Company concluded that the Sorrento SPA and the Scilex-Oramed SPA were entered in contemplation of each other and the issuance of the Oramed Note was accounted as part of the consideration payable for the Purchased Securities acquired from Sorrento.

Pursuant to the terms of the Scilex-Oramed SPA, the Company issued the Oramed Note (see Note 7), which replaced Sorrento's outstanding obligations to Oramed, warrants to purchase up to an aggregate of 4,500,000 shares of Common Stock (the "Closing Penny Warrant") with an exercise price of $0.01 per share and restrictions on exercisability, and warrants to purchase up to an aggregate of 8,500,000 shares of Common Stock (the "Subsequent Penny Warrants" and together with the Closing Penny Warrant, the "Penny Warrants"), each with an exercise price of $0.01 per share and each with restrictions on exercisability. Additionally, the Company agreed to transfer to Oramed 4,000,000 SPAC Warrants, which were acquired by the Company under the Sorrento SPA. There was no change in the terms for the warrants transferred to Oramed as a result of the transactions described above. The remaining consideration for the Purchased Securities was comprised of a credit bid for all amounts of principal and accrued but unpaid interest outstanding under the Junior DIP Facility, a $10.0 million cash payment, and the assumption and assignment of certain obligations of Sorrento for legal fees and expenses amounting to approximately $12.3 million.

The Company allocated the total consideration between the repurchased instruments by allocating to the repurchased Private Warrants their full value, with the remaining consideration allocated to the Common Stock, Series A Preferred Stock, and Public Warrants based on their relative fair values as of September 21, 2023.

Before the closing of the Sorrento SPA transactions and in connection with the transactions contemplated by the Sorrento SPA, the Company formed two entities: (a) Scilex DRE Holdings LLC ("Holdco"), a single purpose entity that is the Company's direct wholly owned subsidiary and (b) Scilex Stock Acquisition Joint Venture LLC, a single purpose bankruptcy-remote entity that is the Company's indirect wholly owned subsidiary ("SCLX JV"), which was

formed to hold the Purchased Securities. Holdco was formed to hold all of the equity interests in SCLX JV. Holdco and SCLX JV are parties to the Security Agreement and Subsidiary Guarantee (see Note 7).

Series A Preferred Stock

Pursuant to the terms of the Sorrento SPA, the Company repurchased all of the outstanding Series A Preferred Stock. The Series A Preferred Stock is classified in permanent equity and does not have any bifurcated features. Therefore, the repurchase of the Series A Preferred Stock by the Company is treated as a redemption of shares and viewed as a deemed dividend. The fair value of Series A Preferred Stock as of the repurchase date of September 21, 2023 was $52.6 million. The Company derecognized the carrying value of the Series A Preferred Stock, with any excess amount allocated as the reduction in additional paid-in capital. The Series A Preferred Stock is currently held as collateral for the Oramed Note.

Treasury Stock

The Common Stock that has been repurchased by the Company under the Sorrento SPA is not intended for constructive retirement, and is being held as collateral for the Oramed Note. In accordance with treasury stock accounting guidance, the consideration allocated to Common Stock is presented under a separate caption of Treasury Stock as a reduction of equity.

Penny Warrants

The Closing Penny Warrant will be exercisable upon the earliest of (i) March 14, 2025, (ii) the date on which the Oramed Note has been repaid in full and (iii) the Management Sale Trigger Date (as defined therein), if any, and will expire on the date that is the fifth anniversary of the issuance date.

The Company issued four Subsequent Penny Warrants, each for 2,125,000 shares of Common Stock, one of which shall vest and become exercisable on the date that is the later of (i) each of March 19, 2024 (the "CS-2 Warrant"), June 17, 2024 (the "CS-3 Warrant"), September 15, 2024 (the "CS-4 Warrant") or December 14, 2024 (the "CS-5 Warrant") (each, the "Subsequent Penny Warrant Vesting Date") and (ii) the earliest of (A) March 14, 2025, (B) the date on which the Oramed Note has been repaid in full and (C) the Management Sale Trigger Date (as defined therein), if any. Each Subsequent Penny Warrant will expire on the date that is the fifth anniversary of the issuance date; provided that, if the Oramed Note is repaid in full prior to the Subsequent Penny Warrant Vesting Date applicable to such Subsequent Penny Warrant, such Subsequent Penny Warrant will expire on the date the Oramed Note is repaid in full.

Pursuant to a letter agreement the Company entered into with Oramed, dated as of August 30, 2024, the parties agreed that: (i) the CS-4 Warrant shall fully vest on August 30, 2024 and (ii) Oramed may immediately exercise the Oramed Warrants with respect to up to 5,437,500 shares of Common Stock. Pursuant to the Oramed Letter Agreement the Company entered into with Oramed, dated as of September 20, 2024, the parties agreed that Oramed may immediately exercise the CS-5 Warrant with respect to up to 1,062,500 shares of Common Stock.

The exercise price of the Penny Warrants is $0.01 per share, subject to adjustments provided therein. The exercise price and number of shares of Common Stock issuable upon the exercise of the Penny Warrants will be subject to adjustment in the event of any stock dividend, stock split, recapitalization, reorganization or similar transaction, as described in the Penny Warrants; provided that there shall not be any adjustment to the exercise price of the Penny Warrants in the event the Company combines (by combination, reverse stock split or otherwise) its Common Stock into a smaller number of shares. Oramed may exercise the Penny Warrants by means of a "cashless exercise." The Closing Penny Warrant and the Subsequent Penny Warrants utilize the same form of warrant.

The Penny Warrants may not be exercised if Oramed, together with its affiliates, would beneficially own in excess of 9.9% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise (the "Oramed Beneficial Ownership Limitation"); provided, however, that upon 61 days' prior notice to the Company, Oramed may increase or decrease the Oramed Beneficial Ownership Limitation.

The Company accounted for the Penny Warrants as an equity classified instrument as they are indexed to the Company's own stock and meet the conditions to be classified in equity under FASB ASC 815, *Derivatives and Hedging,* including sufficient available shares for the Company to settle the exercise of the warrants in shares. The Penny Warrants are recognized in additional paid-in capital in the Company's consolidated balance sheets. The fair value of Penny Warrants as of September 21, 2023, the date of issuance, was $10.4 million.

During the year ended December 31, 2024, there were 6,500,000 Penny Warrants exercised by Oramed for net proceeds of approximately $0.1 million. As of December 31, 2024, there were 6,500,000 Penny Warrants outstanding that were fully vested and such warrants became exercisable on March 14, 2025.

Excise Tax

In December 2022, the Department of the Treasury and the Internal Revenue Service (the "IRS") issued guidelines on the implementation of the new code section added by the Inflation Reduction Act of 2022, which imposes a 1% excise tax on the total fair market value of stock repurchases during the tax year, subject to adjustments. Pursuant to the terms of the Sorrento SPA, the Company repurchased the Purchased Securities from Sorrento. The total fair market value of the Purchased Securities was offset by the fair market value of the shares issued during the year ended December 31, 2023. The Company has accrued $1.3 million of the excise tax liability during the year ended December 31, 2023, which was recorded as accrued expenses under current liabilities on the consolidated balance sheet. During the year ended December 31, 2024, the Company made a total of $0.5 million payments for the excise tax. As of December 31, 2024, the remaining balance of the excise tax liability recorded as accrued expenses was $0.8 million.

9. Stockholders' Deficit

SPAC Warrants

Upon the completion of the Business Combination, the Company assumed the Private Warrants and the public warrants to purchase Common Stock, each with an exercise price of $11.50 per share (the "Public Warrants", and together with the Private Warrants, the "SPAC Warrants").

Holders of the SPAC Warrants are entitled to acquire shares of Common Stock. The SPAC Warrants will expire five years after the completion of the Business Combination or earlier upon redemption or liquidation.

If the reported last sale price of the Common Stock equals or exceeds $18.00 per share for any 20 trading days within a 30-trading day period ending three business days before the Company sends the notice of redemption to the warrant holders, the Company may redeem all the Public Warrants at a price of $0.01 per warrant upon not less than 30 days' prior written notice.

If the Company calls the Public Warrants for redemption, the Company will have the option to require all holders that wish to exercise the Public Warrants to do so on a cashless basis. The Company will not be required to net cash settle the SPAC Warrants.

The Public Warrants are equity-classified warrants and recognized in additional paid-in capital in the accompanying consolidated balance sheets. The Private Warrants are liability-classified warrants and are recognized as liabilities (refer to Notes 1 and 4).

During the year ended December 31, 2023, the SPAC Warrants held by Sorrento were repurchased, and certain of such warrants transferred to Oramed, as a result of the Sorrento SPA (refer to Note 8). On September 20, 2024, the Company repurchased 4,000,000 of the SPAC Warrants held by Oramed (refer to Note 7). Following the repurchase, these warrants were cancelled.

As of December 31, 2024 and 2023, there were 5,467,692 and 6,854,309 Public Warrants outstanding, respectively.

As of December 31, 2024 and 2023, there were 1,000,000 and 3,613,383 Private Warrants outstanding, respectively.

Preferred Stock

The Company is authorized to issue 45,000,000 shares of preferred stock (the "Preferred Stock") of which there are two series in total.

Series A Preferred Stock

As of December 31, 2024 and 2023, there were 29,057,097 shares of Series A Preferred Stock outstanding. On September 21, 2023, the Series A Preferred Stock was repurchased and derecognized for accounting purposes. The Series A Preferred Stock is currently held as collateral for the Oramed Note.

Series 1 Preferred Stock

On October 27, 2024, the Board declared a stock dividend (the "Dividend") consisting of an aggregate of 5,000,000 shares (the "Dividend Stock") of Series 1 Mandatory Exchangeable Preferred Stock, par value $0.0001 per share (the "Series 1 Preferred Stock"), of the Company to record holders of certain of the Company's securities as of the close of business on November 7, 2024 (which date was subsequently changed to April 11, 2025). Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series 1 Mandatory Exchangeable Preferred Stock (the "Certificate of Designation") filed with the Secretary of State of the State of Delaware on October 28, 2024, the Series 1 Preferred Stock ranks senior to the Common Stock but junior to all other series of Preferred Stock with respect to distributions of assets upon voluntary or involuntary liquidation, dissolution, or winding up of the affairs of the Company. The holders of Series 1 Preferred Stock may become entitled to a pro rata portion of the number of shares that represents the lesser of (a) 10% of the shares of the Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted), held by the Company as of immediately prior to the Effective Time (as defined below) (taking into account any adjustment for any stock dividend, stock split, reverse stock split or similar transaction) and (b) that number of shares of Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) equal to $200,000,000 divided by the closing price of such Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) on any national securities exchange on which such shares are listed on the date that is 10 trading days prior to the Determination Date (as defined below), which shares shall be paid from the shares of Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) held by the Company as of immediately prior to the Effective Time (taking into account any adjustment for any stock dividend, stock split, reverse stock split or similar transaction). Furthermore, the holders of Series 1 Preferred Stock shall not be entitled to receive any dividends and shall not have any voting rights by virtue of their ownership of any shares of Series 1 Preferred Stock.

For purposes of the Certificate of Designation, (a) "Effective Time" means the effective time of the Semnur Business Combination as determined under the terms of the Semnur Business Combination Agreement, (b) "Determination Date" means, if the Semnur Common Stock (or such other securities into which or for which such stock may be exchanged or converted) is listed for, and trading on, any national securities exchange, the date that is 15 trading days following the Registration Date, (c) "Registration Date" means the earlier of (i) the Effective Time, at which time the shares of Semnur Common Stock (or such other securities into which or for which such stock has been exchanged or converted) are registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and (ii) the time at which the Registration Statement is declared effective by the Securities and Exchange Commission and (d) "Registration Statement" means a registration statement, whether under the Exchange Act, or the Securities Act, that is filed by Semnur or any successor thereto or affiliate thereof with respect to the registration of the Semnur Common Stock or any securities into which or for which such stock may be exchanged or converted. The Board has the right to change the Record Date and the right to revoke the Dividend at any time prior to the payment date therefor. There can be no assurance that the Board will not revoke the Dividend or that, even if such Dividend is paid, the conditions for the mandatory exchange set forth in the Certificate of Designations will ever occur (including that the Registration Date shall have occurred on or before 11:59 p.m. Eastern time on October 28, 2025).

The Series 1 Preferred Stock does not have any bifurcated features and is classified in equity at par value because the Company had an accumulated deficit position as of Dividend Stock declaration date. As of December 31, 2024 and as of the date of this filing, none of the Dividend Stock or any shares of the Series 1 Preferred Stock were issued or distributed.

Treasury Stock

As of December 31, 2024 and 2023, there were 60,068,585 shares of Treasury Stock.

A&R Yorkville Purchase Agreement

Pursuant to the A&R Yorkville Purchase Agreement, the Company had the right, but not the obligation, in its sole and absolute discretion, to sell to Yorkville up to $500.0 million of shares of Common Stock at its request and subject to certain conditions by delivering written notice to Yorkville at any time until the first day of the month following the 36-month anniversary of the date on which the Company's registration statement on Form S-1 registering such shares was declared effective by the SEC. Pursuant to the A&R Yorkville Purchase Agreement, the shares of Common Stock, if any, that the Company elected to sell to Yorkville pursuant to a sale of Common Stock will be purchased at a price equal to 98% of the VWAP (as defined below) during the applicable pricing period for such advance, which shall be the period commencing upon receipt by Yorkville of an advance notice from the Company (or the open of regular trading hours, if later) and ending on 4:00 p.m. on the same day. For purposes of the A&R Yorkville Purchase Agreement, "VWAP" means, for a specified period, the volume weighted average price of the Common Stock on the Nasdaq Capital Market for such period as reported by Bloomberg L.P. through its "AQR" function. Pursuant to the terms of the Original Purchase Agreement, the Company filed a registration statement on Form S-1 (File No. 333-268607) (as it may be amended or supplemented from time to time, the "Yorkville Registration Statement") related to the Original Purchase Agreement with the SEC on November 30, 2022 (following the execution of the Original Purchase Agreement). The Yorkville Registration Statement was initially declared effective by the SEC on December 9, 2022.

In connection with the execution of the Original Purchase Agreement, the Company issued to Yorkville 250,000 shares of Common Stock. During the year ended December 31, 2024, the Company sold 96,982 shares of Common Stock pursuant to the A&R Yorkville Purchase Agreement for aggregate net proceeds of $0.2 million. During the year ended December 31, 2023, the Company sold 11,552,074 shares of Common Stock pursuant to the A&R Yorkville Purchase Agreement for aggregate net proceeds of $32.3 million. On, and effective as of, March 25, 2024, the Company and Yorkville mutually agreed to terminate the A&R Yorkville Purchase Agreement.

B. Riley Purchase Agreement

Pursuant to the B. Riley Purchase Agreement, the Company had the right, but not the obligation, to sell to B. Riley up to $500.0 million of shares of Common Stock, subject to certain limitations and conditions set forth therein, from time to time at the Company's sole and absolute discretion, during the term of the B. Riley Purchase Agreement.

The Company's right to sell shares of Common Stock pursuant to the B. Riley Purchase Agreement shall end on the first day of the month following the 36-month anniversary of the date on which the B. Riley Registration Statement (as defined below) was initially declared effective by the SEC. Pursuant to the terms of the B. Riley Purchase Agreement, the Company filed a registration statement on Form S-1 (File No. 333-269205) (as it may be amended or supplemented from time to time, the "B. Riley Registration Statement") related to the B. Riley Purchase Agreement with the SEC on January 12, 2023 (following the execution of the B. Riley Purchase Agreement). The B. Riley Registration Statement was initially declared effective by the SEC on January 20, 2023.

The shares of Common Stock, if any, that the Company elects to sell to B. Riley pursuant to an advance under the B. Riley Purchase Agreement will be purchased at a price equal to 98% of the VWAP (as defined in such agreement) during the pricing period prescribed therein.

In connection with the execution of the B. Riley Purchase Agreement, the Company issued to B. Riley 250,000 shares of Common Stock. During the year ended December 31, 2024, the Company did not sell any shares of Common Stock pursuant to the B. Riley Purchase Agreement. During the year ended December 31, 2023, the Company sold an aggregate of 1,414,554 shares of Common Stock for aggregate net proceeds of $3.2 million. On, and effective as of, February 16, 2024, the Company and B. Riley mutually agreed to terminate the B. Riley Purchase Agreement.

Stock Issued under Settlement Agreement with Hudson Bay Parties

In August 2023, the Company, along with Hudson Bay Capital Management LP ("Hudson Bay"), Cove Lane Onshore Fund, LLC ("Cove Lane"), and HBC Investments LLC ("HBC" and collectively, the "Hudson Bay Parties"), entered into several agreements. Under these agreements, the Company agreed to issue and sell up to $118.6 million in securities and warrants to the Hudson Bay Parties. However, on September 15, 2023, a settlement agreement was reached and released all claims related to the previous agreements. The Company acknowledged payments of $8.65 million made to the Hudson Bay Parties as properly earned. To satisfy remaining obligations, the Company agreed to issue shares of Common Stock to Cove Lane and HBC worth $0.3 million and $0.5 million, respectively. This resulted in the issuance of an aggregate of 474,683 shares of Common Stock on September 25, 2023.

At-the-Market Sales Agreement

On December 22, 2023, the Company entered into a Sales Agreement (the "ATM Sales Agreement") with B. Riley Securities, Inc., Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (the "Sales Agents"), which agreement was voluntarily terminated by us effective as of March 5, 2025. Pursuant to the ATM Sales Agreement, the Company was able to offer and sell (the "Offering") shares of Common Stock up to $170,000,000 (the "ATM Shares"), through or to the Sales Agents. The Company had no obligation to sell any shares of Common Stock under the ATM Sales Agreement and could suspend offers at any time.

The ATM Shares offered and sold in the Offering were issued pursuant to the Company's shelf registration statement on Form S-3 (which was initially filed with the SEC on December 22, 2023, as amended, and declared effective on January 11, 2024 (File No. 333-276245)) (the "Shelf S-3 Registration Statement"). The ATM Shares were offered only by means of a prospectus forming a part of the Shelf S-3 Registration Statement.

The Sales Agents were entitled to a commission equal to 3.0% of the gross proceeds from each sale of shares of Common Stock. The Company agreed to reimburse the Sales Agents for certain expenses and has agreed to provide indemnification and contribution to the Sales Agents against certain civil liabilities, including liabilities under the Securities Act.

As of December 31, 2024, the Company sold 2,764,187 shares of Common Stock pursuant to the ATM Sales Agreement for net proceeds of approximately $2.7 million. As of December 31, 2023, no sales of Common Stock had been made under the ATM Sales Agreement.

February 2024 Bought Deal Offering Underwriting Agreement

On February 29, 2024, the Company entered into an underwriting agreement (the "February 2024 BDO Underwriting Agreement") with Rodman & Renshaw LLC and StockBlock, acting as representatives of the underwriters, to sell, in an underwritten offering (the "February 2024 BDO"), 5,882,353 shares of Common Stock (the "February 2024 BDO Firm Shares") and accompanying common warrants to purchase up to an aggregate of 5,882,353 shares of Common Stock (the "February 2024 BDO Firm Warrants"). The securities in the February 2024 BDO were offered and sold by us pursuant to the Shelf S-3 Registration Statement, a base prospectus dated January 11, 2024, and a final prospectus supplement dated February 29, 2024.

The February 2024 BDO closed on March 5, 2024, and the combined price per Firm Share and accompanying February 2024 BDO Firm Warrant paid by the underwriters was $1.564, which amount reflects the combined public offering price of $1.70, less underwriting discounts and commissions. Pursuant to the February 2024 BDO Underwriting Agreement, the Company also granted the underwriters a 30-day option to purchase up to 882,352 additional shares of Common Stock and/or common warrants to purchase up to 882,352 shares of Common Stock (the "February 2024 BDO Optional Warrants", and together with the February 2024 BDO Firm Warrants, the "Common Warrants"). The underwriters did not exercise this option and it expired on March 30, 2024. Subject to certain ownership limitations, the Common Warrants are immediately exercisable, set to expire five years later, with an exercise price of $1.70 per share, subject to adjustments. Additionally, the Company issued the representative warrants (the "February 2024 BDO Representative Warrants") to the underwriters, allowing them to purchase up to 470,588 shares of Common Stock, with these warrants being immediately exercisable at $2.125 per share, representing 125% of the combined public offering price per Firm Share and accompanying February 2024 BDO Firm Warrant.

The Company accounted for the February 2024 BDO Firm Warrants as a liability classified instrument (see Note 4) and the February 2024 BDO Representative Warrants as an equity classified instrument. The February 2024 BDO Representative Warrants are recognized in additional paid-in capital in the Company's consolidated balance sheet. The issuance costs allocated to the equity component are recorded as the reduction of the offering proceeds and the amounts allocated to the liability component are expensed as incurred within the selling, general and administrative expenses in the Company's consolidated statement of operations. The fair value of February 2024 BDO Representative Warrants as of the date of issuance was $0.3 million.

On December 11, 2024, the Company entered into a warrant amendment (the "Warrant Amendment") with one of its investors to exercise the outstanding number of the February 2024 BDO Firm Warrants that the Company issued to such investor in the February 2024 BDO. Pursuant to the Warrant Amendment, the investor agreed to exercise outstanding February 2024 BDO Firm Warrants to purchase an aggregate of 1,764,706 shares of Common Stock in cash at an amended exercise price of $0.59 per share. During the year ended December 31, 2024, there were 2,078,906 February 2024 BDO Firm Warrants exercised for total net proceeds of approximately $1.6 million, including the amended February 2024 BDO Firm Warrants. As of December 31, 2024, there were 3,803,447 February 2024 BDO Firm Warrants and 470,588 February 2024 BDO Representative Warrants outstanding.

April 2024 Registered Direct Offering

On April 23, 2024, the Company entered into a securities purchase agreement (the "April 2024 RDO Purchase Agreement") with the investor named therein, pursuant to which the Company agreed to sell and issue, in a registered direct offering (the "April 2024 RDO"): (i) an aggregate of 15,000,000 shares of Common Stock (the "RDO Shares"), and (ii) common warrants to purchase up to 15,000,000 shares of Common Stock (the "April 2024 RDO Common Warrants"). The offering price per RDO Share and accompanying April 2024 RDO Common Warrant to purchase one share of Common Stock was $1.00, for aggregate gross proceeds to the Company of $15,000,000, before deducting the placement agent fees and other offering expenses. Subject to certain ownership limitations, the April 2024 RDO Common Warrants are exercisable on the six-month anniversary from the date of issuance, will expire on the five-year anniversary of the date of issuance and have an exercise price of $1.10 per share. The exercise price of the April 2024 RDO Common Warrants is subject to certain adjustments, including stock dividends, stock splits, combinations and reclassifications of the Common Stock.

StockBlock and its affiliate, Rodman & Renshaw LLC, acted as exclusive placement agents (the "Placement Agents") in connection with the April 2024 RDO. As compensation for such placement agent services, the Company paid the Placement Agents an aggregate cash fee equal to 8.0% of the gross proceeds actually received by the Company from the April 2024 RDO. The Company also reimbursed the Placement Agents $100,000 for actual, reasonable and documented fees and expenses, inclusive of fees and expenses of legal counsel and out-of-pocket expenses and $15,950 for clearing expenses. The Company has also agreed to issue to the Placement Agents or their respective designees common warrants, substantially in the form of the April 2024 RDO Common Warrants, to purchase up to 1,200,000 shares of Common Stock (the "April 2024 RDO Placement Agent Warrants"), representing up to 8.0% of the total number of the April 2024 RDO Shares issued in the April 2024 RDO. The April 2024 RDO Placement Agent Warrants have an exercise price of $1.25 per share (which represents 125% of the combined offering price per share of Common Stock and the April 2024 RDO Common Warrant sold in the April 2024 RDO), will become exercisable on the six-month anniversary of the date of issuance and expire five years from the commencement of sales in the April 2024 RDO.

The Company accounted for the April 2024 RDO Common Warrants as a liability classified instrument (see Note 4) and the April 2024 RDO Placement Agent Warrants as an equity classified instrument. The April 2024 RDO Placement Agent Warrants are recognized in additional paid-in capital in the Company's consolidated balance sheets. The issuance costs allocated to the equity component are recorded as the reduction of the offering proceeds and the amounts allocated to the liability component are expensed as incurred within the selling, general and administrative expenses in the Company's consolidated statement of operations. The fair value of April 2024 RDO Placement Agent Warrants as of the date of issuance was $0.6 million.

As of December 31, 2024, there were 15,000,000 April 2024 RDO Common Warrants and 1,200,000 April 2024 RDO Placement Agent Warrants outstanding.

December 2024 Registered Direct Offering

On December 11, 2024, the Company entered into a securities purchase agreement (the "December 2024 RDO Purchase Agreement") with the investors named therein, pursuant to which the Company agreed to sell and issue, in a registered direct offering (the "December 2024 RDO"): (i) an aggregate of 26,355,347 shares of Common Stock, (ii) pre-funded warrants to purchase up to 2,401,132 shares of Common Stock (the "December 2024 RDO Pre-Funded Warrants") and (iii) common warrants to purchase up to 57,512,958 shares of Common Stock (the "December 2024 RDO Common Warrants" and together with the December 2024 RDO Pre-Funded Warrants and the warrants issued to StockBlock pursuant to certain contractual obligations between the Company and StockBlock (the "StockBlock Warrants"), the "December 2024 RDO Warrants"). The combined offering price (a) per share of Common Stock and accompanying December 2024 RDO Common Warrants was $0.59 and (b) per December 2024 RDO Pre-Funded Warrant and accompanying December 2024 RDO Common Warrants was $0.5899. The aggregate gross proceeds to the Company from the December 2024 RDO were approximately $17.0 million, before deducting offering fees and expenses. The Company intends to use the net proceeds from the December 2024 RDO for working capital and general corporate purposes, which may include capital expenditures, commercialization expenditures, research and development expenditures, regulatory affairs expenditures, clinical trial expenditures, acquisitions of new technologies and investments, business combinations and the repayment, refinancing, redemption or repurchase of indebtedness or capital stock.

The Company accounted for the December 2024 RDO Common Warrants and December 2024 RDO Pre-Funded Warrants as liability classified instruments (see Note 4) and the StockBlock Warrants as an equity classified instrument. The StockBlock Warrants are recognized in additional paid-in capital in the Company's consolidated balance sheets. The issuance costs allocated to the equity component are recorded as the reduction of the offering proceeds and the amounts allocated to the liability component are expensed as incurred within the selling, general and administrative expenses in the Company's consolidated statement of operations. The fair value of StockBlock Warrants as of the date of issuance was $1.3 million. On December 26, 2024, the December 2024 RDO Pre-Funded Warrants were exercised by the holder for total net proceeds of approximately $0.2 million.

As of December 31, 2024, there were 57,512,958 December 2024 RDO Common Warrants and 4,601,036 StockBlock Warrants outstanding.

10. Stock Incentive and Employee Benefit Plan

2017 Scilex Pharmaceuticals Inc. Equity Incentive Plan

In June 2017, the Board of Directors of the Company adopted the Scilex Pharmaceuticals Inc. Equity Incentive Plan (the "Scilex Pharma 2017 Plan"). In connection with the corporate reorganization in March 2019, the Scilex Pharma 2017 Plan was terminated. Accordingly, after such time, no additional awards were granted under the Scilex Pharma 2017 Plan.

Scilex Holding Company 2019 Stock Option Plan

In May 2019, the Board of Directors of the Company adopted the Scilex Holding Company 2019 Stock Option Plan (the "2019 Stock Option Plan"), which subsequently was amended in December 2020. The 2019 Stock Option Plan was terminated at the closing of the Business Combination, and no further awards have been granted under the 2019 Stock Option Plan thereafter. However, the 2019 Stock Option Plan will continue to govern outstanding awards granted thereunder.

Scilex Holding Company 2022 Equity Incentive Plan

In October 2022, the Board of Directors of the Company adopted the Scilex Holding Company 2022 Equity Incentive Plan (the "Equity Incentive Plan"). As of December 31, 2024, a total of 20,208,843 shares of Common Stock were available and have been reserved for future issuance under the Equity Incentive Plan, which number of shares accounts for the automatic annual increase on January 1, 2024 pursuant to the Equity Incentive Plan.

Scilex Holding Company 2023 Inducement Plan

On January 17, 2023, the compensation committee of the Board of Directors of the Company adopted the Scilex Holding Company 2023 Inducement Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of equity-based awards in the form of non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other awards solely to prospective employees of the Company or an affiliate of the Company, provided that certain criteria are met. The initial maximum number of shares available for grant under the Inducement Plan is 1,400,000 shares of Common Stock (subject to adjustment for recapitalizations, stock splits, reorganizations and similar transactions). No awards were granted under the Inducement Plan during the years ended December 31, 2024 and 2023.

As of December 31, 2024, options to purchase 35,985,182 shares of Common Stock were outstanding under all equity incentive plans.

The following table summarizes stock option activity during the year ended December 31, 2024 (shares in thousands):

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life, in years	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	33,124	$ 4.38	7.5	$ 7,459
Granted	4,515	$ 0.95		
Exercised	(154)	$ 1.48		
Forfeited/Cancelled	(1,500)	$ 4.59		
Outstanding as of December 31, 2024	35,985	$ 3.95	6.4	$ —
Vested and expected to vest as of December 31, 2024	35,985	$ 3.95	6.4	$ —
Exercisable as of December 31, 2024	25,452	$ 3.23	5.5	$ —

Intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the Common Stock for the options that had exercise prices that were lower than the per share fair value of the Common Stock as of the measurement date of the intrinsic value. The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2024 and 2023 was $0.67 and $3.24 per share, respectively. The total intrinsic values of options exercised during the years ended December 31, 2024 and 2023 were $47.3 thousand and $1.1 million, respectively. The maximum term of options granted under each of the equity incentive plans is ten years.

Total stock-based compensation recorded within operating expenses was $15.7 million and $14.6 million for the years ended December 31, 2024 and 2023, respectively.

The total unrecognized compensation costs related to unvested employee and non-employee stock option grants as of December 31, 2024 were $27.8 million, which the Company expects to recognize over a weighted-average period of approximately 2.3 years.

Scilex Holding Company 2022 Employee Stock Purchase Plan

In October 2022, the Board of Directors of the Company adopted the Scilex Holding Company 2022 Employee Stock Purchase Plan (the "ESPP"). The purchase price of the Common Stock is equal to 85% of the lesser of the market value of such shares at the beginning of an offering period or the date of purchase. As of December 31, 2024, the total number of shares of Common Stock that may be issued under the ESPP shall not exceed 4,476,601, which was increased from 2,875,759 shares as a result of automatic annual increase on January 1, 2024.

Total stock-based compensation recorded as operating expense for the ESPP was $242.8 thousand and $21.0 thousand for the years ended December 31, 2024 and 2023, respectively.

There were 334,326 and nil shares of Common Stock issued under the ESPP during the years ended December 31, 2024 and 2023, respectively.

Valuation Assumptions

The Company calculates the fair value of stock options and ESPP awards granted to employees and nonemployees using the Black-Scholes option-pricing method. The Black-Scholes option-pricing method requires the use of subjective assumptions.

The following assumptions were used in the Black-Scholes options pricing model to estimate stock-based compensation on the date of grant for stock options and ESPP:

	Year Ended December 31, 2024
Stock options:	
Expected dividend yield	0.00%
Expected volatility	72.00% - 119.08%
Risk-free interest rate	3.79% - 4.71%
Term of options (in years)	3.0 - 6.3
Employee stock purchase plan:	
Expected dividend yield	0.00%
Expected volatility	129.30%
Risk-free interest rate	5.39%
Expected life (in years)	0.50

Semnur 2024 Stock Option Plan

Concurrent with the signing of the Semnur Business Combination Agreement, the Board, the Company (as the sole stockholder of Semnur) and the board of directors of Semnur approved the 2024 Stock Option Plan ("Semnur 2024 Plan"). Under the Semnur 2024 Plan, 40,000,000 shares of Semnur Common Stock were reserved for future issuance and nonstatutory stock options ("NSOs") to purchase the same amount of Semnur Common Stock were granted to certain executive officers of Semnur. The NSOs were granted on August 30, 2024 and expire on August 30, 2034. No expense was recorded in connection with the NSOs as of December 31, 2024, as until the date on which all payments and all obligations under the Oramed Note have been paid in full in cash, such options will not be or become exercisable, eligible for exchange, redemption or repurchase, eligible to participate in any dividends or distributions or have any voting rights in respect of the Company or any of its current or future subsidiaries of the Company, and following the closing of the transactions contemplated by the Semnur Business Combination Agreement, the Company, Denali or any of their respective current and future subsidiaries, successors and assigns.

Employee Benefit Plan

The Company maintains a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under federal tax regulations. The Company made matching contributions to the 401(k) plan totaling $0.6 million and $0.5 million for the years ended December 31, 2024 and 2023, respectively.

Retainer Shares

On February 13, 2023, the Company entered into a Stock Issuance Agreement (the "2023 SIA") with a law firm for the provision of legal services to the Company. Under the 2023 SIA, the Company issued 4,000,000 shares of Common Stock to the law firm. On July 1, 2024, the Company entered into another Stock Issuance Agreement (the "2024 SIA") with the same law firm for the provision of legal services to the Company. Under the 2024 SIA, the Company issued 10,000,000 shares of Common Stock to the same law firm. All such shares are held by the law firm as collateral for current and future outstanding legal fees due from the Company (the "Retainer Shares"). 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, 2024, it was not probable that any of the Retainer Shares would be applied against any outstanding legal fees.

11. Commitments and Contingencies

Product Development Agreement

In February 2013, Scilex Pharma became a party to a product development agreement (as amended, the "Product Development Agreement") with Itochu and Oishi Koseido Co., Ltd. ("Oishi," and together with Itochu, the "Developers"), pursuant to which the Developers will manufacture and supply lidocaine tape products, including ZTlido and SP-103 (the "Products"), for Scilex Pharma. The Developers initially developed and have intellectual property rights relating to the Products. Pursuant to the Product Development Agreement, Scilex Pharma acquired an exclusive right to develop and commercialize the Products worldwide except for Japan. The Developers are responsible for sourcing and supplying lidocaine for development and commercialization purposes.

Pursuant to the Product Development Agreement, Scilex Pharma is required to make aggregate royalty payments between 25% and 35% to the Developers based on net profits. For each of the years ended December 31, 2024 and 2023, Scilex Pharma made royalty payments in the amount of $8.3 million. As of December 31, 2024 and 2023, Scilex Pharma had ending balances of accrued royalty payables of $4.0 million and $2.4 million, respectively. Total royalty expense recorded within cost of revenue was $9.9 million and $8.5 million for the years ended December 31, 2024 and 2023, respectively. Net profits are defined as net sales, less cost of goods and marketing expenses. Net sales are defined as total gross sales of any Product, less all applicable deductions, to the extent accrued, paid or allowed in the ordinary course of business with respect to the sale of such Product, and to the extent that they are in accordance with GAAP. If Scilex Pharma were to sublicense the licensed technologies, the Developers will receive the same proportion of any sublicensing fees received therefrom. The Product Development Agreement will continue in full force and effect until October 2, 2028, the date that is ten years from the date of the first commercial sale of ZTlido. The Product Development Agreement will renew automatically for subsequent successive one-year renewal periods unless Scilex Pharma or the Developers terminate it upon six months' written notice.

On February 16, 2017, Scilex Pharma entered into a Commercial Supply Agreement (as amended, the "Supply Agreement") with the two Developers to provide commercial supply of ZTlido and SP-103 to Scilex Pharma. The Supply Agreement contains standard terms regarding term, termination, payment, product quality and supply. In addition, the agreement provides additional terms regarding the calculation and amount of marketing expenses that may be deducted from net sales for purposes of determining the amount of net profit under the Product Development Agreement.

Litigation

In the normal course of business, the Company may be named as a defendant in one or more lawsuits. Other than the following four lawsuits, the Company is not a party to any outstanding material litigation and management is not aware of any legal proceedings that, individually or in the aggregate, are deemed to be material to the Company's financial condition or results of operations.

From time to time the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business.

Sanofi-Aventis U.S. LLC and Hisamitsu America, Inc. Litigation

On February 23, 2021, the Company filed an action (the "OTC Action") in the U.S. District Court for the Northern District of California against Sanofi-Aventis U.S. LLC and Hisamitsu America, Inc., two manufacturers of over-the-counter ("OTC") lidocaine patch products, alleging, among other things, false and deceptive advertising and unfair competition under the Lanham Act and California state laws by those companies regarding their respective OTC patch products. This lawsuit sought, among other relief, damages and an injunction enjoining the defendants from continuing to make false or misleading statements of fact about their respective OTC lidocaine patch products. The defendants filed motions to dismiss, which narrowed slightly the Company's claims, but which motions the court largely rejected. Discovery proceeded. On January 26 and February 2, 2024, Scilex Pharma entered into two separate settlement agreements and mutual releases with the two manufacturers that resolved the OTC Action. The terms of those agreements are confidential.

Former Employee Action

On March 12, 2021, Scilex Pharma and Sorrento (the "Plaintiffs") filed an action (the "Former Employee Action") in the Delaware Court of Chancery against the former President of Scilex Pharma, Anthony Mack, and Virpax Pharmaceuticals, Inc. ("Virpax", and together with Mr. Mack, the "Defendants"), a company founded and then headed by Mr. Mack, alleging, among other things, breach by Mr. Mack of a restrictive covenant agreement with Sorrento related to his sale of his Scilex Pharma stock to Sorrento, tortious interference with that agreement by Virpax, breach of Mr. Mack's fiduciary duties to Scilex Pharma, aiding and abetting of that breach by Virpax, and misappropriation of Scilex Pharma's trade secrets by Mr. Mack and Virpax. Such lawsuit sought, among other relief, damages and various forms of injunctive relief. The case was tried from September 12, 2022 to September 14, 2022. On September 1, 2023, the court found in favor of the Plaintiffs on all but three counts deemed to have been waived. In its 95-page opinion, the court instructed the parties to submit supplemental briefing on the appropriate remedy to implement its rulings. On October 18, 2023, the Plaintiffs submitted a supplemental brief on remedies. On November 29, 2023, Defendants submitted a supplemental brief on remedies. On December 21, 2023, the Plaintiffs submitted a supplemental reply brief on remedies. On February 26, 2024, the Company and Virpax entered into a term sheet regarding a mutual release and settlement agreement, pursuant to which the parties have agreed to resolve the ongoing disputes. On February 29, 2024, the Company and Virpax entered into a definitive settlement agreement, which provides for, among other things, that Virpax would be obligated to make the following payments to the Company to settle the Former Employee Action: (i) $3.5 million (the "Initial Payment") by two business days after the Effective Date (as defined therein), which payment has been made; (ii) $2.5 million by July 1, 2024, which payment has been made on July 8, 2024 and (iii) to the extent any of the following drug candidates are ever sold, royalty payments of (a) 6% of annual Net Sales (as defined therein) of Epoladerm; (b) 6% of annual Net Sales of Probudur and (c) 6% of annual Net Sales of Envelta during the Royalty Term (as defined therein). The Company and Virpax provided mutual releases of all claims that existed as of the Effective Date, whether known or unknown, arising from any allegations set forth in the Former Employee Action. Plaintiffs' release relates to claims against Virpax only, which does not affect its claims against Mr. Mack. Plaintiffs have not released Mr. Mack, and litigation against him remains ongoing. The court has requested additional oral argument on the topic of remedies against Mr. Mack, which argument occurred on November 15, 2024. The parties are awaiting a final judgment from the court.

ZTlido Patent Litigation

On June 22, 2022, the Company filed a complaint against Aveva Drug Delivery Systems, Inc. ("Aveva"), Apotex Corp., and Apotex, Inc. (together, "Apotex") in the U.S. District Court for the Southern District of Florida (the "ZTlido Patent Litigation") alleging infringement of certain Orange Book listed patents covering ZTlido (the "ZTlido Patents"). The ZTlido Patent Litigation was initiated following the submission by Apotex, in accordance with the procedures set out in the Hatch-Waxman Act, of an abbreviated new drug application ("ANDA"). Apotex's ANDA seeks approval to market a generic version of ZTlido prior to the expiration of the ZTlido Patents and alleges that the ZTlido Patents are invalid, unenforceable, and/or not infringed. The Company is seeking, among other relief, an order that the effective date of any FDA approval of Apotex's ANDA be no earlier than the expiration of the asserted patents listed in the Orange Book, the latest of which expires on May 10, 2031, and such further and other relief as the court may deem appropriate. Apotex and Aveva were subject to an automatic 30-month stay preventing them from selling a generic version of ZTlido during that time which was extinguished by the U.S. District Court for the Southern District of Florida decision described below. However, to our knowledge, Aveva has not received FDA approval for

any generic version of ZTlido. The two Apotex entities were dismissed from the litigation without prejudice, as they no longer had an interest in the generic product that Aveva seeks to market. Before trial, Aveva dropped its challenge to the validity and enforceability of the Company's patents. Trial in the ZTlido Patent Litigation was held from July 8, 2024 to July 11, 2024. Final post-trial briefing was submitted by the parties on July 25, 2024, and the case was submitted to the U.S. District Court for the Southern District of Florida. On August 26, 2024, that court issued a decision finding that Aveva's product does not infringe the Company's ZTlido Patents. The Company is appealing that decision to the U.S. Court of Appeals for the Federal Circuit, and it filed a Notice of Appeal with the U.S. District Court for the Southern District of Florida on September 25, 2024.

GLOPERBA Patent Litigation

On November 6, 2023, Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") filed a complaint against the Company in the U.S. District Court for the District of Delaware (the "GLOPERBA Patent Litigation") alleging that the Company's filing with the FDA of an application for approval of a proposed revision to the product label for its GLOPERBA product infringed certain Orange Book listed patents covering Takeda's colchicine product, Colcrys® (the "Colcrys Patents"). Takeda sought an order that the effective date of any FDA approval of the Company's labeling revision be no earlier than the expiration date of the asserted patents listed in the Orange Book, and such further and other relief as the court may deem appropriate. The Company had previously accrued $0.5 million with respect to the GLOPERBA Patent Litigation. On March 7, 2024, the Company entered into a Settlement Agreement (the "Settlement Agreement") with Takeda to resolve the action and entered into a license agreement with Takeda pursuant to which Takeda granted a non-exclusive license to the Company and its affiliates of certain patents owned by Takeda. The terms of those agreements are confidential. The Settlement Agreement was subject to review by the Federal Trade Commission and the U.S. Department of Justice, neither of which objected during the review period. After the expiration of the review period, the U.S. District Court for the District of Delaware entered a final consent judgment on May 3, 2024.

Operating Leases

The Company leases administrative and research and development facilities under various non-cancelable lease agreements. Facility leases generally provide for periodic rent increases and may include options to extend. As of December 31, 2024, the Company's leases have remaining lease terms of approximately 2.8 years. The terms of the Company's leases, ranging from 3 to 5 years, include extension options that were not reasonably certain to be exercised. Many of the Company's leases are subject to variable lease payments. Variable lease payments are recognized in the period in which the obligations for those payments are incurred, are not included in the measurement of the ROU assets or lease liabilities, and are immaterial. Additionally, the Company subleases certain properties to third parties. Sublease income is recognized on a straight-line basis and is immaterial.

As the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The Company calculates the associated lease liability and corresponding ROU asset upon lease commencement using a discount rate based on a credit-adjusted secured borrowing rate commensurate with the term of the lease. As of December 31, 2024, the Company has no finance leases.

In April 2023, the Company modified the lease term for its principal executive offices located in Palo Alto, California. The modification extended the lease term for an additional three years, with the lease term expiring in September 2027. As a result of the modification, the Company recognized additional ROU assets and corresponding lease liabilities of $2.5 million.

Lease expense was $1.0 million and $1.1 million for the years ended December 31, 2024 and 2023, respectively, and was primarily comprised of operating lease costs. The lease expense also included variable lease costs and sublease income, which were immaterial for the periods presented.

Supplemental quantitative information related to leases includes the following:

	Year Ended December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases (in thousands)	$ (1,042)	$ (1,021)
Weighted average remaining lease term in years — operating leases	2.8	3.6
Weighted average discount rate — operating leases	11.0%	11.1%

Approximate future minimum lease payments under operating leases were as follows (in thousands):

Year Ended December 31,	Amount
2025	$ 916
2026	944
2027	724
Total lease payments	2,584
Less imputed interest	(347)
Total lease liabilities	2,237
Less current portion of lease liability	714
Lease liability, net of current portion	$ 1,523

12. Income Taxes

Total loss before income taxes for the years ended December 31, 2024 and 2023 did not include a foreign component.

The components of the provision (benefit) expense were as follows for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Current income tax (benefit) expense:		
Federal	$ —	$ —
State	(1)	13
Total current income tax (benefit) expense	(1)	13
Deferred income tax benefit:		
Federal	(16,279)	(16,514)
State	(2,803)	(11,247)
Total deferred income tax benefit	(19,082)	(27,761)
Changes in tax rate	2,155	(1,471)
Changes in valuation allowance	16,927	29,232
Total income tax (benefit) expense from continuing operations	$ (1)	$ 13

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 liabilities and related valuation allowance are as follows as of December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 85,226	$ 71,434
Debt related interest	16,228	16,898
Capitalized research and development	5,228	4,936
Tax credit carryforwards	4,415	3,960
Stock-based compensation	1,157	525
Accrued expense and reserves	1,812	1,584
Purchased revenue liability	1,754	—
Operating lease liabilities	577	774
Other	303	159
Total deferred tax assets	116,700	100,270
Less valuation allowance	(113,703)	(96,776)
Total deferred tax assets	2,997	3,494
Deferred tax liabilities:		
Intangible assets	(2,423)	(2,734)
Operating lease right-of-use assets	(574)	(760)
Total deferred tax liabilities	(2,997)	(3,494)
Net deferred tax liabilities	$ —	$ —

The reconciliation between U.S. federal income taxes at the statutory rate and the Company's provision for income taxes are as follows for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	2023
Income tax benefit at federal statutory rate	$ (15,290)	$ (24,007)
Valuation allowance	18,559	29,232
Compensation expense	2,772	3,798
Acquisition related charges	485	260
Prior year true-up and carryback	(1,182)	(5,079)
State, net of federal tax benefit	(2,705)	(5,127)
Change in fair value of Convertible Debentures	(4,449)	1,752
Change in tax rates	2,155	(1,471)
Other	(346)	655
Income tax (benefit) expense	$ (1)	$ 13

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 valuation allowance of $113.7 million against its deferred tax assets as of December 31, 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.

As of December 31, 2024, the Company had $336.5 million and $248.2 million of federal and state net operating loss carryforwards, respectively. The net operating loss carryforwards begin to expire in 2033 for both federal and state. As of December 31, 2024, the Company had a total of $313.5 million of federal net operating losses that have an indefinite life and will not expire, and had federal research and development income tax credits of $3.7 million which will begin to expire in 2034. As of December 31, 2024, the Company had California research and development income tax credits of $2.2 million that have an indefinite life and will not expire.

Internal Revenue Code 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, 2024 and 2023, there was no impact of such limitations on the Company's income tax provision.

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, 2024.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows for the years ended December 31, 2024 and 2023 (in thousands):

	2024	2023
Gross unrecognized tax benefits at the beginning of the year	$ 1,071	$ 408
Increase related to prior year tax positions	—	536
Increase related to current year tax positions	127	127
Gross unrecognized tax benefits at the end of the year	$ 1,198	$ 1,071

As of December 31, 2024 and 2023, the Company had $1.2 million and $1.1 million in total unrecognized tax benefits, respectively, 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, 2024 and 2023.

The Company believes that no material amount of the liabilities for uncertain tax positions are expected to reverse within 12 months of December 31, 2024.

13. Net Loss Per Share

The following table sets forth the reconciliation of basic and diluted loss per share for the years ended December 31, 2024 and 2023 (in thousands except per share data):

	Year Ended December 31,	
	2024	2023
Net loss	$ (72,807)	$ (114,331)
Premium on redemption of Series A Preferred Stock	—	(52,645)
Net loss for basic loss per share available to common stockholders	$ (72,807)	$ (166,976)
Reversal of mark-to-market adjustment for liability classified warrants	(8,895)	—
Net loss for diluted loss per share available to common stockholders	$ (81,702)	$ (166,976)
Weighted average number of shares outstanding	124,636	130,298
Weighted average common stock warrants exercisable for nominal consideration	6,500	—
Weighted average number of shares, basic	131,136	130,298
Effect of dilutive securities	2,939	—
Weighted average number of shares, diluted	134,075	130,298
Loss per share		
Basic	$ (0.56)	$ (1.28)
Diluted	$ (0.61)	$ (1.28)

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of Common Stock outstanding during the period. Premium paid on redemption of Series A Preferred Stock was added to the net loss to arrive at loss available for common stockholders as it represents a dividend to the Series A preferred stockholder. Diluted earnings per share is computed using the weighted average number of Common Stock and, if dilutive, potential Common Stock outstanding during the period. Potential Common Stock consists of the incremental Common Stock issuable upon the exercise of stock options and warrants (using the treasury stock method or the reverse treasury stock method, as applicable).

In the computation of net loss per share, treasury shares are not included as part of the outstanding shares. Shares of the Dividend Stock, as declared by the Board of Directors of the Company on October 27, 2024 and not yet distributed

as of December 31, 2024, are also excluded from the computation of net loss per share because the associated Series 1 Preferred Stock is not considered to be a participating security.

In accordance with FASB ASC 260, *Earnings Per Share,* Penny Warrants are warrants that would be exercised for no or little consideration and therefore should be included in the calculation of weighted average shares outstanding for purposes of calculating basic and diluted net income (loss) per share. The Closing Penny Warrants become exercisable upon the passage of time and are included in basic and diluted net income (loss) per share from the closing date of September 21, 2023. The Subsequent Penny Warrants to purchase up to an aggregate of 8,500,000 shares of Common Stock were not vested as of the closing date of September 21, 2023 and the vesting was based on the passage of time, the Company's repayment of the Oramed Note or the occurrence of the Management Sale Trigger Date (as defined therein). The Subsequent Penny Warrants became vested during the year ended December 31, 2024, and therefore are included in the computation for basic and diluted net income per share as of December 31, 2024, since all other exercise contingencies were removed except for the passage of time.

The following potentially dilutive outstanding securities were excluded from the computation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	December 31, 2024	December 31, 2023
Stock options	35,985,182	33,123,798
Public Warrants	5,467,692	6,854,309
February 2024 BDO Firm Warrants	3,803,447	—
April 2024 RDO Placement Agent Warrants	1,200,000	—
Retainer Shares	14,000,000	4,000,000
Private Warrants	1,000,000	3,613,383
February 2024 BDO Representative Warrants	470,588	—
Shares Issuable pursuant to the ESPP	77,167	29,806
Shares issuable under the SIPA	300,000	—
Convertible Debentures	—	546,921
October 2024 Placement Agent Warrants	3,669,724	—
December 2024 RDO Common Warrants	57,512,958	—
StockBlock Warrants	4,601,036	—
Shares issuable under Tranche B Notes	40,551,607	—
Total	168,639,401	48,168,217

14. Subsequent Events

Deferral and Consent under Tranche B Senior Secured Convertible Note

Pursuant to the Tranche B Notes, commencing on January 2, 2025 (the "First Amortization Payment Date"), the Company is required to redeem in cash (the "First Amortization Payment") such portion of the principal amount of the Tranche B Notes equal to each Tranche B Noteholder's Holder Pro Rata Amount (as defined in the Tranche B Notes) of $6,250,000 per fiscal quarter at a redemption price equal to 100% of such Amortization Amount (as defined in the Tranche B Notes).

On January 2, 2025, the Company entered into a deferral and consent letter with each of (i) Nomis Bay Ltd and BPY Limited (the "Nomis Bay Consent"), (ii) Oramed (the "Oramed Consent") and (iii) 3i, LP (the "3i Consent" and, together with the Nomis Bay Consent and the Oramed Consent, the "Tranche B Consents"), respectively, pursuant to which the Tranche B Noteholders agreed to defer the Company's obligation to make the First Amortization Payment until January 31, 2025. In consideration of such deferral, and to limit the Tranche B Noteholders' right to exercise certain secured creditor remedies (including recourse against the assets of SCLX JV as a grantor under the Security Agreement (as defined in the Tranche B Consents)), SCLX JV delivered to the Tranche B Noteholders (or their designee) by deposit/withdrawal at custodian with the Depository Trust Company an aggregate of 5,000,000 Scilex Shares held by SCLX JV, of which 2,500,000 shares were delivered to Oramed, 720,000 shares were delivered to BPY Limited, 1,280,000 shares were delivered to Nomis Bay Ltd, and 500,000 shares were delivered to 3i, LP.

In addition, pursuant to the Tranche B Consents, effective as of the latest of (i) the time of execution and delivery of the Tranche B Consents, (ii) the time of the delivery of the Scilex Shares and (iii) the time of grant of the Royalty and Exclusive Rights (each as defined in, and contemplated pursuant to, the Term Sheet that is an exhibit to the Tranche B Consents (the "Term Sheet")), the Tranche B Noteholders agreed to further defer the Company's obligation to make the First Amortization Payment until October 8, 2026, provided that, as contemplated in the Term Sheet, the Company pays an aggregate of $1.1 million in respect of a portion of the First Amortization Payment and related make-whole interest (which amount has been paid).

The Term Sheet provides that the Company and the Tranche B Noteholders would enter into an agreement pursuant to which the Tranche B Noteholders shall collectively receive a 10 year, assignable, freely transferable, 4% royalty on the worldwide Net Sales (as defined therein) of GLOPERBA and ELYXYB, excluding sales of ELYXYB in Canada. Please see section below titled "Gloperba and Elyxyb Royalty Purchase Agreement" for a description of such royalty agreement entered into by us.

Amendment to Senior Secured Note

On January 21, 2025, the Company entered into an amendment letter with Oramed (the "Oramed Amendment"), pursuant to which, among other things, Oramed agreed to extend the Maturity Date under and as set forth in the Oramed Note from March 21, 2025 to December 31, 2025. In consideration of such extension, SCLX JV agreed to deliver to Oramed an aggregate of 3,250,000 shares of Common Stock held by SCLX JV.

ZTlido Rest of World License Agreement

On February 22, 2025 (the "***Lido Effective Date***"), Scilex Pharma entered into a License Agreement (the "***Lido License Agreement***") with RoyaltyVest Ltd. (the "Licensee") with respect to services, compositions, products, dosages and formulations comprising lidocaine that have been or are later developed by or on behalf of Scilex Pharma, including the product and any future product defined as a "Product" under Scilex Pharma's existing (i) Product Development Agreement, dated as of May 11, 2011, with Oishi and Itochu, as amended, and (ii) the associated Commercial Supply Agreement, dated February 16, 2017, between Scilex Pharma, Oishi and Itochu, as amended, which include (a) ZTlido (lidocaine topical system) 1.8%, including the composition of matter with the NDC 69557-111-30 and (b) SP-103 (collectively, the "***Lido Product***"). The Lido License Agreement supersedes and replaces the that certain Rest of World License Term Sheet parties entered into on October 8, 2024.

Under the Lido License Agreement, Scilex Pharma granted to the Licensee during the Lido License Term (as defined below) a worldwide (other than the United States and certain territories stated in the Lido License Agreement), exclusive, non-transferable right, license and interest in, to, and under all Product Rights Controlled (each as defined therein) by Scilex Pharma to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit all Lido Products, in all cases solely for commercialization of the Lido Products outside of the United States and certain territories stated in the Lido License Agreement (the "***Lido Licensee Territory***"). The Licensee granted to Scilex Pharma a non-exclusive, non-transferable, right and license under the Licensee Non-Blocking Patents (as defined therein) (i) in the Licensor Territory (as defined therein), to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit Lido Product for commercialization of Lido Products in the Licensor Territory in the Field (each as defined therein), and (ii) worldwide, to develop and manufacture Lido Product for commercialization in the Licensor Territory in the Field (each as defined therein). Each of the Licensee and Scilex Pharma will receive 50% of the Net Revenue (as defined therein) generated, and the Licensee shall effect the foregoing by paying to Scilex Pharma its share of the Net Revenue on a quarterly basis.

Pursuant to the Lido License Agreement, the Licensee shall (i) use commercially reasonable efforts to obtain and maintain regulatory approval for the Lido Product in at least one Major Market Country (as defined therein) within 18 months after the Lido Effective Date, and (ii) commit $200,000, or its equivalent in kind, annually towards such efforts until it obtains regulatory approval for the Lido Product in the Lido Licensee Territory. Scilex Pharma shall use commercially reasonable and diligent efforts to obtain and maintain regulatory approvals for SP-103 and all existing Lido Products in each country or jurisdiction in the Licensor Territory (as defined therein).

Promptly after the Lido Effective Date, Scilex Pharma is required to (i) facilitate an introduction between Oishi, Itochu, and the Licensee, and (ii) use reasonable efforts to cause each of Oishi and Itochu to accept a direct engagement

with the Licensee for the manufacturing or supply of the Lido Product in finished dosage form. In addition, Scilex Pharma agreed to appoint the Licensee as its exclusive distributor of the Lido Product in the Licensee Territory during the Lido License Term.

The term of the Lido License Agreement commences on the Lido Effective Date and continues until expiration of the last to expire Licensed Patents (as defined therein), unless earlier terminated (the "***Lido License Term***").

Parent Guarantee for Lido License Agreement

On February 22, 2025, in connection with Lido License Agreement, the Company entered into that certain Parent Guarantee for Lidocaine License Agreement (the "***Parent Guarantee***") with the Licensee, pursuant to which the Company agreed to guarantee the due and proper performance of Scilex Pharma's obligations under the Lido License Agreement on the terms and conditions set forth in the Parent Guarantee. Pursuant to the terms of the Parent Guarantee, the Company shall provide the Licensee with written notice of any Change of Control (as defined therein) of Scilex Pharma within five business days after the consummation of such Change of Control, and the Parent Guarantee and the guarantee obligations shall automatically terminate upon the consummation of such Change of Control.

Gloperba-Elyxyb Royalty Purchase Agreement

As contemplated by the Term Sheet in respect of the Royalty and Exclusive Rights described therein, on February 28, 2025 (the "Gloperba-Elyxyb Closing Date"), the Company entered into a Purchase and Sale Agreement (the "Gloperba-Elyxyb Royalty Purchase Agreement") with Scilex Pharma, certain institutional investors (collectively, the "Gloperba-Elyxyb Royalty Investors") and Oramed (together with the Gloperba-Elyxyb Royalty Investors, the "Gloperba-Elyxyb RPA Purchasers"). Pursuant to the Gloperba-Elyxyb Royalty Purchase Agreement, Scilex Pharma sold to the Gloperba-Elyxyb RPA Purchasers the right to receive 4% of all aggregate net sales worldwide (the "Gloperba-Elyxyb Purchased Receivables") with respect to Gloperba, Elyxyb, and any related, improved, successor, replacement and/or varying dosage forms of the foregoing (the "Gloperba-Elyxyb Covered Products").

In consideration of the Further Deferral and representing the "grant of the Royalty and Exclusive Rights" (as defined in the Term Sheet), during the period commencing on the Gloperba-Elyxyb Closing Date and expiring on the tenth anniversary of the Gloperba-Elyxyb Closing Date (the "Gloperba-Elyxyb Payment Term"), Scilex Pharma shall pay to each Gloperba-Elyxyb RPA Purchaser, by wire transfer of immediately available funds in U.S. dollars to such Gloperba-Elyxyb RPA Purchaser's account such Gloperba-Elyxyb RPA Purchaser's Specified Percentage (as defined in the Gloperba-Elyxyb Royalty Purchase Agreement) of the Covered Product Revenue Payments (each as defined in the Gloperba-Elyxyb Royalty Purchase Agreement) for each calendar quarter (commencing with the calendar quarter beginning January 1, 2025) promptly, but in any event no later than 60 calendar days after the end of each calendar quarter.

The Gloperba-Elyxyb Royalty Purchase Agreement shall terminate six months following receipt by the Gloperba-Elyxyb RPA Purchasers of all payments of the Purchased Receivables to which each Gloperba-Elyxyb RPA Purchaser is entitled during the Payment Term.

Royalty Security Agreement

Pursuant to the terms of the Gloperba-Elyxyb Royalty Purchase Agreement, the Company entered into a Security Agreement with Scilex Pharma and the collateral agent (as identified therein) for the benefit of the Gloperba-Elyxyb RPA Purchasers, dated as of February 28, 2025 (the "Gloperba-Elyxyb Royalty Security Agreement").

Under the Gloperba-Elyxyb Royalty Security Agreement, each of our and Scilex Pharma's due performance and payment under the Gloperba-Elyxyb Royalty Purchase Agreement is secured by certain collateral, including a collection account and certain material contracts, intellectual property rights and regulatory approvals, in each case related to the Gloperba-Elyxyb Covered Products.

Subordination Agreement

In connection with the Gloperba-Elyxyb Royalty Purchase Agreement and the Gloperba-Elyxyb Royalty Security Agreement, the Company entered into that certain Subordination Agreement, dated as of February 28, 2025 (the "Gloperba-Elyxyb Subordination Agreement"), by and among the Company, Scilex Pharma the Gloperba-Elyxyb RPA Purchasers and the Note Agent (each as defined in the Subordination Agreement). Pursuant to the Gloperba-Elyxyb Subordination Agreement, the parties agreed that all obligations, liabilities and indebtedness under the Gloperba-Elyxyb Royalty Purchase Agreement are secured by first priority liens on the collateral under the Gloperba-Elyxyb Royalty Security Agreement (the "Gloperba-Elyxyb Royalty Collateral") and the Note Agent's lien on the Gloperba-Elyxyb Royalty Collateral is subordinated and becomes a second priority lien.

Amendment No. 1 to ZTlido Royalty Purchase Agreement

On February 28, 2025, the Company and Scilex Pharma entered into an Amendment No. 1 to Purchase and Sale Agreement (the "ZTlido Royalty Amendment") with the purchasers (the "ZTlido Royalty Purchasers") under that certain Purchase and Sale Agreement, dated as of October 8, 2024 (the "ZTlido Royalty Purchase Agreement"). Pursuant to the Royalty Amendment, the Company and Scilex Pharma may assign their respective rights or delegate their respective obligations under the ZTlido Royalty Purchase Agreement without the prior written consent of the Purchasers if the Company receives a commitment, contingent upon an asset purchase of Covered Products (as defined in the ZTlido Royalty Purchase Agreement), that would allow the Company to pay in full all obligations owed under the Debt Instruments (as defined therein), provided that such purchaser of Covered Products agrees to assume all of the obligations of the Company and Scilex Pharma under the ZTlido Royalty Purchase Agreement.

Gloperba Rest of World License Agreement

On February 28, 2025 (the "Effective Date"), the Company entered into a License Agreement (the "Gloperba License Agreement") with Scilex Pharma and the Licensee with respect to (i) services, compositions, products, dosages and formulations comprising Gloperba that have been or are later developed by or on behalf of the Company, including the product and any future product defined as a "Licensed Product" under the Romeg License Agreement, as amended and as may be further amended or restated from time to time, and (ii) any related, improved, successor or replacement forms of any such product Controlled (as defined therein) by the Company ((i) and (ii) collectively, the "Gloperba Product").

Under the Gloperba License Agreement, the Company granted to the Licensee during the Gloperba License Term (as defined below) a worldwide, exclusive, non-transferable (except in connection with a permitted assignment of the Gloperba License Agreement) right, license and interest in, to, and under all Product Rights Controlled (each as defined therein) by the Company to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit all Gloperba Products, in all cases solely for commercialization of the Gloperba Products outside of the United States in the Field (as defined therein). The Licensee granted to the Company a non-exclusive, non-transferable (except in connection with a permitted assignment of the Gloperba License Agreement), right and license under the Licensee Non-Blocking Patents (as defined therein) (i) in the United States, to develop, manufacture, obtain and maintain regulatory approvals for, commercialize and otherwise exploit Gloperba Product for commercialization of Gloperba Products in the United States in the Field (as defined therein), and (ii) worldwide, to develop and manufacture Gloperba Product for commercialization in the United States in the Field (as defined therein). Each of the Licensee and the Company will receive 50% of the Net Revenue (as defined therein) generated based on Licensee's sale of the Gloperba Products, and the Licensee shall effect the foregoing by paying to the Company an amount required for the Company to receive its share of the Net Revenue on a quarterly basis.

Pursuant to the Gloperba License Agreement, the Licensee shall obtain and maintain regulatory approval for the Gloperba Product outside of the United States in accordance with its own business judgment and in its sole and absolute discretion.

Promptly after the Effective Date, the Company is required to (i) facilitate an introduction between the Licensee and the Company's contract manufacturer of the Gloperba Product (the "Gloperba CMO") as of the Effective Date, and (ii) use reasonable efforts to cause such Gloperba CMO to accept a direct engagement with the Licensee for the manufacturing or supply of the Gloperba Product in finished dosage form. In addition, the Company agreed to appoint

the Licensee as its exclusive distributor of the Gloperba Product in the entire world other than the United States during the Gloperba License Term.

The term of the Gloperba License Agreement commences on the Effective Date and continues until expiration of the last to expire Licensed Patents (as defined therein), unless earlier terminated (the "Gloperba License Term").